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Attorneys for Respondents



BEFORE THE NEVADA STATE I	BOARD OF PHARMACY
NEVADA STATE BOARD OF PHARMACY, Petitioner, v.	) CASE NOS. 18-021-PH-S ) 18-021-RPH-A-S ) 18-021-RPH-B-S ) 18-021-RPH-C-S 18-021-RPH-D-S
WALGREENS PHARMACY #4854, Pharmacy License No. PH01293, MINHQUANG D. NGUYEN, RPH, Certificate of Registration No. 15913, and	) RESPONDENTS' ANSWER AND NOTICE OF DEFENSE )
DIMITRIS EFSTATHIOU, RPH, Certificate of Registration No. 17277, MADIA CRUZ DPH	) ) )
MARIA CRUZ, RPH, Certificate of Registration No. 18166,	) )
Respondents.	

Respondents Walgreens Pharmacy #4854, 5814, Minhquang D. Nguyen, RPh, Dimitris Efstathiou, RPh, , and Maria Cruz, RPh by and through their counsel William J. Stilling, of and for Stilling & Harrison, PLLC, answer and provide notice of their defense to the Notice of Intended Action and Accusation ("Notice") in the above-entitled matter and declare as follows.

# **REQUEST FOR HEARING**

Respondents request a hearing on the Notice.

# RESPONSES TO ALLEGATIONS AND CAUSES OF ACTION

In answer to the Notice, Respondents admit, deny, and allege as follows:

# **JURISDICTION**

- 1. Respondents admit the allegations in paragraph 1.
- 2. Respondents admit the allegations in paragraph 2.

#### **FACTUAL ALLEGATIONS**

- 3. Respondents admit the allegations in paragraph 3.
- 4. Respondents lack sufficient knowledge to admit or deny the allegations in paragraph 4 and therefore deny the same.
  - 5. Respondents admit the allegations in paragraph 5.
  - 6. Respondents admit the allegations in paragraph 6.
  - 7. Respondents admit the allegations in paragraph 7.
  - 8. Respondents admit the allegations in paragraph 8.
  - 9. Respondents admit the allegations in paragraph 9.
  - 10. Respondents admit the allegations in paragraph 10.
- 11. Respondents admit that on or about December 24, 2017, prescription no. 1874629, post-dated 11/07/2017, was processed, filled and dispensed and that data entry review was performed by Cruz. However, there was nothing on the prescription 1874629 to indicate that it had been previously filled. Respondents deny all remaining allegations in paragraph 11.
- 12. Respondents admit that: (i) on or about January 29, 2018, prescription no. 1886042, post-dated 12/07/2017, was processed, filled and dispensed; (ii) data entry review and final verification were performed by Nguyen who did not place a fill sticker on the back of the original hard copy of the prescription. Respondents deny all remaining allegations in paragraph 12.

13. Respondents admit that: (i) on or about February 28, 2018, prescription no. 1896898, post-dated 12/07/2017, was processed, filled and dispensed and (ii) data entry review was performed by Cruz. However, there would have been nothing on the prescription 1896898 to indicate that it had been previously filled. Respondents deny all remaining allegations in paragraph

#### **COUNT ONE**

# Recordkeeping Violations

(Respondents Nguyen and Efstathiou)

- 14. Paragraph 14 is a statement of law and is not susceptible to admission or denial. To the extent that paragraph 14 implies any unprofessional or unlawful conduct, Respondents deny the same.
  - 15. Respondents deny the allegations in paragraph 15.

#### **COUNT TWO**

# Failure to Identify Duplicate Dispensed Medication/Unprofessional Conduct (Respondents Nguyen and Cruz)

- 16. Paragraph 16 is a statement of law and is not susceptible to admission or denial. To the extent that paragraph 16 implies any unprofessional or unlawful conduct, Respondents deny the same.
  - 17. Respondents deny the allegations in paragraph 17.
  - 18. Respondents deny the allegations in paragraph 18.

#### **COUNT THREE**

# Managing Pharmacist Responsibility

(Respondent Nguyen)

19. Respondents deny the allegations in paragraph 19.

# **COUNT FOUR**

Pharmacy/Pharmacy Owner Responsibility (Respondent Walgreens Pharmacy #4854)

20. Paragraph 20 is a statement of law and is not susceptible to admission or denial. To the extent that paragraph 20 implies any unprofessional or unlawful conduct, Respondents deny the same.

21. Respondents deny the allegations in paragraph 21.

# RESERVATION OF RIGHTS, DEFENSES, AND GENERAL DENIAL

22. Each Count fails to state a claim upon which relief can be granted.

23. To the extent Respondents did not specifically admit allegations in the Notice, they deny such allegations.

24. Sanctioning Respondent Maria Cruz would be unfair and unjust in light of her circumstances. Maria Cruz retired March 2021. She now lives in the Philippines. She no longer has a pharmacy license and never intends to practice pharmacy again. Her decision to retire had nothing to do with this case. Ms. Cruz has never been sanctioned for any act or omission during her eleven years of practice in Nevada or anywhere else. Maria Cruz recognizes that the Board needs to be consistent in its decisions. But some cases are different and require wise use of discretion as fairness requires. This is such a case. If the Board agrees to dismiss the claims against Maria Cruz, it would not set a precedent that a pharmacist can escape sanctions by retiring. Rather, a decision to dismiss the claims against her or to forego any sanctions would simply recognize that it is fair not to impose sanctions on a pharmacist who retires some three years after an alleged violation and before any Notice of Intended Action is filed, who moves back to her native country, and who has never before been sanctioned by a board of pharmacy. Ms. Cruz did not act unprofessionally or unlawfully because she had no reason to believe there was a duplicate of the prescription she was filling as described in paragraphs 11 and 13. Even if this Board finds that Maria Cruz engaged in

unprofessional conduct, it should not impose sanctions. Just because a government body has the power to do something does not necessarily mean that it should do so—especially when fairness dictates otherwise.

# **PRAYER FOR RELIEF**

- 25. Respondents pray for the following relief:
  - a. That the Notice be dismissed or that the Board finds that the allegations in the Notice and all evidence presented to the Board do not support imposing discipline on any of the Respondents.
  - b. That the Board dismiss all Causes of Acton in in the Notice.
  - c. That the Board provide further relief to Respondents as it finds just and proper.

DATED this 31st day of May 2023.

William J. Stilling

STILLING & HARRISON, PLLC.

Attorneys for Respondents

William Sh

# **CERTIFICATE OF SERVICE**

I hereby certify that on May 31, 2023, I caused to be served a true and correct copy of the foregoing **ANSWER AND NOTICE OF DEFENSE** by the method indicated below to:

<ul> <li>□ U.S. Mail postage</li> <li>prepaid</li> <li>□ Hand delivery</li> <li>□ Overnight Mail</li> <li>□ Facsimile</li> <li>☑ Electronic Mail</li> </ul>
<ul> <li>□ U.S. Mail postage</li> <li>prepaid</li> <li>□ Hand delivery</li> <li>□ Overnight Mail</li> <li>□ Facsimile</li> <li>☑ Electronic Mail</li> </ul>
<ul> <li>□ U.S. Mail postage</li> <li>prepaid</li> <li>□ Hand delivery</li> <li>□ Overnight Mail</li> <li>□ Facsimile</li> <li>☑ Electronic Mail</li> </ul>
William Stall

# BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

WALGREENS PHARMACY #4854, Pharmacy License No. PH01293, and

MINHQUANG D. NGUYEN, RPH, Certificate of Registration No. 15913,

Respondents.

CASE NOS. 19-100-PH-S 19-100-RPH-S 18-021-RPH-A-S

STIPULATION AND ORDER [RESPONDENTS WALGREENS PHARMACY #4854 & NGUYEN ONLY]

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Walgreens Pharmacy #4854, Pharmacy License No. PH01293, and Respondent Minhquang D. Nguyen, RPh (Nguyen), Certificate of Registration No. 15913, jointly by and through counsel, William Stilling, Esq. of Stilling & Harrison, **HEREBY STIPULATE AND AGREE THAT**:

- 1. The Board has jurisdiction over Respondents and these matters.
- 2. Respondent Nguyen entered into two (2) prior stipulations for discipline before the Board. In April 2013, Respondent Nguyen, as the managing pharmacist of Kmart Pharmacy #3719, stipulated in case no. 13-006-RPH, to a public reprimand and a \$500.00 fine for failing to verify the registration status of each pharmacy employee in his charge. On October 12, 2022, Respondent Nguyen, as the managing pharmacist of Walgreens Pharmacy #7864, stipulated in case no. 18-055-RPH, to pay a \$1,000.00 fine, attorney's fees and costs of \$500.00, and to complete two additional hours of continuing education for failing to accurately verify medication at data entry review, overriding a DUR and dispensing a duplicated and mislabeled prescription.

- 3. On or about October 14, 2022, Board Staff served Respondents with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondents and Notice of Hearing in Case Nos. 19-100-PH-S and 19-100-RPH-S.
- 4. On or about February 6, 2023, Board Staff served Respondents with the First Amended Notice of Intended Action and Accusation (First Amended Accusation) on file in this matter together with the Statement to Respondents and Notice of Hearing in Case Nos. 18-021-PH-S and 18-021-RPH-A-S.
  - 5. Respondents jointly filed an Answer and Notice of Defense to each Accusation.
- 6. Respondent Walgreens Pharmacy #4854 has entered into a separate stipulation resolving Case No. 18-021-PH-S.
- 7. Respondents are aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering this Stipulation.
- 8. Respondents are aware of the right to a hearing on the matters alleged in each Accusation, their right to reconsideration, their right to appeal, and any and all other rights which may be accorded pursuant to NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.
- 9. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents, or any of them, have failed to comply with the provisions of this Stipulation, Respondents hereby knowingly and voluntarily waive their rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to them by NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.

- 10. Respondents admit that evidence exists, and that Board's staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the First Amended Accusation filed in Case No. 18-021-RPH-A-S, *to wit*, that:
- A. By failing to place a fill sticker on the back of the original hard copy of the prescription when filling prescription no. 1886042, Nguyen violated NRS 639.236(2) and is subject to discipline pursuant to NRS 639.210(12);
- B. Nguyen engaged in unprofessional conduct as defined in NAC 639.945(1)(d) and (i) when he performed data entry review and final verification on prescription no. 1886042 and failed to identify that patient L.S. had already received the three fills prescribed on her patient profile, and is therefore subject to discipline pursuant to NRS 639.210(4); and
- C. As the managing pharmacist of Walgreens Pharmacy #4854 at the time of the violations alleged in Case No. 18-021-RPH-A-S, including the failure to note the prescription number on the original hard copy of prescriptions, in violation of NRS 639.236, NAC 639.706 and/or NAC 639.910, resulting in the duplicate prescriptions, Nguyen is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1) and/or NAC 639.702.
- 11. Respondents admit that evidence exists, and that Board's staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation filed in Case Nos. 19-100-PH-S and 19-100-RPH-S, *to wit*, that:
- A. Nguyen violated NRS 585.370 and NAC 639.601(1) and engaged in unprofessional conduct as defined in NAC 639.945(1)(i) he failed to segregate and/or dispose of adulterated and/or expired drugs in the pharmacy's inventory and is subject to discipline pursuant to NRS 639.210(4) and (12);

- B. Nguyen engaged in unprofessional conduct as defined in NAC 639.945(1)(h) when he misrepresented to the Board inspector that all adulterated and/or expired drugs in the pharmacy's inventory had been segregated and/or dispose of and is subject to discipline pursuant to NRS 639.210(4) and (9); and
- C. As the pharmacy/pharmacy owner at which the violations of law alleged Case Nos. 19-100-PH-S and 19-100-RPH-S occurred, Walgreens Pharmacy #4854 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).
- 12. Those violations are plead with particularity in each Accusation and are grounds for action pursuant to NRS 639.210 and NRS 639.255.
- 13. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Minhquang D. Nguyen, RPh, Certificate of Registration No. 15913, stipulate to the following penalties. Nguyen's Certificate of Registration No. 15913 is hereby revoked pursuant to NRS 639.255(1)(d). The revocation is stayed, and Nguyen is placed a probation for two (2) years pursuant to NRS 639.255(1)(b) subject to the following conditions:
- A. Nguyen currently owns and serves as managing pharmacist of ICARE Pharmacy, License No. PH04402, which shall be subject to quarterly unannounced inspections by Board staff at Nguyen's expense pursuant to NRS 639.090, NRS 639.289, NAC 639.482 and/or NAC 639.935;
- B. Pursuant to NRS 639.255(1)(e), Nguyen shall accept this Stipulation and Order as a public reprimand regarding his duties and responsibilities as a managing pharmacist;
- C. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Nguyen shall pay a fine of Five-Thousand Dollars (\$5,000.00) for the violations;

- D. Pursuant to NRS 622.400, Nguyen shall pay One Thousand Dollars (\$1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs; and
- E. Nguyen shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon the successful completion of probation, Nguyen's Certificate of Registration No. 15913 will be fully restored.

- 14. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Walgreens Pharmacy #4854, Pharmacy License No. PH01293, stipulate to the following penalties:
- A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Walgreens Pharmacy #4854 shall pay a fine of Two-Thousand Dollars (\$2,000.00) for the violations; and
- B. Pursuant to NRS 622.400, Respondent Walgreens Pharmacy #4854 shall pay One-Thousand Dollars (\$1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.
- 15. Any failure by any Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing the non-compliant Respondent(s) to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by any Respondent, the Board may impose additional discipline upon the non-compliant Respondent(s) consistent with the provisions of NRS Chapter 639. If such a hearing results in a finding of a violation of this Order by Nguyen, the Board may lift the stay and immediately revoke Certificate of Registration No. 15913.

- 16. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on June 14, 2023. Respondents will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or counsel are not present at the meeting.
- 17. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.
- 18. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.
- 19. Upon approval of this Stipulation by the Board, Respondents shall pay the fines agreed to herein by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.
- 20. Upon approval of this Stipulation by the Board, Respondents shall pay the attorney's fees and investigative costs agreed to herein by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.
- 21. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the

facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents have fully considered the charges and allegations contained in the *First Amended Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:	
Signed this day of June 2023	Signed this day of June 2023
MINHQUANG D. NGUYEN, RPH Certificate of Registration No. 15913	WALGREENS PHARMACY #4854 Pharmacy License No. PH01293
APPROVED AS TO FORM AND CONTENT this day of June 2023	Signed this day of June 2023
WILLIAM J. STILLING, ESQ. Counsel for Respondents	BRETT KANDT, ESQ. General Counsel Nevada State Board of Pharmacy

# **ORDER**

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Walgreens Pharmacy #4854, Pharmacy License No. PH01293, and Respondent Minhquang D. Nguyen, RPh, Certificate of Registration No. 15913, in Case Nos. 19-100-PH-S, 19-100-RPH-S and 18-021-RPH-A-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

# IT IS SO ORDERED.

Entered this day of June 2023.	
	Helen Park, Pharm.D.
	President
	Nevada State Board of Pharmacy

#### BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Petitioner,

v.

WALGREENS PHARMACY #4854, Pharmacy License No. PH01293,

MINHQUANG D. NGUYEN, RPH, Certificate of Registration No. 15913,

DIMITRIS EFSTATHIOU, RPH, Certificate of Registration No. 17277, and

MARIA CRUZ, RPH, Certificate of Registration No. 18166,

Respondents.

CASE NOS. 18-021-PH-S 18-021-RPH-C-S

STIPULATION AND ORDER [RESPONDENTS WALGREENS PHARMACY #4854 & EFSTATHIOU ONLY]

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Walgreens Pharmacy #4854, Pharmacy License No. PH01293, and Respondent Dimitris Efstathiou, RPh (Efstathiou), Certificate of Registration No. 17277, jointly by and through counsel, William Stilling, Esq. of Stilling & Harrison, **HEREBY STIPULATE**AND AGREE THAT:

- 1. The Board has jurisdiction over Respondents and these matters.
- 2. On or about February 6, 2023, Board Staff served Respondents with the First Amended Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondents and Notice of Hearing.
  - 3. Respondents jointly filed an Answer and Notice of Defense to the Accusation.
- 4. Respondents are aware of the right to seek the advice of counsel in this matter and obtained the advice of counsel prior to entering this Stipulation.

- 5. Respondents are aware of the right to a hearing on the matters alleged in the Accusation, their right to reconsideration, their right to appeal, and any and all other rights which may be accorded pursuant to NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.
- 6. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondents, or any of them, have failed to comply with the provisions of this Stipulation, Respondents hereby knowingly and voluntarily waive their rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to them by NRS Chapter 233B, Nevada Administrative Procedure Act, NRS Chapter 622A, Administrative Procedure Before Certain Regulatory Bodies, and NRS Chapter 639, Nevada Pharmacy Act.
- 7. Respondents admit that evidence exists, and that Board's staff prosecuting this case could present such evidence at an administrative hearing, to establish a factual basis for the violations alleged in the Accusation, *to wit*, that:
- A. By failing to place a fill sticker on the back of the original hard copy of the prescription when filling prescription no. 1893870, Efstathiou violated NRS 639.236(2) and is subject to discipline pursuant to NRS 639.210(12); and
- B. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Walgreens Pharmacy #4854 is responsible for those violations pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(2).
- 7. Those violations are plead with particularity in the Accusation and are grounds for action pursuant to NRS 639.210 and NRS 639.255.

- 8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Dimitris Efstathiou, Certificate of Registration No. 17277, stipulate to the following penalties:
- A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Efstathiou shall pay a fine of One-Thousand Dollars (\$1,000.00) for the violations; and
- B. Pursuant to NRS 622.400, Respondent Efstathiou shall pay Five-Hundred Dollars (\$500.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.
- 9. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent Walgreens Pharmacy #4854, Pharmacy License No. PH01293, stipulate to the following penalties:
- A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Respondent Walgreens Pharmacy #4854 shall pay a fine of Two-Thousand Dollars (\$2,000.00) for the violations; and
- B. Pursuant to NRS 622.400, Respondent Walgreens Pharmacy #4854 shall pay One-Thousand Dollars (\$1,000.00) to partially reimburse the Board for recoverable attorney's fees and investigative costs.
- 10. Any failure by any Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing the non-compliant Respondent(s) to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by any Respondent, the Board may impose additional discipline upon the non-compliant Respondent(s) consistent with the provisions of NRS Chapter 639.
- 11. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on June 14, 2023.

Respondents will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondents or counsel are not present at the meeting.

- 12. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.
- 13. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.
- 14. Upon approval of this Stipulation by the Board, Respondents shall pay the fines agreed to herein by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.
- 15. Upon approval of this Stipulation by the Board, Respondents shall pay the attorney's fees and investigative costs agreed to herein by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway Suite 206, Reno, Nevada 89521, within thirty (30) days of entry of this Order.
- 16. Subject to the approval of this Stipulation by the Board, the Board and Respondents agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondents have fully considered the charges and allegations contained in the *First Amended Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:	
Signed this day of June 2023	
WALGREENS PHARMACY #4854 Pharmacy License No. PH01293	
Signed this day of June 2023	
DIMITRIS EFSTATHIOU, RPH Certificate of Registration No. 17277	
APPROVED AS TO FORM AND CONTENT this day of June 2023	Signed this day of June 2023
WILLIAM J. STILLING, ESQ. Counsel for Respondents	BRETT KANDT, ESQ. General Counsel Nevada State Board of Pharmacy

# **ORDER**

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Walgreens Pharmacy #4854, Pharmacy License No. PH01293, and Respondent Dimitris Efstathiou, RPh, Certificate of Registration No. 17277, in Case Nos. 18-021-PH-S and 18-021-RPH-C-S, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

# IT IS SO ORDERED.

Entered this day of June 2023.	
	Helen Park, Pharm.D.
	President
	Nevada State Board of Pharmacy



#### BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Case No. 22-027-CS-S

Petitioner.

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JONATHAN R. SORELLE, MD, Certificate of Registration Nos. CS16072 and PD00567,

v.

STIPULATED FACTS

Respondent.

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Jonathan R. Sorelle, MD, Certificate of Registration Nos. CS16072 and PD00567, by and through counsel, Joshua M. Dickey, Esq., **HEREBY STIPULATE TO THE FOLLOWING OPERATIVE FACTS IN THIS MATTER:**<sup>1</sup>

- 1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events herein, Respondent Jonathan R. Sorelle, MD, held a controlled substance registration, Certificate of Registration No. CS16072, and dispensing practitioner registration, Certificate of Registration No. PD00567, issued by the Board.
- 2. On or about May 9, 2019, Board staff conducted an annual inspection of Respondent's practice, the Minimally Invasive Hand Institute, located at 9080 W. Post Road #200 in Las Vegas. The inspection revealed that Respondent's dispensing technician, Ashley Pagan, Certification of Registration No. TD01687, failed to properly segregate and/or dispose of expired dangerous drugs, including, without limitation:

1

All agreements and admissions made by Respondent are solely for final disposition of this matter before the Board and any subsequent related administrative proceedings before the Board or civil litigation involving the Board and Respondent. Therefore, Respondent's agreements and admissions are not intended or made for any other use, such as in the context of another State or Federal government regulatory agency proceeding, any State or Federal civil or criminal proceeding, and State or Federal court proceeding, and/or any credentialing and/or privileges matter.

- A. Losartan 50mg Expiration 12/2017
- B. Ciprofloxacin 500mg Expiration 12/2018
- C. Marcaine 50ml vial Expiration 12/2018
- 3. The inspection also revealed that Ms. Pagan dispensed a limited number of prescriptions without Respondent's initials verifying that he had checked the prescriptions for accuracy. None of the prescriptions that were dispensed without Respondent's initials were controlled substances.
- 4. Respondent relieved Ms. Pagan from her duties as dispensing technician, the expired medications were promptly and properly disposed of, and additional measures were put into place to ensure that expired medications are properly segregated and/or disposed of in conformance with federal and state law.
- 5. The two subsequent annual inspections of the Minimally Invasive Hand Institute did not reveal any further deficiencies with regard to the proper segregation and/or disposal of expired drugs or the verification of dispensed prescriptions.
- 6. A separate Board investigation initiated in September of 2021 revealed one-hundred twenty-one (121) fraudulent prescriptions for Oxycodone 30mg, 90 tablets, falsely documenting Respondent as the prescribing practitioner, were issued from July 13, 2020, to September 9, 2021 as follows:
  - July 2020 6 fraudulent prescriptions
  - August 2020 5 fraudulent prescriptions
  - September 2020 3 fraudulent prescriptions
  - October 2020 5 fraudulent prescriptions
  - November 2020 3 fraudulent prescriptions
  - December 2020 5 fraudulent prescriptions
  - January 2021- 6 fraudulent prescriptions
  - February 2021 5 fraudulent prescriptions

- March 2021 10 fraudulent prescriptions
- April 2021 15 fraudulent prescriptions
- May 2021 10 fraudulent prescriptions
- June 2021 15 fraudulent prescriptions
- July 2021 15 fraudulent prescriptions
- August 2021 15 fraudulent prescriptions
- September 2021 3 fraudulent prescriptions
- 7. Respondent fully cooperated in the Board's investigation and a related criminal investigation, which revealed no evidence of Respondent or his staff's actual involvement in the forged prescriptions or the resulting unlawful diversion of approximately 10,890 Oxycodone tablets.
- 8. Respondent did not review his prescriber activity (MyRx) in the Prescription Monitoring Program (PMP) between September 23, 2016, and August 13, 2022.
- 9. Prior to December 2022, Respondent had staff members Leticia Tamayo, Shelby Jackson, and Gary Gaje, access the PMP using his credentials to obtain patient utilization reports for Respondent's review prior to Respondent's issuance of controlled substance prescriptions.
- 10. On or about December 28, 2022, Leticia Tamayo and Shelby Jackson were approved by the Board as delegates to access the PMP and to obtain patient utilization reports on behalf of Respondent.

Respondent has fully considered the charges and allegations contained in the *First Amended Notice of Intended Action and Accusation* in this matter and has knowingly and voluntarily agreed to the stipulated facts set forth herein and thereby waived certain rights to contest the stipulated facts and to require the State to prove each stipulated fact by a preponderance of evidence.

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Signed this 2 nd day of June 2023

JONATHAN R. SORELLE, MD.

Certificate of Registration Nos. CS16072 and

PD00567

Signed this 6th day of June 2023

BRETTKANDT, ESQ. On behalf of

General Counsel

Nevada State Board of Pharmacy

APPROVED AS TO FORM AND CONTENT this 5th day of June 2023

JOSHUA M. DICKEY, ESQ.

**Counsel for Respondent** 

8984 Spanish Ridge Avenue Las Vegas, Nevada 89148-1302

TELEPHONE 702.562.8820 FACSIMILE 702.562.8821 www.BaileyKennedy.com



# JOSHUA M. DICKEY

DIRECT DIAL 702.851.0050 JDICKEY@BAILEYKENNEDY.COM

June 14, 2023

#### Via Email: bkandt@pharmacy.nv.gov

Brett Kandt, Esq., General Counsel Nevada State Board of Pharmacy 985 Damonte Ranch Parkway, Suite 206 Reno, Nevada 89521

Re: Nevada State Board of Pharmacy v. Jonathan Sorelle, MD, Case No. 22-027-CS-S

Dear Mr. Kandt:

The Board of Pharmacy's First Amended Notice of Intended Action and Accusation (the "Complaint") contains two claims for diversion. Specifically, Counts One and Two allege violations of the Federal Controlled Substance Act and Nevada Law, specifying that:

By failing to review his prescriber activity in the PMP and enabling persons to act under Respondent's authority to issue one-hundred twenty one (121) fraudulent prescriptions for Oxycodone 30mg, 90 tablets, resulting in the unlawful diversion of 10,890 Oxycodone tablets as alleged in Paragraphs 4 and 5 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate, or knowingly permitted, allowed, condoned or failed to report a violation of [federal law and state law] and is subject to discipline pursuant to NRS 453.236(1) and NRS 639.210(11) [and (12)].

Neither the law nor the evidence supports a finding of diversion. Rather, the Stipulated Facts provide that "Respondent fully cooperated in the Board's investigation and a related criminal investigation, which revealed no evidence of Respondent's actual involvement in the forged prescriptions or the resulting unlawful diversion of approximately 10,890 Oxycodone tablets. Absent some participation in the underlying criminal activity, Dr. Sorelle cannot have committed diversion.

Nor can there be any doubt that Dr. Sorelle lacked both the knowledge and requisite mental state to be liable for aiding and abetting or conspiring to engage in diversion. *See United States v. Klimavicius-Viloria*, 144 F.3d 1249, 1264 (9th Cir. 1998) ("To aid and abet, "it is necessary that a defendant in some sort associate himself with the venture, that he participate in it as in something that he wishes to bring about, that he seeks by his action to make it

Stipulated Facts ¶ 7.



Brett Kandt, Esq. June 14, 2023 Page 2

succeed.'..." The government must show more than mere participation; the defendant must 'intentionally assist[] in the venture's illegal purpose.") (citations omitted); *United States v. Otunye*, 995 F.3d 1191, 1210 (10th Cir. 2021) (conspiracy requires "(1) an agreement with another person to violate the law, (2) knowledge of the essential objectives of the conspiracy, (3) knowing and voluntary involvement, and (4) interdependence among the alleged conspirators.") (citations omitted). *See also Sharma v. State*, 118 Nev. 648, 655, 56 P.3d 868, 872 (2002) (aiding and abetting in the criminal context requires one to "knowingly [aid] the other person with the intent that the other person commit the charged crime."); *Dow Chemical Co. v. Mahlum*, 114 Nev. 1468, 1490–91, 970 P.2d 98, 112–13 (1998), *rev'd on other grounds*, *GES*, *Inc. v. Corbitt*, 117 Nev. 265, 271, 21 P.3d 11, 15 (2001). (2002) (A party must knowingly and substantially assist "or encourage another's conduct in breaching a duty to a third person" in order for civil liability for aiding and abetting to attach); *see also Guilfoyle v. Olde Monmouth Stock Transfer Co., Inc.* 130 Nev. 801, 812–13, 335 P.3d 190, 198 (2014).

We accordingly request that the Board agree to dismiss Counts One and Two in the Complaint as lacking any basis in law or in fact. Please feel free to reach out if you have any questions or would like to discuss this further. Thank you.

Sincerely,

Joshua M. Dickey

JMD\rc



# BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

Case No. 17-105-PH-S

17-105-RPH-A-S 17-105-RPH-B-S 17-105-RPH-C-S

Petitioner,

v.

WALGREENS PHARMACY #3842, Pharmacy License No. PH01249,

KRISTI NGUYEN, RPH, Certificate of Registration No. 18861,

CHERYL METTUS, RPH, Certificate of Registration No. 17225, and

THUY TRANDAC, RPH, Certificate of Registration No. 17658,

Respondents.

STIPULATED FACTS

Brett Kandt, General Counsel for Petitioner the Nevada State Board of Pharmacy (Board), and Respondent Kristi Nguyen, RPH (Nguyen), Certificate of Registration No. 18861, Respondent Cheryl Mcttus, RPH (Mettus), Certificate of Registration No. 17225, and Respondent Thuy TranDac, RPH (TranDac), Certificate of Registration No. 17658, and Respondent Walgreens Pharmacy #3842, Pharmacy License No. PH01249, jointly by and through counsel, William Stilling, Esq. of Stilling & Harrison, HEREBY STIPULATE TO THE FOLLOWING OPERATIVE FACTS IN THIS MATTER:

1. The Board has jurisdiction over this matter because at the time of the events alleged herein, Respondent Nguyen, Certificate of Registration No. 18861, Respondent Mettus, Certificate of Registration No. 17225, and Respondent TranDac, Certificate of Registration No. 17658, were pharmacists registered with the Board, and Respondent Walgreens Pharmacy #3842, Pharmacy License No. PH01249, was a pharmacy licensed by the Board.

- 2. Respondents Nguyen, Mettus and TranDac were employed by Walgreens Pharmacy #3842 at the time of the events herein.
- 3. On or about August 13, 2017, an electronic prescription from practitioner M.S. was transmitted to Walgreens Pharmacy #3842 for gabapentin 600 mg tablets for patient T.M., designated prescription no. 2931510, and dispensed to the patient.
- 4. On or about August 16, 2017, T.M. tendered a written prescription from practitioner E.S. for gabapentin 300 mg capsules for T.M to Walgreens Pharmacy #3842; this was designated prescription no. 2933209. Data review for prescription no. 2933209 was performed by a Walgreens pharmacist located in an out-of-state Central Pharmacy Operation Center (CPO), who was not registered with the Board; during data review DUR alerts were overridden. On or about August 18, 2017, Respondent Mettus dispensed prescription no. 2933209 to the patient.
- 5. On or about August 29, 2017, T.M. tendered two (2) written prescriptions from practitioner Z.G. for T.M to Walgreens Pharmacy #3842: 1) Aricept (generic donepezil) 5 mg, designated prescription no. 2939936; and 2) Seroquel (generic quetiapine) 100 mg, designated prescription no. 2939938. Prescription no. 2939936 included an order to discontinue Zaleplon 5 mg capsules previously prescribed by practitioner W.T. and designated prescription no. 2933781. Data review for prescription no. 2939936 was performed by a Walgreens pharmacist located in an out-of-state CPO, who was not registered with the Board. Respondent Nguyen performed product review on prescription no. 2939936. The Zaleplon 5 mg prescription no. 2933781 was not discontinued.
- 6. On or about September 13, 2017, T.M. tendered a written prescription from practitioner Z.G. for Zyprexa (generic olanzapine) 10 mg tablets for T.M. to Walgreens Pharmacy #3842; this was designated prescription no. 2948045. The prescription also had an order to discontinue Seroquel (generic quetiapine). Data review for prescription no. 2948045

was performed by a Walgreens pharmacist located in an out-of-state CPO, who was not registered with the Board. Respondent Nguyen overrode a DUR alert that olanzapine and quetiapine are similar therapies.

- 7. On or about September 24, 2017, Respondent TranDac overrode DUR alerts and refilled prescription no. 2939936.
- 8. On or about September 27, 2017, Respondent Mettus performed product review and dispensed Seroquel (generic quetiapine) 200 mg tablets for prescription no. 2942008, and refilled prescription no. 2939938 for quetiapine 100 mg tablets. DUR alerts for both prescriptions were overridden by a Walgreens pharmacist located in an out-of-state CPO, who was not registered with the Board.
- 9. On or about September 27, 2017, Respondent Mettus performed product review and refilled prescription no. 2933781 for Zaleplone 5 mg; in the process Mettus overrode a DUR alert on the belief that the prescribing practitioner had determined it medically appropriate for T.M. to take the medication for longer than the recommended duration of 35 days.

**AGREED:** 

Signed this / day of June 2023

WILLIAM STILLING, ESO.

Counsel for Respondents

Signed this

day of June 2023

BRETT KANDT, ESO.

**General Counsel** 

Nevada State Board of Pharmacy

# EXHIBIT 1 Case No. 22-479-CS-S Malcolm Paul, M.D.



# **NEVADA STATE BOARD OF PHARMACY**

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

# **CONTROLLED SUBSTANCE APPLICATION**

Non-Refundable \$200 fee Rev (05/19/2021)

(This application cannot be used by PA's or APRN's)

Section 1: Personal Information		
First: Nalcorm, Middle: David Last: Paul		
Date of Birth: SSN or ITINSex: #21M	X	
Home Address: W. Sahar Ave		
City:		
Telephone: Email: <u>wmostcsmithsunger</u> , a		
Degree: MA Practitioner License #: 21553 Specialty: Plas tics		
(You MUST have a current and active license with your respective BOARD to apply for and maintain a controlled substance registra	ition.)	Allen Herrore
Section 2: Practice Information (A practice address is required for processing of your application.)		
Practice Name (if any): Smith Plastic Sungery		
Practice Address: 7650 w. Sahara Ave Suite #:		
City: Las Vegas State: NV Zip: 89117		
Telephone: 702 838 2455 Fax: 702 838 7055 Email: wmo4+@smith	1	
receptione. 702 8 30 24) Frax. 702 000 70 5 Elitali. WW. B. 4 T. C. SMIT G.	SUN	jey.
Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		V
<ol><li>Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under</li></ol>		
conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the		
Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the		
capacity of a commissioned officer while on active duty in defense of the United States and separated		
from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		
Section 4: Federally Mandated Residence (AIDS 425 520 AIDS 520 420)	Yes	No
Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	103	
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		
2. Are you in compliance with the order or the plan approved by the district attorney or other public		

agency enforcing the order for the repayment of the amount owed pursuant to the order?

Section 5: Personal and Profes	sional His	tory				Yes	No
<ol> <li>Have you been diagnosed of physical condition that woo</li> </ol>							v
2. Have you been charged, ar	rested or o	convicted of a f	elony or misdemea	nor in <u>any</u> state?			V
3. Have you been the subject pending in <u>any</u> state?	of a board	d citation or an	administrative action	on whether complet	ed or		V
4. Has your license been subj	ected to a	ny discipline fo	r violation of pharm	acy or drug laws in g	any state?		
If you marked YES to any question Copies of any documents that ide			The transfer of the state of th	TO THE PARTY OF TH			<u>n</u> .
<b>Board Administrative Action:</b>		State:	Dat	te:	Case	#:	
Criminal Action:	State:	Date:	Case #:	County:		Court:	

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Malcolm PAI	11/18/22
Print Name (First, Last)	Date
Malc Value	11/18/22
Original Signature (electronic, copies or stamps not accepted)	Date

Board Use Only: Date Processed: \_\_\_\_\_\_ Amount: 200.000 CC

#### Nevada State Board of **Medical Examiners**

LICENSE CARD.

This is to certify that

MALCOLM DAVID PAUL

holds ACTIVE status as a Medical Doctor

in the state of Nevada in accordance with Nevada Revised Statutes Chapter 630.

21553

For the most up-to-date information about this licensee please visit our online-licensee lackup at metiboard.nv.gov.

The second second THIS IS YOUR WALLET I.D. CARD. SIGN, -DETACH AND CARRY IT WITH YOU AS YOU WOULD YOU! DRIVER'S LICENSE. THERE IS A FEE TO REPLACE THIS CARD.



NEVADA STATE BOARD OF MEDICAL EXAMINERS

9600 Ghteway Drive, Reno, Nevada 89521

This certifies that:

Malcolm David PAUL, M.D. holds Active status Medical Doctor licensure in the state of Nevada in accordance with Nevada Revised Statutes Chapter 630.

License No: 21553.

/Effictive:

9/28/2021

6/30/2023. ..

Licensee Signature,

A CONTRACTOR OF THE PARTY OF TH

DEA REGISTRATION NUMBER THIS REGISTRATION FEE PAID EXPIRES FP1056096 03-31-2025 \$888 SCHEDULES **BUSINESS ACTIVITY** ISSUE DATE 2,2N, PRACTITIONER 12-27-2021 3.3N.4.5 PAUL, MALCOLM SMITH PLASTIC SURGERY 7650 W. SAHARA AVE AS VEGAS, NV 89117-0000

#### **NEVADA STATE BOARD OF PHARMACY**

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

# CONTROLLED SUBSTANCE APPLICATION

Non-Refundable \$200 fee Rev (05/19/2021)

(This application cannot be used by PA's or APRN's)

Section 1: Personal Information  First: MALCOCM Middle: DAVII)  Date of Birth: SSN or ITIN  Home Address: DAVI State: WY 7ip: PAIN F DIA Telephone: Email:  Degree: May Practitioner License #: 21553 Specialty: PAIN F CYON MUST have a current and active license with your respective BOARD to apply for and maintain a controlled substance registration.	X  MG  ation.)	
Section 2: Practice Information (A practice address is required for processing of your application.)  Practice Name (if any): SM 714 EVNGENY CONTEN		
Practice Name (if any): JWI 114 TVICEPIG CENTER  Practice Address: 7650 W. CAHARA JW, Suite #:		
City: 645 VE645 State: 11 Zip: 89117		
Telephone: (70+/838- Fax. 70+/838- Email:	10	
3455 7055 INFO (0) + 141 Af JUI	(60)	27,0
Section 3: Military Service (NRS 622.120)	Yes	No
<ol> <li>Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)</li> </ol>		
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		-
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		
Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		V
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		V

12/13

Section 5: Personal and Profes				AND THE PROPERTY OF THE PARTY O	OF THE PROPERTY OF THE PARTY OF	THE STATE OF THE S
					Yes	No
Have you been diagnosed of physical condition that would be a second to the secon						V
						/
2. Have you been charged, an						V
3. Have you been the subject pending in <u>any</u> state?	of a board citation or a	n administrative actio	on whether comp	oleted or		/
4. Has your license been subje	ected to any discipline	for violation of pharm	acy or drug laws	in any state?		/
If you marked YES to any question Copies of any documents that ide						<u>n</u> .
Board Administrative Action:	State:	Dai		Case	DESCRIPTION OF THE PARTY OF THE	
Criminal Action:	State: Date:	Case #:	County:		Court:	
application is approved I ag governing this license or reg	ree to comply with a		and state state	In the event utes and regu	this	d by
application is approved I ag	ree to comply with a istration and unders	ll applicable federa	and state state	In the event utes and regu	this	
application is approved I ago governing this license or reg	ree to comply with a ristration and unders	ll applicable federal	and state state tion may result	In the event utes and regu	this	

Amount: \$200 CC

Board Use Only: Date Processed:

# Malcolm David Paul

License Number: 21553

License Type: Medical Doctor

License Status: Active

Initial License Date: Sep-28-2021

**Expiration Date:** Jun-30-2023

Public Address: 7650 W Sahara Ave.

Public City: Las Vegas Public State: Nevada

Public ZIP Code: 89117

**Public Country: United States** 

**Public Phone Number:** (702) 863-7891

#### **Specialties**

Specialty

Surgery, Plastic

#### **Education History**

Institution Degree/Certificate Date Enrolled Date To

University of Maryland School of

Medical Doctor Degree Aug-01-1965 Jul-01-1969 Medicine

# **Postgraduate Training**

Institution	Program Type	Specialty Type	Start Date	End Date
Mount Sinai Hospital	Internship/Residency	Surgery,General	Jul-01-1969	Jun-30-1971
George Washington University Program	Residency	Surgery, General	Jul-01-1971	Jun-30-1973
George Washington University Program	Fellowship	Surgery,Plastic	Jul-01-1973	Jun-30-1975

#### **Board Actions**

Summary

None.

Current Employment Status / Conditions / Restrictions on License / Prior Malpractice Claims

Summary

None.

## Fw: PENDING Controlled Substance Number to Apply/Transfer for DEA

Monitoring Program <pmp@pharmacy.nv.gov>

Thu 9/29/2022 9:56 AM

To: Shannan Johns <Sjohns@pharmacy.nv.gov>

98 partents 22-479-5

Thank you,

Nevada Prescription Monitoring Program 775-687-5694

This information is provided as a courtesy on behalf of the Nevada Prescription Monitoring Program. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission. Thank you.

From: Monitoring Program <pmp@pharmacy.nv.gov>

Sent: Monday, February 14, 2022 11:15 AM To: Candy Nally <cnally@pharmacy.nv.gov>

Subject: Re: PENDING Controlled Substance Number to Apply/Transfer for DEA

PMP NOT ready

Thank you,

Nevada Prescription Monitoring Program 775-687-5694

This information is provided as a courtesy on behalf of the Nevada Prescription Monitoring Program. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

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From: Candy Nally <cnally@pharmacy.nv.gov> Sent: Monday, February 14, 2022 7:10 AM

To: Monitoring Program <pmp@pharmacy.nv.gov>

Subject: FW: PENDING Controlled Substance Number to Apply/Transfer for DEA

From: Malcolm Paul M.D. <mpaulmd@hotmail.com>

Sent: Sunday, February 13, 2022 3:21 PM

To: Candy Nally <cnally@pharmacy.nv.gov>

Subject: Re: PENDING Controlled Substance Number to Apply/Transfer for DEA

**WARNING** - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Dear Candy,

I was unable to go to: <a href="nevada.pmpaware.net">nevada.pmpaware.net</a>
The site could not be opened on my computer.
Please advise
thank you,

## Malcolm D. Paul, M.D., FACS

Clinical Professor of Surgery Department of Plastic Surgery University of California, Irvine 1401 Avocado Ave., Suite 810 Newport Beach, CA 92660 Office Phone: (949) 760-5047 Office Fax: (949) 706-7880

Mobile:

The information contained in this email may be confidential and/or legally privileged. It has been sent for the sole use of the intended recipient(s). If the reader of this message is not an intended recipient, you are hereby notified that any unauthorized review, use, disclosure, dissemination, distribution, or copying of this communication, or any of its contents, is strictly prohibited. If you have received this communication in error, please contact the sender by reply email and destroy all copies of the original message

From: Candy Nally <<u>cnally@pharmacy.nv.gov</u>>
Sent: Monday, December 13, 2021 12:17 PM

To:

Cc: Zavestoski, Jennifer N. < Jennifer.N. Zavestoski 2@dea.gov >; Mark I. Sedar < msedar@pharmacy.nv.gov >

Subject: PENDING Controlled Substance Number to Apply/Transfer for DEA

Name: Malcolm Paul, MD

Follow each step below IN ORDER to ensure successful processing of your application.

Step 1: Your PENDING CS registration number is: 114363

Expiration Date: 10/31/2022

You will receive your ACTUAL CS registration number after you complete Steps 2 and 3 below. Step 2: Obtaining your Drug Enforcement Administration (DEA) number

- A. Complete the on-line DEA application at deadiversion.usdoj.gov. If you already have a DEA number from another state, and you want to transfer that DEA number to Nevada, you will need to complete "Make changes to my DEA registration". (\*NOTE: You must have your <u>PENDING CS</u> registration number to complete the DEA application or the Registration Change Requests form.)
- B. Once you complete the DEA application or the Registration Change Requests form, you will receive your DEA certificate in the mail. You <u>MUST</u> email (<u>cnally@pharmacy.nv.gov</u>) a copy of your Nevada DEA certificate to the Nevada State Board of Pharmacy. Once you email a copy of your Nevada

DEA certificate to the Nevada State Board of Pharmacy, proceed to Step 3 to apply for your PMP account.

Step 3: Nevada Prescription Monitoring Program (PMP) account

(VETERINARIANS ARE EXEMPT FROM THIS STEP)

- A. Go to <a href="nevada.pmpaware.net">nevada.pmpaware.net</a> and complete the on-line PMP application: YOU WILL USE YOUR PENDING CS NUMBER TO APPLY FOR THE PMP ONCE YOU HAVE RECEIVED YOUR DEA.
- B. Click "Create an Account" and follow the instructions.

YOU ARE NOT AUTHORIZED TO PRESCRIBE CONTROLLED SUBSTANCES UNTIL WE HAVE A COPY OF YOUR DEA, YOU HAVE REGISTERED WITH THE PMP AND HAVE RECEIVED YOUR PERMANENT CONTROLLED SUBSTANCE CERTITICATE OF REGISTRATION. THE PENDING NUMBER CANNOT BE USED FOR CREDENTIALING PURPOSES.

Thanks,

Candy M. Nally Licensing Specialist Nevada State Board of Pharmacy cnally@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

## EXHIBIT 2 Case No. 22-479-CS-S Malcolm Paul, M.D.

05/30/2023

RX# 2501493 ·· ··

## **Rx Image**

Message ID: MID13766TID1NEWRX20482

7027962980

Patient:

11:41AM

Address: pinehurst or Las Vegas NV 89109 DOS: <u>G</u>ender: F MRN: 21966

Phone

<del>(FRIMARY)</del> DAW: NO PRODUCT SELECTION INDICATED

Unit: Tablet

Digital Signature:

Refills Auth: 0

**DAW Reasont** 

Prescribed Drug;

Percocet 10 mg-325 mg tablet

Prescribed NDC: 63481-0629-70 Strength: 10-325

Oty: 40.0

Days Supply: 7.0

DEA Schedule: C-II

Diagnosis Codes:

I tab po q 4-6 hours pro palo g89,28 z41.1

Message:

Authorizing\_Agent:

AP6532988

Phane: 702-838-7055

Prior Auth:

Start Date:

Sent Date:

Sent Time:

Expiry Date:

Delivery Due:

Written Date:

Received Date:

Received Time:

1124108253

(FAX)

12-30-2021

12-30-2021

12-30-2021

12-30-2021

10:00 AM

10:00 AM

Supervising Prescriber:

Electronically Signed by: Malcolm Paul From ID: 6453085493007

Rx electronically transmitted to:

Sav-On Pharmacy #662

2885 East Desert Inn RoadLas VegasNV89121

2982242

Time

User

Image Note



## **Audit / Board of Pharmacy Inspection Report**

Rx #: 2880260-3 Store #: 5369 Sold Date: 01/03/2022

## **Prescription Image Side 1**

12/30/2021		eRx
DO NOT DISPENSE BEFORE: 12/30/2021	1	
Patient		
JE E		Ph:
Gender: F		
harbor ave LAS VEGAS, NV, 89002		
Prescriber		
MALCOLM PAUL		F: 702-838-7055 <b>Ph: 702-838-2455</b>
7650 W. Sahara Avenue Las Vegas, NV, 8	9117	
NPI: 1124108253 DEA:AP6532988		
Rx		
Percocet 7.5 mg-325 mg tablet		
1 Tab PO Q 4-6 Hours PRN Pain x7d Dx	:: G89.28, Z41.1	
#10 Tablet(s)	7 days supply	
Refills: 0		
Substitution Allowed		
		Page 1 of 3

## **Prescription Image Side 2**

eRx Sent to Store: 5369 NCPDP ID: 2976655	Sent Time: 12/30/21 09:32:00 PST
1500 S BOULDER HWY HENDERSON, NV 890158506	Message ID: MID13766TID1NEWRX20479 Prescriber Order Number: 20479RX21299
	Page 2 of 3

This report is considered a confidential Walgreens document. It is intended to be used for Board of Pharmacy inspections and Third 4

Party audits. Professional discretion should be used prior to releasing this document.

# Page 3 of 3 Patient Third Party Info Plan1: OPTUMRX COMMERCIAL PCN: 9999 Recipient ID: 17002878000 Group: UNEVADA Cardholder: J E Additional Prescriber Info Clinic Name: Smith Plastic Surgery



## **Audit / Board of Pharmacy Inspection Report**

Rx #: 2880260-3 Store #: 5369 Sold Date: 01/03/2022

## Annotations

1. "12/30/2021 09:32:12 AM

Digital Signature Received." - by SYSTEM on 12/30/2021 09:32:12 at 5369

## **Prescription Information**

All times are Central Standard Time except DUR comments which is local time

Patient

Name: J E E Address:

HARBOR AVE

HENDERSON NV. 89002

Date of Birth

Allergies/Health Conditions: No known allergies.

Drug

Drug: OXYCODONE/ACETAMINOPHN 7.5

MFG: MALLINCKRODT NDC: 00406-0522-01

Generic for: PERCOCET 7.5/325 MG TABLETS

Drug Class: C2

**Directions:** TK 1 T PO Q 4 TO 6 H PRF PAIN FOR 7 DAYS.

Qty: 10 Days Supply: 7 Original Date: 12/30/2021 00:00 Refills remaining when entered: 0

Prescriber

Name: MALCOLM PAUL DEA #: AP6532988

Address:

1401 AVOCADO AVE

NEWPORT BEACH, CA. 92660-8708

(949) 760-5047

Fill History

Scanned by Escribe on 12/30/2021 11:32:16 at 5369
Pat selected by Escribe on 12/30/2021 11:32:16 at 5369
Pbr selected by L. OCONNOR on 12/30/2021 11:35:50 at 5369
Entered by R. L. RALPH on 12/30/2021 13:16:57 at 5369
Pat/Pbr rev by R. L. RALPH on 12/30/2021 12:00:20 at 2445
Data Prod rev by R. L. RALPH on 12/30/2021 12:00:20 at 2445

Filled by L. A. OCONNOR on 12/30/2021 15:19:41 at 5369 Prod rev by M. M. TRINH on 12/30/2021 15:42:36 at 5369

Sold Date: 01/03/2022 15:34:36 RPH of Record: M. M. TRINH

Consultation

Consultation Required:Y

Consultation Type:SYSTEM GENERATED

Initiating

**Comments:** 12/30/21; 01:17 PM;In order to comply with state regulations, all new and copy prescriptions are blocked for

patient consultation in this state.

Resolution

**RPh:** M.M.TRINH on 01/03/22; 03:33 PM at store#5369 **Comments:** 01/03/22; 03:33 PM;MMT;Consultation

Completed:

DUR

**DUR Type:** NO DUR IDENTIFIED

DUR Description: DUR Severity: DUR Overridden:

DUR Overridden completed by:

**DUR Comment:** 



## **Audit / Board of Pharmacy Inspection Report**

Rx #: 533498-1 Store #: 6167 Sold Date: 01/03/2022

## **Prescription Image Side 1**

01/03/2022	eR.
DO NOT DISPENSE BEFORE: 01/03/202	
Patient	
L I	Ph:
Gender: F	
binehurst dr Las Vegas, NV, 89109	
Prescriber	
MALCOLM PAUL	F: 702-838-7055 <b>Ph: 702-838-245</b> 5
7650 W. Sahara Avenue Las Vegas, NV, 8	9117
NPI: 1124108253 DEA:AP6532988	
Rx	
Dilaudid 4 mg tablet	
take 1 tablet q4-6h prn pain X4d, DX: Z4	1.1, G89.28
#24 Tablet(s)	4 days supply
Refills: 0	
Substitution Allowed	
	Page 1 of

## **Prescription Image Side 2**

eRx Sent to	Store: 6167	NCPDP ID: 2979497	Sent Time: 01/03/22 15:00:00 PST
3025 LAS VE	GAS BLVD S	LAS VEGAS, NV 89109190	Message ID: MID13766TID1NEWRX20531 Prescriber Order Number: 20531RX21357
			Page 2 of 3

## **Prescription Image Side 3** Additional Prescriber Info Clinic Name: Smith Plastic Surgery Page 3 of 3



## **Audit / Board of Pharmacy Inspection Report**

Rx #: 533498-1 Store #: 6167 Sold Date: 01/03/2022

## **Annotations**

1. "01/03/2022 03:00:25 PM

Digital Signature Received." - by SYSTEM on 01/03/2022 15:00:25 at 6167

## **Prescription Information**

All times are Central Standard Time except DUR comments which is local time

Patient

Name: L Address:

PINEHURST DR LAS VEGAS, NV. 89109

Date of Birth:

Allergies/Health Conditions: Penicillins

Drug

Drug: HYDROMORPHONE 4MG TABLETS

MFG: MALLINCKRODT NDC: 00406-3244-01

Generic for: DILAUDID 4MG TABLETS

Drug Class: C2

Directions: TK 1 T PO Q 4 TO 6 H PRN P

Qty: 24 Days Supply: 4 Original Date: 01/03/2022 00:00 Refills remaining when entered: 0

Prescriber

Name: MALCOLM PAUL DEA #: AP6532988

Address:

1401 AVOCADO AVE

NEWPORT BEACH, CA. 92660-8708

(949) 760-5047

Fill History

Scanning overridden.

Pat selected by D. THOMPSON on 01/03/2022 17:03:00 at 6167

Pbr selected by D. THOMPSON on 01/03/2022 17:03:00 at 6167

Entered by D. R. THOMPSON on 01/03/2022 17:03:37 at 6167 Pat/Pbr rev by D. R. THOMPSON on 01/03/2022 17:07:19 at 6167

Data Prod rev by D. R. THOMPSON on 01/03/2022 17:07:19 at 6167

Filled by D. R. THOMPSON on 01/03/2022 17:14:14 at 6167 Prod rev by D. R. THOMPSON on 01/03/2022 17:16:11 at 6167 Sold Date: 01/03/2022 18:46:45

RPH of Record: D. R. THOMPSON

Consultation

Consultation Required:Y

Consultation Type:SYSTEM GENERATED

Initiating

Comments: 01/03/22; 05:03 PM;In order to comply with state regulations, all new and copy prescriptions are blocked for

patient consultation in this state.

Resolution

RPh: D.R.THOMPSON on 01/03/22; 06:45 PM at

**DUR** 

**DUR Type:** NO DUR IDENTIFIED

DUR Description: DUR Severity: DUR Overridden:

DUR Overridden completed by:

**DUR Comment:** 

store#6167	
store#6167 Comments: 01/03/22; 06:45 PM;DRT;Consultation Completed:	
Compiciou.	
	1

## EXHIBIT 3 Case No. 22-479-CS-S Malcolm Paul, M.D.



Registration	Roles	Users	Tile Layout Views		
Advanced Options	PERS	ONAL DEA N	<b>UMBER</b> fp1056096 🔀	Search	

No Users found.

## Address Card

## EXHIBIT 4 Case No. 22-479-CS-S Malcolm Paul, M.D.

**Attorney Timesheet for Peter Keegan and Courtney Lee** 

MALCOLM PAUL, M.D. - CASE NO. 22-479-CS-S

DATE TIME

December 14, 2022 1.1

Courtney Lee - reviewed investigative file with Executive Secretary David Wuest and Deputy Executive Secretary Yenh Long; legal research; discuss investigation with Board staff including Investigator Dena McClish, determined to proceed with drafting cease and desist and citation and fine.

December 15, 2022 0.5

Courtney Lee – Draft Cease & Desist and Citation & Fine submit for review and Executive Secretary signature.

December 27, 2022 0.6

Peter Keegan – Assume responsibility for case, review investigation and citation and fine as well as Respondent's notice of appeal. Emails and telephone conference with Dr. Malcolm Paul.

March 13, 2023 1.0

Peter Keegan – Prepare Statement to the Respondent and Notice of Hearing submit for Executive Secretary review and signature.

March 20, 2023 0.3

Peter Keegan – Telephone conference with Dr. Malcolm Paul regarding options for hearing and resolution, confirm continuance of hearing until Board's June 14, 2023 meeting in Las Vegas.

May 26, 2023 1.6

Peter Keegan – Review of case and investigation file, emails to licensing staff and investigator. Prepare exhibits for hearing and timesheets. Discuss matter with Deputy Executive Secretary.

June 13, 2023 0.9

Peter Keegan – Prepare to prosecute appeal of citation and fine in Case No. 22-479-CS-S.

June 14, 2023 1.0

Peter Keegan – Prosecute appeal of citation and fine in Case No. 22-479-CS-S.

**TOTAL 7 hours x \$59.97/hour = \$419.79** 

## **Timesheet for Kristopher Mangosing –**

## Malcolm Paul Case No. 22-479

DATE TIME

3/14/2023 0.25

Prepared 21 day notice for mailing.

5/12/2023 0.25

Prepared 21 day notice for mailing.

5/23/2023 0.25

Prepared documents for Board Book

**TOTAL POSTAGE \$8.10 X 2 = 16.20** 

TOTAL 0.75 hours x \$34.86/hour = \$26.15

**TOTAL \$42.35** 

## Timesheet for Darlene Nases -

## Malcolm Paul - CASE NO. 22-479-S

DATE TIME

12/20/2022 0.25 Certified and mailed out Cease & Desist/Citation

Certified Mailing Cost: \$7.82

3/14/2023 0.25 Certified and mailed out 233B Statement

Certified Mailing Cost: \$9.00

• TOTAL .50 hours x \$34.86/hour = \$17.43

• Total Expenses for Certified Mailings: \$16.82

## **TOTAL TIME & COST SUMMARY**

## Case No. 22-479-CS-S – Malcolm Paul, M.D.

Total	\$496.39
Certified Mailing Postage	\$16.82
Board Coordinator Darlene Nases – 0.5 hours @34.86/hr =	\$17.43
Certified Mailing Postage	\$16.20
Board Coordinator Kristopher Mangosing – 0.75 @34.86/hr =	\$26.15
Attorneys Courtney Lee & Peter Keegan – 7 hours @\$59.97/hr =	\$419.79

## EXHIBIT 1 Case No. 22-063-RPH-S Michael Burkintas, RPh.



Data: 03/08/2022

## NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206, Reno, NV 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

· Web Page: bop.nv.gov

## **Complaint Form**

Date	
Complainant Name: Desert View Hospital	
Address: 360 S. Lola Lane	City, State, Zip: Pahrump, NV 89048
Telephone Numbers: Home N/A	Business 775-751-7500
Patient Name: N/A	Date of Birth: N/A
Physician Name: N/A	Telephone Number: N/A
Address: N/A	City, State, Zip:
Drug Prescribed: N/A	Prescription Number: N/A
Pharmacy Name & Address: Desert View H	lospital Pharmacy - See above
Pharmacist/Staff: Michael Burkintas - Lie	cense #15419
	**************************************

STATEMENT OF COMPLAINT: Type or neatly print your complaint below. Be as concise as possible. Use reverse side if necessary. Make copies and attach any documents you have which support your allegation(s). After completing your statement of complaint, please sign and date it. <u>The Board does not have jurisdiction over complaints involving rudeness. customer service and/or pricing/billing disputes.</u>

As a result of an audit being performed in Desert View Hospital Pharmacy, Pharmacist Michael Burkintas was asked to submit to a random drug and alcohol screening on 2/18/2022. Michael's test came back positive for Amphetamines. The Medical Review Officer from the reference lab contacted Michael on 03/01/22 to discuss any possible medications he was prescribed that could have resulted in a positive test. Based on Michael's responses, the MRO determined that there was no medical reason for the positive result and released the final result to the Hospital. (Please see the final drug screening result attached). Based on the positive result and the Hospital's strict zero tolerance drug policy - employment was immediately separated.

Please understand that by signing and submitting this form to the Board of Pharmacy, you are authorizing and allowing this Board's staff to access your medical history and records, including pharmacy records, as needed to investigate your complaint. If you would like to limit what the Board's staff can review, you must inform us of those limitations in writing.

Name	License	# City	State	Country	Dis
	15419	PAHRUMP	NV	United States	None
ne :	Burkintas			First Name :	Michael
ity :	PAHRUMP			State:	NV
ip:	89048				
ite :	09/04/2001			Status:	Active
er:	15419		•	Type:	Pharmacist
,	. •			Discipline:	None
ate:	10/31/2023				

## **Total Compliance Network**

5646 West Atlantic Boulevard \* Margate, FL 33063 \* Telephone (954) 677-1200 \* Fax (954) 677-1201

Medical Review Officer Determination / Verification Report

DESERT VIEW REG MED CENTER 360 S. LOLAN LANE PAHRUMP, NV 89048 ATTN: QIS 2 System

Donor Name:

MICHAEL BURKINTAS

Specimen ld:

510302364840481

Donor Id:

276761

Location: Date Collected:

2/18/2022

Reason or Type Of Test:

Other

FINAL DETERMINATION:

**Positive** 

Positive For:

**Amphetamines** 

**Additional Comments:** 

Contact made: [3/1/2022] No medical reason.

The results for the identified person are in accordance with the applicable screening and confirmation cut-off levels established by Federal SAMHSA, NIDA, or Florida AHCA mandatory guidelines for Workplace Testing Programs.

Reporting MRO:

SETH PORTNOY, D.O.

Date Verified:

Mar-01-2022

Seth Portnoy, D.O.

Total Compliance Network / MRO Service 5646 West Atlantic Boulevard Margate, FL 33063

Retain this form in the employee qualification file. Include this information in the file each time the employee is tested.

## EXHIBIT 2 Case No. 22-063-RPH-S Michael Burkintas, RPh.

## BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY,

**CASE NO. 22-063-RPH-S** 

Petitioner,

V

MICHAEL BURKINTAS, RPH, Certificate of Registration No. 15419,

Respondent.

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**SUBPOENA** 

The Nevada State Board of Pharmacy sends greetings to:

Dawn Hahn or Custodian of Records Quest Diagnostics 10101 Renner Blvd Lenexa, KS 66219

Pursuant to the authority of NRS 639.246(1), **WE COMMAND YOU**, that all singular, business and excuses being set aside; you shall produce and deliver to the Nevada State Board of Pharmacy, the materials as set forth in this Subpoena:

Properly authenticated and complete copies of any and all testing records for Michael Burkintas, RPH, a former employee of Desert View Hospital located in Pahrump, Nevada, Specimen #510302364840481, Donor ID #276761, date of collection 2/18/2022, including, but not limited to, the total litigation packet, laboratory results, chain of custody, correspondence by and between medical director and Burkintas, test result(s), and any explanatory notes regarding the test result(s).

Said records shall be forwarded to the Nevada State Board of Pharmacy, Attn: Courtney Lee, General Counsel, 1140 N. Town Center Drive, Suite 300, Las Vegas, NV 89144 or electronically to

1 SUBPOENA

1	c.lee@pharmacy.nv.gov within ten (10) days from the date of service of this subpoena. Failure to
2	comply and produce said records at the aforesaid time and place may subject you to possible action,
3	including NRS 639.246(5).
5	Additionally, compliance with this subpoena is deemed compulsory.
6	Dated this
7	
8	NEVADA STATE BOARD OF PHARMACY
9	
10	Yenh Long, Pharm.D., Deputy Executive Secretary of
.1	the Nevada State Board of Pharmacy, for and on behalf of J. David Wuest, R.Ph., Executive Secretary of the
L2 L3	Nevada State Board of Pharmacy
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## **DOCUMENTATION PACKAGE**

## **PROVIDED BY:**

QUEST DIAGNOSTICS INCORPORATED 10101 RENNER BLVD. LENEXA, KS 66219

## **DOCUMENTATION PACKAGE COVER SHEET**

Attached is a summary and copies of laboratory documents related to the analysis of Donor ID # 276761, Specimen ID # 4840481 with Accession Number 692504Z. The following 123 pages are true and accurate copies of the original documents that were generated during the normal course of business by Quest Diagnostics Incorporated. The original documents were generated at or near the time of each process.

The urine specimen (692504Z) screened positive for Amphetamines by enzyme immunoassay and confirmed positive for Amphetamine by Gas Chromatography/Mass Spectrometry. The validity of the specimen was assessed by creatinine, pH and general oxidant testing was determined to be acceptable. The blood specimen was missing the tamper evident seal and was rejected for testing. Following review of the analytical data and chain of custody documentation, a Positive result for Amphetamine and Rejected for Testing: Fatal Flaw, Bottle A label/seal missing were reported.

Documentation Package Reviewed by:

Kenneth Reine
Printed Name
Signature

Lab Manager NOV 1 1 2022

Title
Date

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## GENERAL OVERVIEW OF LABORATORY PROCEDURES

## Specimen Receipt

The laboratory acknowledges receipt of the specimen(s), verifies ID, and verifies that there is no evidence of tampering by examining the tamper-evident bag and specimen security seal. The external Custody and Control Form (CCF) is completed and the internal laboratory Chain of Custody (COC) is initiated. All specimen and subsequent aliquot handling is carefully documented via internal COC.

## Order Entry/Log-In

Client account number, specimen identification number, donor identification and testing information are logged into the specimen tracking computer system. A unique accession number is assigned to the specimen and an accession barcode label is affixed to the specimen container and accompanying Custody and Control Form.

### Aliquot for Screening Test

The specimen container is opened (breaking the seal) and a small portion of the sample is removed for the initial screening tests. Aliquots may be taken by manual or automated (CV-2000) methods. The aliquot is transferred to the testing laboratory and the original specimen is placed in temporary secured storage. The handling of the specimen and the aliquot is documented on internal chain of custody forms.

## **Drugs of Abuse Screening Test**

The initial screening test for drugs of abuse is conducted using enzyme immunoassay procedures on Beckman chemistry analyzers. A specimen is considered negative if the response for a given analyte is below that of the cutoff standard. If the response is equal to or greater than the cutoff standard, the specimen is scheduled for confirmation testing.

## Specimen Validity Tests (TestSure not ordered)

In order to assess the validity of each specimen, the laboratory routinely tests each specimen for pH and creatinine concentration. Specific gravity testing is performed on all specimens that have a creatinine concentration that is less than 20 mg/dL. If specimen adulteration or substitution is suspected, the laboratory performs a confirmation test on the specimen. The confirmation test is performed on a second aliquot of the specimen that is obtained from the original specimen container.

### Specimen Validity Tests (TestSure ordered)

In order to assess the validity of each specimen, the laboratory routinely tests each specimen for pH, creatinine concentration and general oxidants. Specific gravity testing is performed on all specimens that have a creatinine concentration that is less than 20 mg/dL. If specimen adulteration or substitution is suspected, the laboratory performs a confirmation test on the specimen. The confirmation test is performed on a second aliquot that is obtained from the original specimen container.

## Verification

The specimen identification number on the tamper evident seal is inspected a second time and verified as accurate.

### Confirmation Test for Drugs of Abuse

If the initial test result is positive, a second aliquot, obtained from the original specimen container, is tested by Gas Chromatography/Mass Spectrometry (GC/MS). A concentration less than that of the client specific cutoff for a given analyte is reported as negative. A concentration equal to or greater than that of the client specific cutoff is considered to be positive.

### Certification

All data goes through a two-tier review process: initial review and certification. During the initial review process, the analyst reviews all analytical data. During the certification review process, a certifying scientist reviews all analytical data and evaluates all documentation for acceptability and adherence to laboratory standard operating procedures.

## Quality Assurance/ Quality Control

A comprehensive quality assurance/quality control program is used to ensure the quality of all test results. The program addresses all aspects of testing, method performance, quality of reagents and standards, specimen handling and documentation, automation, and procedural consistency. A minimum of 10% open controls and 1% blind controls are included in all testing processes.

### Reporting

The drug test result is transmitted in a confidential manner directly to the individual responsible for the interpretation of the report.

## Confidentiality and Security

The laboratory is a secure facility and is protected by numerous physical and electronic security systems. Specimens are maintained in a secured limited access area, separate from the testing laboratory. Tests are never conducted directly on the original specimen, but on aliquots that are obtained from the original specimen. Internal laboratory accession numbers are assigned to the specimens to ensure anonymity during the testing process. The computer system used is designed to require security clearances for use by authorized staff. The system is designed to ensure the confidentiality of a donor's data at all phases and precautions are taken to prevent any tampering with the specimen, data, or result.

**CUSTODY AND CONTROL FORMS** 

r	
DRENS DRUG TESTING CUSTODY AND CON	TROL FORM 692504Z
	Quest Diagnostics 18191 Renner Elud Lerunco, KS 66219
5/030236 4840481 SPECIMEN ID NO. STEP 1: COMPLETED BY COLLECTOR OR EMPLOYER REPRES	ENTATIVE LAB ACCESSION NO.
A. Employer Name, Address, I.D. No.	8. MRO Name, Address, Phone and Fax No. 17040 15 Service of the State
360 1 1004 L0 PARRORE BY 05048 PR 760 111 7628 FAN 775-751-7895	BEAS DESCRIPTION FOR SEASON TO BE WITH THE SEASON THE S
C. Donor SSN or Employee I.D. No. 1976, 767	To CAMAGE
E. Donor ID Verified: Photo ID Emp. Rep.	
F. Reason for Test: Pre-employment (1) Rendom (3) PRETURN to Duty (6) Follow-up	Restansible Suspicion/Cause (5) Post-Assident (2) Promotion (22) (23) Other (specify) (99)
G. Drug Tests to be Performed:	a state of the sta
Dut	TO COLOR
H. Collection Site Name: 340 SLOW VIIIL	Collector Phone No. 775 -75/-7500
City, State and Zip:	Collector Fax No.:
	imen Ojlecijon.
	Split Single None Provided (Enter Remark) Observed (Enter Remark)
REMARKS STEP, 3: Collector affixes hours seal(s) to bottle(s). Collector dates as	al(a). Donor nitials sacils!. Donor completes STEP 5.
STEP 4: CHAIN OF CUSTODY - INITIATED BY COLLECTOR AN	D COMPLETED BY LABORATORY
Court of many 2 1 8 13	SPECIMEN BOTTLE(S) RELEASED TO:  Quest Diagnostics Courier   Fadex
PECEIVED COllector's Name (First, Nr. Last)  Date (Mo. Co. Wind)  VETO TO NTERNAL OWN OF CLERON'S	Name of Onlivery Service Transferring Specimen to Lab  Primary Specimen SPECIMEN BOTTLE(S) RELEASED TO:
Signature of Access one FFR 2 2 2022 /	Bottlo Seal Intact
(Print) Accessioner's Name (First, Mt. Link) Bare (Mo-Day/Yr.)	No, Erner Homer
STEP 5: COMPLETED BY DONOR  To could that I provided my specimen in the solitoring that I have not adult a part in a new manner.	each apacieus botto part west to take to the tarious evident as in the botto the following on and
numbers provided an this form and on the lates afficed to each appeliant battle is correct.	A COLUMN TO THE STATE OF THE ST
Significant and Donor	CHARL OUREIN THE Less)
Daysima Phone No.	
فه دو کا کا	
Photocopied CCF:	
Original wet	
upon receipt	

**Accessioning Trouble Log A** 

Specimen (Number Fro				7.38		
7		FATAL FLAWS UNRECOVERABLE PRO "Do not aliquot" "Transfer to Exception	BLEMS	Pin Pin		
FQNS3		QNS-Specimen volume in primary bottle (Bottle A) < 20 mL- ins	sufficient Amount Collected			
FQNS4	7. 3	Regulated ONLY— Reject the specimen for testing if it cannot be redesignated.  Leaked in Transit and QNS-Specimen volume in primary bottle (Bottle A) < 20 mL  Regulated ONLY— Reject the specimen for testing if it cannot be redesignated.				
FNOR2	SA	No CCF-Specimen received without a CCF: Regulated and SAP				
FNOS2		No Specimen -CCF received without a specimen: Regulated and SAP—Reject for testing.		-		
FQIDMM, FQID	Bullet Bullet	Mismatch CCF and Bottle-Specimen ID on CCF does not match Regulated and SAP—Reject the specimen for testing. Bottle ID	h bottles:			
FQIDMM, FQIDAB	100	Bottle A and B ID mismatch-Specimen ID on A and B bottle do not match:  Regulated and Sap—Reject for testing. Bottle A ID				
FQIDN	1000	Bottle ID missing -Specimen identification not present on bottle: Regulated – Reject for testing for EITHER A or B missing bottle SAP— Reject the specimen for testing if it cannot be redesignate				
FQIDMM, FIDI2	, i	Bottle ID illegible-Specimen identification is illegible on specime Regulated—Reject for testing for EITHER A or B bottle has illegible SAP—Reject the specimen for testing if it cannot be redesignate	n bottle:			
FTSC2	λ.	Two collections performed on one CCF: Regulated and SAP – Reject for testing.	G .	-		
FMSS9	X	Specimen bottle has no seal: Regulated* and SAP — Reject for testing if specimen cannot be redesignated *Bottle must contain specimen ID to redesignate regulated				
FMSS10		Specimen bottle seal misapplied: Regulated and SAP – Reject the specimen for testing if it cannot be redesignated				
FMSS5		Specimen bottle has broken/torn seal:  Regulated and SAP— Reject the specimen for testing if it cannot be redesignated.				
FMSS6		Specimen bottle seal shows evidence of tampering: Regulated and SAP— Reject the specimen for testing if it cannot be redesignated.				
FNAMC SAP Only)	Mariana	Donor name and signature do not match:	The same of the sa			
FCOL2		No Collector's Signature AND no printed name on CCF: Regulated and SAP -Reject specimen for testing				
FICOL SAP Only)		Improper Collection				
FMSS3		Hair Improperly sealed. (Hair only)				
FQNSH Hair/Oral F)		QNS- Insufficient specimen quantity				
TNP/FFF	-7	Fatal flaw that affects the forensic defensibility (e.g. Altered Standard comments below to clarify if needed)	p ID, wrong seals on regulated eCCF).			

DATE	Released By Signature/Printed Name	Received By Signature/Printed Name	Purpose of Chain of Custody
FEB 2 2 2022	ALEXUS MARCILLE	EXCEPTIONS BIN	Temporary Storage

ACTION COMPLETED	SIGNATURE	NAME	DATE
Specimen bottle(s) removed from Exception Bin for TIQ investigation.  [ ] Fatal flaw identified, Flexi-log and specimen(s) placed in temp storage.  Non-fatal flaw identified, specimen(s) placed in temp storage.	S	SERRA GARDNER	
If Needed	and the contract of		
Specimen bottle(s) removed from Temp	1	NAOMI BETTS	1/22/22

## INITIAL TEST INFORMATION

## INITIAL TEST DESCRIPTION

Initial testing for drugs of abuse is performed on the Beckman chemistry analyzer by enzyme immunoassay. The cutoff for each drug of abuse assay is assigned a value of 1.000 based on the response of a calibrator that contains drug at the cutoff concentration of the assay. If a donor specimen has a response that is less than 1.000, the specimen is determined to be negative for the specific test. If a donor specimen has a response that is greater than or equal to 1.000, the specimen is determined to be positive for the specific test and requires additional confirmation testing. Each batch contains both negative and positive quality control samples along with one blind quality control sample that is inserted into the batch in a random position.

### Testsure example:

Initial testing for specimen validity is performed by a colorimetric method on the Beckman chemistry analyzer. The specimen is evaluated for pH, creatinine concentration and the presence of general oxidants. All specimens with a pH value of <4.5 or ≥9.0 are subject to a second pH test on a pH meter. All specimens with a creatinine concentration of < 20 mg/dL are subject to specific gravity testing and if applicable, further confirmation testing. All specimens with an abnormal general oxidant response are subject to confirmation testing. Each batch contains quality control samples with target values that are at or near the critical decision points of each specimen validity test.

### Non-Testsure example:

Initial testing for specimen validity is performed by a colorimetric method on the Beckman chemistry analyzer. The specimen is evaluated for pH and creatinine concentration. All specimens with a pH value of <4.5 or  $\geq$ 9.0 are subject to a second pH test on a pH meter. All specimens with a creatinine concentration of < 20 mg/dL are subject to specific gravity testing and if applicable, further confirmation testing. Each batch contains quality control samples with target values that are at or near the critical decision points of each specimen validity test.

PAGE

. 02/24/2022

# CHAIN OF CUSTODY LOG

DATE	RELEASED BY		RECEIVED BY	PURPOSE
02/24/2022 Name	Temporary_Storage	Sign. Name	LIN, LILY	TRANSFER
FEB 2 4 2022 Sign.	LIVIN	Sign. Name	PROGESSING TS	TEMP STORAGE
FEB 2 4 2022 Sign.	MARIE DE LE SECTION DE LA COMPANION DE LA COMP	 Sign.	Shan	TEMPSTORAGE
FEB 2 4 2022 Sign.	PROCESSING TS Shay	Name Sign.	SHALEAH VOLKMAN	ALIQUOTTING
Name	SHALEAH VOLKHAN	Name	PROCESSING TS	TEMP STORAGE
Sign. Name		Sign. Name		
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Sign. Name		Sign. Name		
Sign. Name		_Sign. _Name		

691255Z	27258N	G036553/A/1	Split Rec'd
691384Z	66405N	G036553/A/10	Split Rec'd
691218Z	35190N	G036553/A/2	Split Rec'd
691203Z	65105N	G036553/A/3	Split Rec'd
691240Z	34061N	G036553/A/4	Split Rec'd
691286Z	27215N	G036553/A/5	Split Rec'd
691309Z	35190N	G036553/A/6	Split Rec'd
691355Z	35105N	G036553/A/7	Split Rec'd
691341Z	45105N	G036553/A/8	Split Rec'd
691276Z	65190N	G036553/A/9	Split Rec'd
691323Z	27215N	G036553/B/1	Split Rec'd
691130Z	27258N	G036553/B/10	Split Rec'd

PULL LIST FOR WORKLIST(S) TXNSAP3

PAGE

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02/24/2022

WORKLIST :	TXNSAP3			
ACCESSION	PARTICIPANT	UNIT CODE	STORAGE BOX/ROW/COL	
691331Z		34647N	G036553/B/2	Split Rec'd
690968Z		65105N	G036553/B/3	Split Rec'd
691190Z		65105N	G036553/B/4	Split Rec'd
691173Z		27215N	G036553/B/5	Split Rec'd
691168Z		65105N	G036553/B/6	Split Rec'd
691158Z		65105N	G036553/B/7	Split Rec'd
691148Z		65105N	G036553/B/8	Split Rec'd
691141Z		65105N	G036553/B/9	Split Rec'd
691121Z		65105N	G036553/C/1	Split Rec'd
691064Z		27420N	G036553/C/10	Split Rec'd
690929Z		6405N	G036553/C/2	Split Rec'd
690959Z		35105N	G036553/C/3	Split Rec'd
691011Z		65105N	G036553/C/4	Split Rec'd
				NVBOP - 0

**NVBOP - 019** 

690999Z	Contract of	65105N		G036553/C/5	Split	Rec'd
691019Z		29188N	•	G036553/C/6	Split	Rec'd
691030Z		31920N		G036553/C/7	Split	Rec'd
691038Z		65105N		G036553/C/8	Split	Rec'd
691050Z		27119N		G036553/C/9	Split	Rec'd
691084Z		27119N		G036553/D/1	Split	Rec'd
691267Z		35105N		G036553/D/10		
691097Z		27258N		G036553/D/2	Split	Rec'd
690985Z		6405N		G036553/D/3		
691071Z		35,190N		G036553/D/4		
691105Z		27800N		G036553/D/5		
691113Z		32720N		G036553/D/6		
691184Z		31521N		G036553/D/7		

PULL LIST FOR WORKLIST(S) TXNSAP3

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02/24/2022

WORKLIST :	TXNSAP3		CITICAL A CITI	
ACCESSION	PARTICIPANT	UNIT CODE	STORAGE BOX/ROW/COL	===
690978Z		65186N	G036553/D/8	7-37-63
690914Z		35765N	G036553/D/9	
690864Z		46633N	G036553/E/1	
690923Z		35765N	G036553/E/10	Split Rec'd
691349Z		27913N	G036553/E/2	
691375Z		35765N	G036553/E/3	
691366Z		36663N	G036553/E/4	
690898Z		27119N	G036553/E/5	
692504Z	276761	35190N	G036553/E/6	
692495Z		35190N	G036553/E/7	
692342Z		26921N	G036553/E/8	

**NVBOP - 020** 

		G036553/E/9	35545N	692356Z
Rec'd	Split	G036553/F/1	65105N	690891Z
		G036553/F/2	35105N	690908Z
Rec'd	Split	G036553/F/3	35105N	690868Z
Rec'd	Split	G036553/F/4	27800N	690876Z
Rec'd	Split	G036553/F/5	27806N	690885Z

# C.T./C.S. Calibration/Control Review Checklist

Instrument: 91 | FEB 2 4 2022

ORAL FLUID URINE 07/15/2013

The undersigned hereby state that they have reviewed the attatched data and found the calibration data to be present and acceptable, and all open controls complete and results interpreted correctly.

C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
WHORE GROVER FEB 2 5 2022	KRISTOFER PARKER	KUDAKWASHE FEB 2 4 2022
MIONI GIROTALI I ED T. I	FEB 27 2022 √	MURANDA
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Frinted Name, Date:
Jen 27 2022	GAVIN SMULL	ELIZABETA FED 2 6 2022
J CD 2 . 22	FEB 2 5 2022	LAR PED Z 0 ZUZZ
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./Crs. signature, Printed Name, Days:  JAMES LIND
DONNA FEB 2 5 2022	JACK RICHARDSON	The Live I
	FEB 2 4 2022	<b>FEB 25 2022</b>
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
JONATHAN RAMPONE	FREDLIN JOSEPH	DECHHEN FEB 2 4 2022
FEB 2 5 2022	FEB 24 2022	
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
FEB 2 5 2022	WWIGH	HALEY CALL FEB 2 4 2022
HENDERSON SESS FEB 2 5 2022	KERRY FEB 2 4 2022	Well W
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Frinted Name, Date:	C.T./C.S. Signature, Printed Name, Date:
	Ab .	
MEENU THAMAN FEB 2 5 2022	SALEH FEB 2 4 2022	TOP FEB 2 4 2022
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
JESSICA CARROLL		ROY ODUOR FEB 2 1/2022
FEB 2 5 2022	ELIAS BESONG (FEB 2 4 2022	
	C.T./C.S. Signature, Printed Name, Date:	C.T./s.s. Signature, Printed Name, Date:
XX	MEMIN BRITTON FEB 2 4 2022	$ \mathcal{V} $
SCHLICHT-HUGO TOB 2 5 2022	9	LYNETTE STONE FEB 2 4 2022
	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Dater
JEPHTAH KENEI FEB 2 4 2022	OSCAR ONYANGO FEB 2 4 2022	HAYDEN FEB 2 L 2022
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	MANUEL C.T./C.S. Signature, Printed Name, Date:
100	1	SUNSHINE ARTERBURN
EWURAMA FEB 2 2002	SOLOMON FEB 2 4 2022	FEB 2.4(2022)
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
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FEB 2 4 2022	SANDRA MARKHAM FEB 2 4 2022	ELENITA IRVING A FEB 2 4 2022
, ,		/\/



# C.T./C.S. Calibration/Control Review Checklist

The undersigned hereby state that they have reviewed the attatched data and found the calibration data to be present and acceptable, and all open controls complete and results interpreted correctly.

C.T./C.S. Signature, Printed Name, Date:  ANNA CARR  FEB 2 7 2022	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
C.T./C.S. Signature, Printed Name, Date:	MAR 0 1 2022 C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
C.T./C.S. Signature, Printe LAlame, Date: SHERRI YOUNGER	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
FEB 2 8 2022 C.T./C.S. Signature, Printed Mane, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
C.T./C.S. Signature, Printed Name, Date:	FEB 2 8 2022  C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
JUDAH BANNING MAR 0 1 2022	and the second s	C.T./C.S. FIGNATURE Printed Name, Date:  MAR 03 2022
C.T./C.S. Signature, Printed Name, Date:  DANSON KAMUNYU  FEB 2 8 2022	C.T./C.S. Signature, Printed Name, Date: FAIZA ISLAWAYIT WAR 0 1 2022	C.T./C.S. Signature, Printed Name, Date:
C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:	C.T./C.S. Signature, Printed Name, Date:
C.T./C.S. Signature, Printed Name, Date:	William K. FEB 2 7 2022	C.T./C.S. Signature, Printed Name, Date:



# Toxicology Department Screening Calibration Verification Checklist

Form #5850C 09/04/2012

Date:	FEB 2 3 2077	
Operator:	TORI WESCHE Ju	
Instrument:	517	
Da	aily Maintenance Performed	FEB 2 3 2022 J
	Operation Startup Complete	FEB 2 3 2022 Ju
All C	Calibration Data Acceptable	FEB 2 3 2022 Ju
Controls Acce	eptable & Results Recorded	FEB 2 3 2022 Jw
initial Review:	EDWIN KANGETHE KER	Date: FEB 2 3 2022  Date: FEB 2 3 2022  RY Date: PEB 2 4 2022

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MIDA SYSTEM SAF DRUG SCREEN NO WORKLIST: TXNSAP3

LDAD: 0224114

\*NDARWP03 02/24/2022 9:31A PAGE: 1

BUILT: 02/24/2022 9:30 AM BY: KSSV04 CUPS: 1-64

TOTE NUMBER: 81077

SIGNATURE PRINTED HAME EVAN ROBERTS FEB 2 4 2022 INTERFRETED BY: REVIEWED/ FEB 2 4 2022 RELEASED BY:

ALIQUOT CHAIN OF CUSTODY LOG

DATE.	RELEASED BY		RECEIVED BY	PURFOSE
02/24/22 STON NAME	VOLKMAN, SHALEY	SIGH.	PASS THRU	TEMP STORAGE
FEB 2 4 2022 SIGN.	- PASS-THRU	SIGH.	ATISHA CASTLEBERRY	TRANSFER
FEB 2 4 2022 STGN	LATISHA CASTLEBERRY	SIGN. HAME	ANALY7FR 17	ANALYSI
FEB 2 4 2022 SIGN.	A.ST	SIGM.	EVAN ROBERTS CO	OMPLETE ANALYSIS
FEB 2 4 2023 IGN NAME	EVAN ROBERTS	SIGH. NAME_	-DISCARD-	Middle and the second state of the second
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HIDA SYSTEM SAP DRUG SCREEN #3 NORKLIST: TXNSAP3 LOAD: 0224114

BUILT: 02/24/2022 9:30 AM BY: KSSV04 CUPS: 1-64

TOTE NUMBER: 81077

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2	60412	691219Z		8927774 7914982477	35170M
3	60413	691203Z		8927759 CC04557510	6S10SH
4	60414	691240Z	-	8727783 7917165877	34061N
57	60415	691286Z	-	8927 <b>833</b> 7902668 <b>91</b> 4	27715N W
ත	60416	6913092		8927848 CC071 <b>753</b> 52	35190N
7	60417	6 <b>9</b> 1355Z	-	8727882 00071 <b>75</b> 355	35105N MV
Z	60418	6913417	-	4617644	45105H
- <b>9</b>	60419	691276Z		a9278 <b>22</b> CC07175 <b>3</b> 54	65190N
10	50420	691 <b>384</b> Z		0499812	66405M
11	60421	*SAPET			
12	60422	6913232	-	8927853 7902668923	27715H NV
13	60423	6913317		8927868 CC07870089	34647R
14	60424	690968Z	-	89275 <b>96</b> 0.06557500	6510SN
15	60425	6911902		8927751 CC06557506	6510SN
16	60426	691173Z		0°27 <b>737</b> 790266 <b>891</b> 1	27215H NV

MIDA SYSTEM SAF DRUG SCREEN #3 MORKLIST: TXMSAP3 LOAD: 0224114

BUTLT: 02/24/2022 9:30 AM RY: KSSV04 CUPS: 1-64

TOTE NUMBER: 81077

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17	60427	6911687	-	892 <b>7732</b> CC065 <b>57509</b>	65105N
18	60428	6911587		8927 <b>727</b> CC045 <b>57</b> 513	<b>65105</b> M
19	60429	8 <b>9</b> 1148Z		8927719 CC0655 <b>750</b> 7	65105N
20	50430	691141Z		8927715 CCQA557508	65105N
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53	60432	6911217		892 <b>770</b> 3 CC0655 <b>7</b> 512	6510SN
23	66433	<b>69092</b> 97		89275 <b>69</b> 7918221309	5405N
24	60434	690959Z		9927590 7907470734	39 LOSA
25	60435	691011Z		8927617 CCO8001125	65105N
23	60436	690999Z		0464215	65105M
27	60437	691019Z	-	9 <b>727626</b> 79052 <b>894</b> 62	29186N
20	50439	69103 <b>0</b> Z		5774985	31920H
27	50 <b>4</b> 39	69103 <b>8</b> Z		8927 <b>640</b> CC06 <b>557511</b>	¢S105N
30	30440	691050Z		9927653 CC09010681	27119N
31	50441	*SAPALTI	91		
3.3	50442	691064Z	-	8927 <b>666</b> 7914 <b>9</b> 82473	27420N

NIDA SYSTEM SAF DRUG SCREEN #3

WORKLIST: TXNSAP3 LOAD: 0224114 BUILT: 02/24/2022 9:30 AN FY: K95V04 CUPS: 1-64

TOTE HUMBER: 81077

Frq	Instild	ACN	Participant	Rog# SpecimenID	UC Ordered
32	<b>⊍04</b> 43	691084Z		99276 <b>78</b> CC09010760	27119N
34	50444	6909852		8927605 7918221308	6405N
30	6 <b>044</b> 5	691071Z		892786 <b>9</b> 7714646766	35196N
36	60416	691105Z		89. <b>27690</b> 7914 <b>7889</b> 94	27900н
37	60447	651113Z		8927 <b>695</b> 7918221305	32720W
33	50446	6911842		89277 <b>45</b> 79146 <b>467</b> 65	31521H
39	60449	89088SZ		8v27538 7918570106	278064
40	60450	702319Z		8937102	26743H
41	60451	*5VT2			
43	60452	490978Z		8927 <b>602</b> 791 <b>8221</b> 306	65186N
43	60453	<b>69</b> 0976Z		8927533 <b>7</b> 915712756	2790 <b>0</b> N
44	50.454	650714Z		8927555 7913622551	35745N
4:5	66455	6908687		8927528 CC0724 <b>9</b> 428	35105H
45	60476	6912672		892781 <b>7</b> 7916425136	351054
47	60457	6908647		R110726	46633)(
4	60458	69134 <b>9</b> Z		8927876 CC07065987	27913N

NIDA SYSTEM SAF DRUG SCREEN HS

UNRKLIST: TXNSAP3 LOAD: 0224114

BUILT: 02/24/2022 9:30 AM BY: KSSU04 CUPS: 1-64

TITTE NUMBER: 81077

िल्य	lrst]d	ACN	Participant	Req# SpecimenID	IIC Dade	m m.d
100 Mg 1 1000 mg	A 21 CD Cy A LB	\$ \$4.09	Est for The H	pheciment.		Fig. 1
49	50.459	6913 <b>75</b> Z		89 <b>27691</b> <b>7</b> 9161 <b>304</b> 00	35745N	
50	60460	691366Z		89278 <b>85</b> <b>79</b> 16130399	366534	
Si	60461	*EUT1				
52	60462	6908982	-	1138265	27119N	
53	60463	692504Z	276761	4840481	351 <b>70</b> H	NU
	8500 ND SEAL	ON BLOOD				
54	60464	692495Z		0136408	35190N	NV
	8500 BLDOD H	ISA NO SHA	L			
55	A <b>04</b> 65	6923422		8528 <b>589</b> CC0 <b>7227</b> 013	34510H	NO
	Split Indica	tor with	no Split Unit Co	de		
55	6 <b>04</b> 68	692356Z		4899582	3554511	
<b>57</b>	60467	690923Z		8127560 CC07304719	35765N	
58	áC468	6900917		0135751	65105N	
57	60469	690908Z		8919495	35105N	
67	60470	*NEGATIV	ā			
61	60471	*FEDAT				
62	60472	*SAPAT				

MIDA SYSTEM SAF DRUG SCREEN #3

WURKLIST: TXNGAP3 LOAD: 0224114

BUILT: 02/24/2022 9:30 AM BY: KSSV04 CUPS: 1-64

TOTE NUMBER: 81077

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Seq	InstId	ACH	Participant	SpecimenID	UC Orvered
CAN THE PERSON	and beginning to Angel day him, april 1985, the second order to second step managers apply the	grigated thank field the and	By \$100 and \$100 pt 1 may 1 to a second 1 or 3 or 5	the second secon	In the set that were pagent or the modellow with indicate a second consideration, and seed to provide the second of the second o

63 60473

\*FEDALTAT

64 60474

#SAPALTAT

END OF WORKLIST



Filename: QDSCREENINGCORRECTIVEACTIONFORM

# Quest Diagnostics - Lenexa Forensic Toxicology

# SCREENING CORRECTIVE ACTION FORM

Date FEB 7 4 2022 Forensic	ScientistEVAN	ROBERTS	
Worklist:  TXNSAP3 TXNFED TXNUAL TXNHSAP2 TXNDILA Instruments: 511 512 513			
Load Number			
(Check One) Problem: 1. ☐ QC 2. ☐ Instrument	j.	Explain Below	
QC TYPE	Assay - Result	Assay - Result	Assay - Result
☐ FEDBT / SAPBT		- Account	Assay - Nesult
☐ FED ALTBT/SAP ALTBT			
SVT2 (Nit 240 / Cre 1.5)	Ge - 1.9		
☐ SVT1 (Low pH / Cre 3.0)	-		
☐ NEGATIVE(Creat 25/pH 11/OXID 625)	4	V	-
☐ FEDAT / SAPAT	•	•	
☐ FED ALTAT / SAP ALTAT	•	•	•
☐ XRAT	•	•	•
☐ OTHER	•		•
□ OTHER:	•		
□ OTHER:			Committee of the second second
	DESCRIPTION		MANAGEMENT OF
☐ Unit Malfunction	☐ Rack Jan	n	O THE SECOND STREET, ST. ST. ST. ST.
☐ QC Short Sampled	☐ Barcode	Scan Error	
☐ Recalibration Needed	Random	Error	
☐ Reagent Empty	☐ Data Trai	nsmission Error	
☐ Reagent Probe Error	☐ Other	tel production of the land	
RESOLUTION	S (CHECK ALL TI	HAT APPLY)	4. 被影响为1000
☐ Selective Channel Download	☐ No Corre	ctive Action Neede	d/QC Rules Apply
☐ Retransmit Data	Resched	uled Donors 4	
☐ Re-run for unit assays			

Date: 05/2021

Version 7

BENZ = (2.217FH) REM1 = No Result

PCP = (1.98205)

6911057

691113Z

691184Z

690885Z

7023197

36

37

38

39

40 \* 70:

QA BLIND ID=PCF

Open QC Failed Blind QC OK

690978Z

690876Z 690914Z

590968Z

691267Z

690864Z

691349Z

6913752

691366Z

690898Z

692504Z

692495Z

6923422

692356Z

690923Z

690891Z

690908Z

60 \*NEGATIVE

61 \*FEDAT

62 #SAPAT

63 \*FEDALTAT

64 ØSAPALTAT

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44 45

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5.2

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L.C.

56 57

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51 \*SVT1

## UP ACCESSION PART-ID INST-ID

```
= (-0.006) A500
                                           = (-0.023) A300
                  AMP
                                                                = (0.020)
                                                                                  QC ID = SVT2
                  BARB
                          = (0.006) BARB200 = (-0.025) BENZ
                                                                = (-0.110)
                                                                                  CREA QC Out
                                             = (-0.021) C150
                 BENZ200 = (-0.091) CDC
                                                                 = (-0.031)
                                                                 = (-0.275)
                 THC
                          = (-0.153) T50
                                             = (-0.261) T20
                 METD
                          = (-0.105) METe
                                             = (-0.057) MDAS
                                                                 = (-0.05i)
                 MDAS250 = (-0.327) OPI2K
                                             = (-0.020) \text{ OPI2KM} = (-0.016)
                 OP1
                          = (-0.214) 6 MAM
                                             = (0.038) \text{ OXYSIOO} = (-0.062)
                 SUPIS
                          = (-0.137) FCP
                                             = (-0.083) PROP
                                                                 = (0.001)
                 ETOH
                          = (0.054) CREA
                                            = (1.9HH) NITHRON =
                                                                 (237)
                 CREAR = (19.6L) SPGR = No Result REM1 = No Result
                 CREAR = (8. OL) SPGR = No Result REM1 = No Result
                 T50 = (1.924FH) REM1 = No Result
                 REM1 = Msg: HTEMP
                 AMP
                          = (0.007) A500
                                            = (0.008) A300
                                                               = (-0.007)
                                                                                  QC ID = SVT1
                          = (-0.273) BARB200 = (-0.399) BENZ
                 BARB
                                                               = (-0.097)
                 BENZ200 = (-0.104) COC
                                         = (-0.051) \text{ C150}
                                                              = (-0.076)
                 THE
                          = (-0.156) T50
                                             = (-0.255) T20
                                                                 = (-0.240)
                          = (-0.094) METO
                 METD
                                             = (-0.052) MDAS
                                                                 = (-0.073)
                 MDAS250 = (-0.414) OP12K
                                             = (-0.019) \text{ OPI2KM} = (-0.022)
                          = (-0.219) 6MAM
                 OFI
                                             = (-0.442) \text{ OXYS100} = (-0.064)
                 SOPIS
                         = (-0.122) PCP
                                             = (-0.079) PROP
                                                              = (0.034)
                          = (0.054) CREA
                 ETOH
                                                (3.3) PH
                                                               = (3.0)
                 NITHRON =
                                (0)
276761
                 AFF = (1.963FH) REM1 = No Result
                 CREAR = (12.4L) SPGR = No Result REM1 = No Result
                 AMP
                         = (0.010) A500
                                            = (0.004) A300 = (0.038)
                                                                                 QC ID = NEGATIV
                 BARB
                         = (-0.027) \text{ BARR200} = (-0.043) \text{ BENZ}
                                                              = (-0.009)
                 BENZ200 = (0.036) COC
                                            = (-0.025) C150
                                                                = (-0.038)
                 THC
                         = (-0.130) TSO
                                             = (-0.181) T20
                                                                 = (0.031)
                 METO
                          = (-0.048) METQ
                                             = (-0.031) \text{ MDAS}
                                                                 = (-0.012)
                 MDAS250 = (-0.134) DP12K = (-0.013) DP12KM = (-0.007)
                 OPI
                         = (-0.035) 6MAM
                                            = (0.029) \text{ OXYSIOO} = (-0.043)
                 SOPIS
                         = (-0.069) PCF
                                            = (-0.053) PROP
                                                                 = (-0.055)
                         = (0.054) CREA
                 ETOH
                                            = (25.8) PH
                                                               = (9.0)
                 NITHROM = (595)
                 A500
                         = (1.366) C150
                                            = (1.252) T50
                                                               = (1.348)
                                                                                 QC ID = FEDAT
                 OF TEK
                         = (1.171) \text{ OPI2KM} = (1.159) \text{ OXYS100} = (1.270)
                 PCP
                         = (1,333) CREA
                                            = (25.5) PH
                                                               = (6.8)
                 MITHRON =
                               (0)
                                                               = (1, 120)
                 BARB
                         = (1, 110) RENZ
                                            = (1,249) COC
                                                                                 QC ID = SAPAT
                 THC
                         = (1.282) METD
                                            = (1.140) METQ
                                                               =(1.479)
                                            = (1.317) PROP
                 MDAS250 = (1.500) OPI
                                                               = (1.216)
                 CKEA
                         = (26.3) PH
                                            = (6.9) NITHROW =
                                                                     (0)
                 BARB200 = (1.244) BENZ200 = (1.409) MDAS
                                                               = (2.227)
                                                                                 QC ID = FEDALTA
```

= (1.185) SOFIS = (1.166)

**NVBOP - 035** 

SHAM

on Instrument worklistWDRKLIST: TXNSAP3 Load: 0224114

02/24/2022 11:49:55 AM

Open QC Failed Blind QC OK

UP ACCESSION PART-ID INST-ID

AMF' CREA

= (1.205) T20 = (1.506) ET0H = (1.392)= (24.9) PH = (7.0) NITNRQN = (0) = (1.506) ETOH = (1.392)

OC ID = SAPALT

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**CONFIRMATION TEST INFORMATION** 

# CONFIRMATION TEST DESCRIPTION

Confirmation testing for drugs of abuse is performed by mass spectrometry. The concentration of drug in each donor specimen is determined by comparison of the response of the specimen to the response of calibrators of known concentration. If a donor specimen has a concentration of drug that is less than the client specific cutoff, the specimen is determined to be negative for the confirmation test. If a donor specimen has a concentration of drug that is greater than or equal to the client specific cutoff, the specimen is determined to be positive for the specific test. Each batch contains both negative and positive quality control samples along with one blind quality control sample that is inserted into the batch in a random position.

If required, confirmation testing for specimen validity is performed by the same or, if available, a second definitive method that can be utilized to identify specimens as adulterated, substituted or invalid. Each confirmation test is performed on a second aliquot that is obtained from the original specimen container and all confirmation batches contain appropriate quality control samples to verify the performance of the procedure.

02/24/2022

FL/NV39

### CHAIN OF CUSTODY LOG

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WORKLIST :	TXNAM192			STORAGE				1
ACCESSION	FARTICIPANT	UNIT CODE		BOX/ROU/CGL	. CHU	KR'	STAL BARRIER	
692504Z	276761	ZNHAMP		G036558/E/6			FEB 27 2022	
633410Z		ZHNAMP		G036568/1/5			1	
692274Z		ZHNAMP		G036573/C/6	Split	Rec'd		
71.4252Z		ZNNAMP		6036574/0/8			~	
660111Z		ZNHAMP		P047197/A/4	Split	Rec'd	LUELLO HENDERSON FOSS	FEB 2 8 2022
715166Z		ZNNAMP		P047213/0/8			7	
69 <b>3718</b> Z		%NNA500		P047230/E/8	Split	Rec 'd		
712545Z		ZNNAMP		P047231/H/7				
714914Z		ZNNAMP		P047234/H/7				

WURKLIST :	TXNAMMS2			
ACCESSION	PARTICIPANT	UNIT CODE	STORAGE BOX/ROW/COL	
and he is allowed to the above the	standings all and the particular for Lor			
71 <b>3645</b> Z		ZNNAMP	P047235/1/6 Split	Rec 'd
70371.6Z		XNNAMP	V066223/0033563/6	
704691Z		ZNNA500	V066228/0079295/7	
710084Z		XNNAME	V066239/0079313/10	
699577Z		ZNNAMP	V066259/0058377/3	
701428Z		XNNA500	V066267/0076665/7	Split Rec'd
71045 <b>7Z</b>		XNNA500	V066324/0055430/8	Split Rec'd
712181Z		XNNA500	V066337/0079749/5	Split Rec'd
712674Z		ZHNARP	V066340/0055587/6	Split Rec'd
7:3616Z		ZNHAMP	V066340/0055592/4	Split Rec'd
71 <b>3985Z</b>		CHNAME	V066340/CU80028/6	Split Rec'd
712593Z		%NNA500	V066341/0063691/9	Split Rec'd
71 <b>3631Z</b>		ZNNAMP	V066348/0076881/2	Split Rec'd
713879Z		ZHNAMP	V066348/0076882/8	Split Rec'd
713794Z		ZNHASOO	V066353/0081422/4	Split Rec'd
714220Z		XHNAMP	V066353/0081426/3	
71409 <b>8Z</b>		ZNNAMP	V066354/0010777/5	Split Rec'd
7) 4439Z		ZNNAMP	V06635 <b>7</b> /00280 <b>3</b> 5/5	Split Rec'd
715025Z	<b>THE</b>	ZNNA500	V066357/0083005/7	
714611Z		XNNAMP	V066358/0028381/2	
715356Z		ZNNA500	V066359/0071646/8	Split Rec'd
714931Z		%NNA500	V066361/0058389/2	Split Rec'd
7149012		ZHNAMP	V066362/0023391/7	
709852Z		ZNNA500	X066241/D/2	

Total accessions for worklist TXNAMMS2 = 33

^MDATWP1		1018 AMPHETAMINES CUNFIRM	ALIUN BY MS 02/24/2022 10:19P	PAGE: 1
This loa	d contains 2 sample(s)	with a Received Date/Tim	e older than 48 hours.	
INTERFRE	The second secon	PRINTED NAME	KRYSTAL BARRIER FEB 27 2022	
REVIEWED RELEASED		AUELLA HENDERS	1.5	
	ALIQUOT C	HAIN OF CUSTODY LOG		
DATE	RELEASED BY	RECEIVED BY	PURPOSE	
02/24/22	NAME PHILLIPS, WILLIAM	NAME PASS THRU	TEMP STORAGE	
FEB 2 4 202	2 <sub>sion.</sub> Mare <u>Pass Thru</u>	SIGN CAMP VANC	TRANSFER	
FEB 2 4 202	2 SIGN AMY VAN	SIGN. NAME ÆTS	TEMPSTORAGE	
FEB 2 5 20	225IGN. ETS	SIGN. NAME	QTALIQUOT / DISCARD EXCESS	EXTRACTION
EB <u>2 5 202</u> 2	SIGN. MANE	SIGN. GC/MS TS	TEMP STORAGE	
FR 2 5 7022	SIGN. GCMS TS	SIGN. 12 Julie	TRANSFER	
CD 2 5 2022	SIGN. IL KELL HAME JOSEPH KUBIAK	SIGN. NAME GCMS_A7	NJECT	
7-2612	SIGN GCMSA73	S SIGN. Aloson J.	Hey sayle	
nrorr	SIGN. Alisa Jeffer	SIGN. VIALTS		
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mana Manas — Safara adam and A	SIGN.	SIGN.	returns, every reterminate participation of the second	

SIGN. SIGN. NAME NAME

WORKLIST: TXNAMMS2

LOAD: 0224018 AMPHETAMINES CONFIRMATION BY MS 02/24/2022 10:19P PAGE: 2

SEQ	INSTR ID	ACCESSION	PARTICIPANT	CLJENT #	REQ #/ SpecimenID	EMIT ST	WORKLIST
1	uddagail (1964) Seegeriyaga (1966) (1966) - mai deighandak	*CAL	nagurin 1960 - y sa dibanum ani naguri pada isrita dindah				
QAMP	gmanf	Management Systems and a season					
2		*40Z					
QAMF	OMANF	er-related worker, the annivers					
3		*125% NRC					
QAME	omanif.	giri yaasi ilina hijifanajilin na					
4		*NEG					
GAME	orians	anageriser when					
5~		6925047.	276761	51030236	4840481	1. 96347	NV
AMF					1 Julion Factor		
NETAM	RONR						
	HU						
6		692274Z Decimen ID	Verification:	11128117 9021058460	QD21058460	1,60890	
	Dilution:	Sample	_ Diluent	D	ilution Factor_	a profit majar majaja nag	
AM METAM		METAI	1QAMP	QMAN	AMPTIR DI	IR .	
.56	CS52 QD AMP (	OXCD T50.					
7/1	a	6601117	Verification:	65509895 791551172	7915511723	5. 03961	
	Dilution.	Sample	So Diluent	1900	ilution Factor_	Uho	

WORKLIST: TXNAMMS2 LOAD: 0224018 AMPHETAMINES CONFIRMATION BY MS 02/24/2022 10:19P PAGE: 3

BE.Q	INSTR	10	ACCESSION	PARTICIPANT	CLIENT #	REG #/ SpecimenID	EMIT S	<b>WORKLIST</b>
AMP	) Wy suddinangan	AMET	METAM	OAMP	35319 QMANP	+ AMPMR +		
TAHR:	( + 35319.76 175510. 175510							
	RC1 (1:2	8 0	1:40) FOR ME	(H-175510COL)	F/AMP-353190	QN		
8			7151667			8946653 7916444650	1.07193	
		\$	pecimen ID Ve	erification:			ied	
	Diluti	on:	Sample	Dilwent <sub>.</sub>	Di	lution Factor	nespector : en	
ATF	ned danigh kriljskingspo	AMPT	HETAI1	- QAMP	@MAITP	AMPTIR DNR		
HETANR	DNR							
9 ,			693718Z		10493983	8929572	1 25,00	5.01.1
		ç	pecimen ID Ve	A 15-21 (50 - 45) (10 - 15)		7916939412		111
			possins in its	it ti teeotom.	77.07.07414.	ve: T.	160	
	Dilutio	on:	Sample	Diluent	D1.	lution Factor	······································	
AMPM		ETAN	GATH	Qriamp	A500	AMFMK DNR		
ETAMR	DNR							
10			7125457		10547281		1. 30733	
		5	pecimen ID Ve	rification:	7914260299	7914260299 Verif	ied	
	Million and a	Maria	Com la	Nilimak	n.	and an Cambana		
AMD						ution Factor	is implement of the last	
ETANR		7-8-16	windstancesons i Ha L CTL C	Alle II.	or strangerspectuated All Suit II.	AMPMR DNR		
the trusts	MIN							
11			7136452		10858660	8945225 0D20544980	1. 64553	
		S	pecimen ID Ve	rification:	QD20544980	Verif:	ied	
	Dilutie	16	Samola	Diluant	Dit	ution Factor		

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WORKLIST: TXNAMMS2

LOAD: 0224018 AMPHETAMINES CONFIRMATION BY MS 02/24/2022 10:19P PAGE: 4

SEQ					REG #/ SpecimenID			
		PM META	II GAMP	(MAN)	AMPMR D	NR		
HETANR	DNR							
12/		7037162		10909114	8937929 7913639247		-VIOLA	P3 1
		Specimen ID	Verification:	7913839247	Ve	rified	0224	146/26
	Dilution	Sample	Diluent	- Oi	lution Factor_	Make the part of the control of the	02,24 9)2/	24626
AMF	AH	PH META	M QAMP	QMATTP	AMPTIR D	MR		
HETAMR	DNR							
13		7046912		10493983	<b>89386</b> 32 7918599925	3. 4319	78 NV	
		Specimen ID	Verification:	7918599925		rified		
	Dilution	Sample	Diluent	Di.	lution Factor_	plantification and construction and con-		
ANFM	HET	'Arı QAr	IF GMAMF	A500	AMPHR D	NR		
hETAHR	DNR							
14		710084Z		10234100	9942648 7917176479	1.8363	30	
		Specimen ID	Verification:	7917176479		rified		
					lution Factor_			
amp	AM	IPMMETA	nn qamp	GMANP	AMPTIR D	NR		
NETANR	DNR							
15		6995772		11089553	8934367 QD16415764	1. 9348	B2 NV	
		Specimen ID	Verification:	QD16415764		rified		
	Dilution	: Sample	Oilwent	D1.	lution Factor_	are the contract of the contra		
AMP	Art	IPM META	m gamp	GHAMP	AMPTIR D	MR		
METAMR	ONR							

SE.Q					REQ #/ SpecimenID		WORKLIST
16 1		7014287			7390652		NV
	S	ipecimen ID V	erification:	7390652	Veri	fiea	
	Dilution	Sample	Diluent	Di.	lution Factor	ndjuljajajevom s 10.	
AMPM	METAN	1 QAMP	- QMAMP	A500	AMFHR DNR		
METAMR	DNR						
17		7104572		80126732	1115177	1.09224	
	9	Specimen ID V	erification:	1115177	Veri	fied	
	Dilution:	Sample	Diluent	Di.	lution Factor	and his same and the	
AHFM	METAN	1 GAMP	GMAMP	A500	AMPMR DNR		
HETAHR	DNR						
18	c	712181Z Specimen ID V	-		<b>8944004</b> AA08736449 Vari		
	`	aparament are s	the fact of the term of the term of the	ratus russ ru			
	Dilution:	Sample	Diluent	Di.	lution Factor	BYTTALL SECTION	
AMPM	METAI	1 QAMF	QMAMP	A500	AMPMR DNR		
HETAMR	DNR						
19		7126 <b>74</b> Z		65778802	6575084	1. 22769	
	Ş	Specimen ID V	erification:	6575084	Veri	fied	
	Dilution	Sample	Diluent	Di	lution Factor	Dunggito oppis tyradi laste	
AMP	AMF1	1 METAM	QAMP	QMANF	AMPMR DNR		
METAMR	DNR						
20		7185462		20009998	8948966		
	Dilution:	Sample	Diluent	, Di	lution Factor	-	

^HDATWF18 WORKLIST: TXNAMMS2 LOAD: 0224018 AMPHETAMINES CONFIRMATION BY MS 02/24/2022 10:19P PAGE: 6 REQ #/ INSTR ID ACCESSION PARTICIPANT CLIENT # SpecimenID EMIT SI WORKLIST SEQ AMP AMPM METAM GAMP GMAMP AMPMR DNR HETAMR DNR 65911212 8945168 21 713616Z 7911798475 Specimen ID Verification: 7911798475 Verified Dilution: Sample Diluent Dilution Factor AMP AMPM METAN QAMP QHANF AMPHIC DNR METAMR DNR 22 713985Z 15074676 4870458 1.14812 Specimen ID Verification: 4870458 Verified Dilution: Sample Diluent Dilution Factor\_\_\_\_ AMPT METAN GAMP GHAMP AMPTIR DNR METAMR DNR 7918540705 1. 04014 23 712593Z 10734540 Specimen ID Verification: 7918540705 Verified Dilution: Sample Diluent Dilution Factor \_\_\_\_ AMPTI METAM DAMP CMAMP ASOO AMPTIR DNR

Dilution: Sample Diluent Dilution Factor\_\_\_\_\_\_

AMPM METAM GAMP GMAMP ASGO AMPMR DNR

Specimen ID Verification: QD20846451

7098527

80023485 8942464 4. 74277

Verified

QD20846451

METAMR DNR

24

\*MDATWP18

WORKLIST: TXNAMMS2 LOAD: 0224018 AMFHETAMINES CONFIRMATION BY MS 02/24/2022 10:19P PAGE: 7

SEQ	INSTR IO	ACCESSION	PARTICIPANT	CLIENT #	REQ #/ SpecimenID	EMIT SI	WORKLIST
Print (min	Section of the sectio	713631Z Specimen ID V	erification:		8945206 QD18498406 Verif		
AMP					lution Factor	ephnopara kua	
METAMR	DNR						
26	ş	713879Z Specimen ID V			4713838 Verif		
AMP NETAMR	Affr				lution Factor	mandal allerations from	
27 🗸			Verification:		5368967 Verif		HV
AMP					Lution FactorAMPNR DNR	dishidayya yas	
METANR	DNR NV						
28	;	713794Z Specimen ID V	Verification:		6048275 Verit		
AMPM	META				lution Factor		
29		*	Verification:		7914522640 Veri		
	Dilution	Sample	Diluent	Di	lution Factor	and day "v	

\*HDATWP16

WORKLIST: TXNAMMS2 LOAD: 0224018 AMPHETAMINES CONFIRMATION BY MS 02/24/2022 10:19P PAGE: 8

			ACCESSION		CLIENT #	REQ #/ SpecimenID	EMIT SI	WORKLIST
AMP NETAKR	0.000	1FM	METAM	QAMP	energy QMAMP	AMPHR DNR		
30		Sp	714220Z ecimen ID V	erification:		5919846 Veri		
AMP NETANR	A					ution Factor		
31		Sp	714252Z pecimen ID V	Verification:		8945931 7200500482 Veri		
AMF NE <b>TAM</b> R	A					ution Factor		
32		Sį	715025Z pecimen ID V	Perification:		8946552 0D17802074 Veri	3, 03 <b>04</b> 9 i <b>fie</b> d	
AMPM METAMR	TE					otion Factor		
33 🗸				/erification:		3506356 Ver	4.65028	HV
AMP	to an experiment and entered					Lution FactorAMPMR DN		

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**MDATUP18** 

WORKLIST: TXNAMMS2 LOAD: 0224018 AMPHETAMINES COMFIRMATION BY MS 02/24/2022 10:19P PAGE 9

SE.O	IMSTR ID	ACCESSION	PARTICIPANT	CLIENT #	REG #/ SpecimenID	EMIT SI	WORKLIST
34		715354Z	erification:		8946784 CC07585003		and a spain results and a spain and a spai
		obecrmen in A	eritication:	CC0/080003	ver	ified	
	Dilution:	Sample	Diluent	Di	lution Factor	ganghamayddi Yayaydayn Ma	
AHFM	METAN	T QAMF	QHAMP	<b>A5</b> 00	AMPTIR DNI	₹ .	
METAMR	DNR						
35		7149012		80319218	2406860	2. 20 <b>9</b> 24	
	S	Specimen ID V	erification:	2406860	Ver:	ified	
	M 9			pts. a			
· ·					lution Factor		
AMP	ATIP	1 METAN	QAIP	QMAMP	AMPMR DNF	₹	
HETAMR	DNR						
36		7144397		11164192	6387592	1, 55900	
	5	Specimen ID V	erification:	6387592	Veri	fied	
	O d Tarabad man	Canala	041	6.1	lution Factor		
e terre							
		I FIETAIT	WARP'	White-	ATIPMR DNF	•	
HETAMR	DNR						
37		714611Z		10228065	8946270 QD20922037	4. 23136	
	9	pecimen ID V	erification:	0020922037		fied	
	Dilution	Samola	Diluant	Di	lution Factor		
た神や					AMPTIR DNF		
		Personal Title 1 PH 1	Provinces or all \$ 12.0.48 ES.	AND STATE	AND THE PARTY		
HETAMR	WHIT						
38		7149312		11378686	8946477 QD20956208	3. 74420	
	S	pecimen ID Ve	erification:	QD2095620B		fied	
	Dilution:	Sample	Diluent_	D1.	iution Factor	dal d.c. vorelevon Virging	

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\*NDATWP18

WURKLIST: IXNAMMS2 LOAD: 0224018 AMPHETAMINES CONFIRMATION BY MS 02/24/2022 10:19F PAGE: 10

REQ #/

SEQ INSTR ID ACCESSION PARTICIPANT CLIENT # SpecimenID EMIT ST WORKLIST

ANFTI METAN QAMP QMAMP A500 AMPTIR DNR

METAMR DNE

39

\*125%

QAMP \_\_\_\_\_ GMAMP \_\_\_\_\_

END OF WORKLIST

Exit

Non Instrument worklistWORKLIST: TXNAMMS2 Load: 0224018 02/27/2022 10:21:28-AM KRYSTAL BARRIER Open QC Failed Blind QC Failed FEB 27\_2022 Reviewed and Verified by Date: CUP ACCESSION PART-ID INST-ID 1 \*CAL 250 250 QC ID = CAL No QC Results 2 \*40% 112.7 111.5 QC ID = 40% 3 \*125% NRC 681.0 679.4 No QC Results QC ID = 125% NRC No QC Results QC ID = NEG No QC Results 692504Z : AMPM= 276761 AMP= METAM= 5715 **5**00 500 AMP MAMP 6922742 AMP= : AMPM= METAM= 4281 500 AMP 1 0 500 MAMP : AMPM= 7 660111Z AMP= : 1:20 METAM= 1:40 39090 251337 36896 AMP/ MAMP 240662 RC1 (1:20 & 1:40) FOR METH-175510COLF/AMP-35319C @ N by: KSAV03 on 02/24/2022 715166Z AMP= : AMPM= METAM= 1538 / 500 AMP 0 / 500 MAMP 693718Z AMPM= : METAM= A500= 1055 / 250 AMP MAMP 250 7125452 AMP= 10 : AMPM= METAM= 0′ 500 0′ 500 AMP MAMP FEB 2 8 2022 HENDERSON RE 7136452 AMP= : AMPM= METAM= 0 / 500 0 / 500 AMP MAMP 12 703716Z AMP= : AMPM= METAM= 687 500 AMP 614 500 MAMP 13 704691Z

Open QC Failed Blind QC Failed

CUP A	ACCESSION	PART-ID	INST-ID									
				AMPM=	: META	M=						
				A500=	:	· · ·		•				
				AMP	7304	250						
				MAMP	7504	250						
				PICH	v							
14	710084Z			AMP=	: AMPM=		:					
14	1100042		2	METAM=	. Ara ra-		•					
				AMP	3860	500						
				MAMP	0 /	500						
15	699577Z	THE PARTY OF		AMP=	: AMPM=		:					
				METAM=	٠,							
				AMP	5776							
				MAMP	0 ~	500						
47	704/207			AMDM-	. 4574	M=						
16	701428Z			AMPM=	: META	M=		:				
				A500= Amp	: 0 ^	250						
				MAMP	0 ^	250						
				PIAPE	•	٥٥٥						
17	7104572			AMPM=	: META	M=		:				
				A500=	:							
				AMP	0 %	250						
				MAMP	0	250						
			-									
18	7121812			AMPM=	: META	M=	:	:				
				A500=	:							
				AMP	02	250						
				MAMP	0	250						
19	7126742			AMP=	: AMPM=		:					
				METAM=								
				AMP	639	500						
				MAMP	375	500						
			•									
20 *	718546Z	B. H.		AMP=	: AMPM=		:				QA BLIND	ID=NEGATIVE
				METAM=	:							
				AMP	0.0	No. Ci	+~ff	Egypd	fon	%NNAMP		
				Arir	U s	NO CE	1011	Fouriu	101	MNAPIP		
				MAMP	0 /	No Cu	itoff	Found	for	%NNAMP		
			kor								QC Out	
21	713616Z			AMP=	: AMPM=		:					
				METAM=								
				AMP	454	500						
			2000	MAMP	3391	טטכ						
22	7139852	1000		AMP=	: AMPM=		:					
				METAM=	:							
				AMP	0%	500						
				MAMP	o <b>ʻ</b>	500						
			60									
23	7125932		l .									

Open QC Failed Blind QC Failed

CUP	ACCESSION	PART-ID INST-I	D		
			AMPM= A500= AMP MAMP	: METAM : 518 0	250
24	709852z		AMPM= A500= AMP MAMP	: METAM : 23167 0	250 >10000
25	713631Z		AMP= METAM= AMP MAMP	: AMPM= 7 4 14 0 0 0	: 500 500
26	713879z		AMP= METAM= AMP MAMP	: AMPM= : 5625 / 0 /	
27	633410Z <b>(</b>		AMP= METAM= AMP MAMP	: AMPM= : 1329 / 6012 /	250
28	71 <b>3</b> 7942		AMPM= A500= AMP MAMP	: METAM : 8229 0	250
29	7149142		AMP= METAM= AMP MAMP	: AMPM= : 8606 -	500
30	714220Z		AMP= METAM= AMP MAMP	: AMPM= : 8409 ^ 0 ^	:
31	7142522		AMP= METAM= AMP MAMP		: 500 500
32	715025z		AMPM= A500= AMP MAMP	: METAM : 4272 /* 0 /	= : 250 250
33	714098z		AMP= METAM= AMP MAMP	: AMPM= : 10379. 90100.	500 510000 500 >10000
34	715356Z				

Open QC Failed Blind QC Failed

CUP A	CCESSION PA	ART-ID INST-ID				
			AMPM=	: META	M=	:
			A500=	:		
			AMP	1085	250	
			MAMP	10		
35	714901z		AMP=	: AMPM=		:
			METAM=	:		
			AMP	7640 🖊	500	
			MAMP	0	500	
36	714439Z		AMP=	: AMPM=		:
			METAM=	:		
			AMP	3073 🥕	500	
			MAMP	0 1	500	
37	714611z		AMP=	: AMPM=		:
			METAM=	:		
			AMP	4164	500	
			MAMP	69027.	500/5	COOD
38	714931z		AMPM=	: META	1=	
			A500=			
			AMP	6314	250	
			MAMP	0	250	
70 *	1259 270	17 21	08			

QC ID = 125% No QC Results

Вох	#	G
DOV	π	



# MS VIAL DISPOSAL LOG

RUN		Removed for analysis (sign & date)	Disposed (√)	Comment
	INITIAL/DATE	(Gigii di anii)		
SBISCEN 0235001	9 02-26-22		V/	
TXNAMNEZ OZZ4018.	\$ 02-26-22		V/	
TXNAMMSZ OZZSOOT	902-26-22		V/	
TXNAMMS2 0225008	9 62-26-22		4	
TXNAMMS2 0225013	6 05-50-55		4	
TYNMDAMS 0224001	CL 2/26/22		V/	No. 20 - 20 - 20 - 20 - 20 - 20 - 20 - 20
TENDL 0224003	12 26/22		V/	
TXNAMMS20225011	162/26/12		V/	
TXNAMMS2 0225001	(C1/26/25		V/	
TNAMMS2 0725003	CL 2/26/12		V	
TXN AMMS20725002	Cr5/52/15		<b>Y</b>	
TENOL 0224002	Wzher		<del>- // -</del>	
TYNAMMS2 0225016	02 26/12		\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\\	
TXNAM 520225 004	alletu		V	
TXNAT (12010)	CL2/26/12		$\rightarrow$	
TXNAMM 50225006			<del>\</del> //	
TXUMDAMS 0224002	(62/26/22		-7/-	
TXNM12AMS2 0225001	1 0 6 0 -		7/-	
TXNAMMS20225018	1		4	The state of the s
TXNPCMS 0223001	The 2/26/22		7,	
TXNAMAS 022322 KI 12,3 TXN PCMS 0225001	811 2/26/22		1//	
TXNAMMSA 0225012	Th 212-122		7	
12012	212100			

ALS Vials Discarded by:

Sign:

Print/Date:

MAR 0 9 2022

TIARA WHATLE

**NVBOP - 063** 

-38

1557

0.002

Pos

On

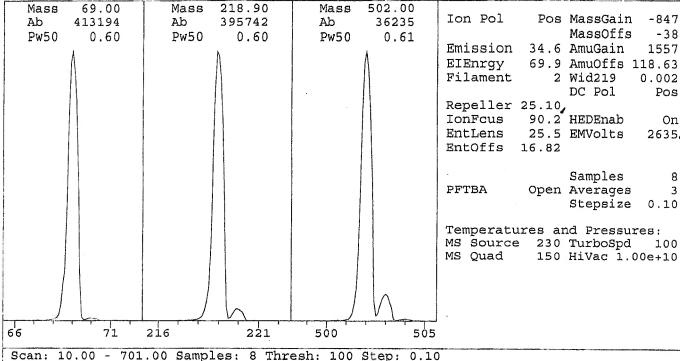
8

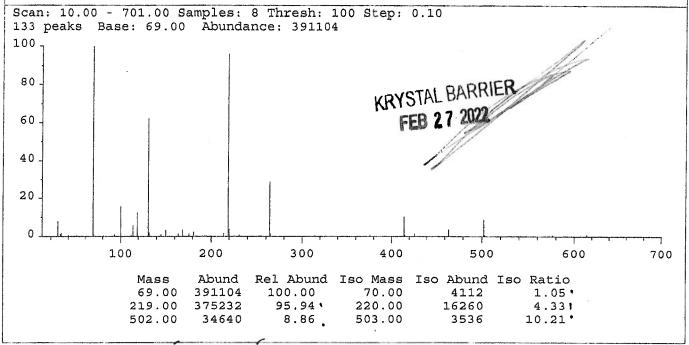
3

0.10

100

2635





N2~8.03% O2~1.76% CO2~0.21% N2/H2O~414.68% Air/Water Check: H20~1.94%

Column(1) Flow: 1.646 Column(2): 0 ml/min. Interface Temp:

Ramp Criteria:

volts using ion 502; Ion Focus Maximum 90 EM Gain 144013 35 volts using ion 219; Gain Factor Repeller Maximum 1.44

MassGain Values(Samples): -842(3) -834(2) -823(1) -807(0) -807(FS)

TARGET MASS: 50 69 131 219 414 502 1050 . . . . . . . . . . . . ----\_\_\_\_ \_\_\_\_ \_\_\_\_ ~ - - - -\_ \_ \_ \_ \_ 118.6 118.6 118.6 118.6 118.6 118.6 118.6 Amu Offset: Entrance Lens Offset: 16.8 16.8 16.8 16.8 16.8 16.8 16.8 2125122





# **Confirmation Certification Checklist**

By signing below, I certify I have reviewed the following documents for confirmation batch ID TXNAM. 152 02.24018.

# CONFIRMATION REVIEW

- Calibrator(s)/Controls (Open and QA) acceptable
- Control Range Sheet
  - O Verified Lot #
  - o Controls within range
- Confirmation Data (chromatograms) including Original Data Packet when applicable
- Autotune acceptable when applicable
- Worklist documentation
- Sequence Table (Seq verification and Solvent verification)
- Internal Standard Abundance Criteria worksheet when applicable
- D/L Calculation worksheet when applicable -verify version
- Corrective Action(s) (if applicable)
- Certification Summary Report

# CHAIN OF CUSTODY REVIEW

- Internal aliquot chain of custody (worklist)
- Internal bottle chain of custody (pull list)

Certification completed and batch released by: UEIIA HENDERSON ROSS 2/28/2022

Certifying Scientist

Name/Date/Signature

# **Confirmation Re-Certification**

By signing below, I certify I have reviewed the documents listed above and the confirmation data (chromatogram) for sample(s) of interest.

FEB 2 8 2022

Certifying Scientist Name/Date/Signature

Certifying Scientist Name/Date/Signature

Certifying Scientist Name/Date/Signature

Certifying Scientist Name/Date/Signature

Open QC OK Blind QC OK

Reviewed and Verified by LUELLA HENDERSON

Date: 2/28/2022

Rev	lewed and Verified by LUCLLA	LUCINDED	SON NOSS	Date: L/10/01
CUP	ACCESSION PART-ID INST-ID			
1	*CAL	QAMP	= (250) QMAMP	= (250)
2	*40%	QAMP	= (112.7) QMAMP	= (111.5)
3	*125% NRC	QAMP	= (681.0) QMAMP	= (679.4)
4	*NEG	QAMP	= (O) QMAMP	= (0)
5	• 692504z 276761 <b>\( \sqrt{\sq}}}}}}}\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sq}}}}}}}\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sqrt{\sq}}}}}}}\sqrt{\sqrt{\sin}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}}</b>	AMP= AMP MAMP	DNR: AMPM=POSITIVE 5715	: METAM=NEGATIVE:
6,	• 6922742	AMP= AMP MAMP	DNR: AMPM=POSITIVE 4281 \$500 0 .500	: METAM=NEGATIVE:
<b>~</b> 7	· 6601112 20/40.	AMP	DNR: AMPM=POSITIVE 36896 • 500 240662 500	
8	• 7151662	AMP= AMP MAMP	DNR: AMPM=POSITIVE 1538 • 500 0 • 500	: METAM=NEGATIVE:
9	• 6937182 • • • • • • • • • • • • • • • • • • •	AMPM=POS AMP MAMP	SITIVE: METAM=NEGATI 1055 <sub>4</sub> 250 0 250	VE: A500= DNR:
10	* 712545z	AMP=NEGA AMP MAMP	ATIVE: AMPM= DNR 0 1 500 0 500	: METAM= DNR:
11	• 7136452 ••••••••••••••••••••••••••••••••••••	AMP=NEGA AMP MAMP	ATIVÊ: AMPM= DNR 0	: METAM= DNR:
√ <sub>12</sub>	* 7037162 dl ~	AMP	DNR: AMPM=POSITIVE	
13	• 704691Z	AMPM=POS AMP MAMP	FITIVE: METAM=NEGATIV 7304 • 250 0 250	/E: A500= DNR:
14	• 710084z	AMP= AMP	DNR: AMPM=POSITIVE: 3860 • 500 0 • 500	: METAM=NEGATIVE:
15	• 6995772 W.	MAMP AMP= AMP	DNR: AMPM=POSITÎVE: 5776 • 500	: METAM=NEGATIVE:
16	• 6995772 NV .	MAMP	0 . 500	

KRYSTAL BARRIER FEB 27 2022

QC ID = CAL

QC ID = 40%

QC ID = NEG

QC ID = 125% NRC

Open QC OK Blind QC OK

CUF	AC(	CESSION	PART-ID	INST-ID											
	• • • •				AMPM=	DNR:	MET	AM=	DNR	: A500:	=NEGATIVE	:			
					AMP	•		250	15						
					MAMP		0	250							
							•	,							
17	7 .	710457Z		•	AMPM=	DNR:	MET	AM=	DNR	: A500	=NEGATIVE	:			
					AMP		0 •	250			•				
					MAMP		0	250							
18	3 •	712181Z			AMPM=			AM=   250	DNR	: A5UU:	=NEGATIVE	•			
					AMP MAMP			250							
					PPAP		v	. 230							
19	, ,	7126742	ALC: N	١.	AMP=	DNR:	MPM	=POSI	rÎVE:	METAM=I	NEGATIVE:				
		, , , , , , ,		5.7	AMP			500							
					MAMP			500							
							,								
* 20	) *	718546Z	ALC: N	•	AMP=NEGAT	IVE:	MPM	=	DNR:	METAM=	DNR:	:	" QA BL	IND ID=N	IEGAT I VE
					AMP						for %NNA				
					MAMP		0	No (	Cutoff	Found	for %NNA	MP			
21		713616Z	ALL D		AMP=	DNR:	MPM	=NEGAT	IVE: I	MFTAM=	OSITIVE:	<u>.</u>			
-				·	AMP			500				•			
					MAMP	339	21 .	500							
22	•	713985z		<b>M</b> .	AMP=NEGAT				DNR:	METAM=	DNR:	1			
					AMP			500							
					MAMP		0 '	500							
27		7125932			AMPM=POSI	TIVE.	мет	1 M-NE	ATIVE	. 4500-	= DNR				
۲.,	•	1163736		š . •	AMP			250	SK I I V C	. AJ00-	אאט	•			
					MAMP			• 250							
									T.						
24	•	709852Z	MAN .		AMPM=POSI				ATIVE	: A500=	= DNR	:			
	•	•			AMP			250							
					MAMP		ο,	250							
25		713631z		).	AMP=NEGAT	11/5: /	MDM-	_	DND.	1ETAM=	DNR:				
		1 130312		•	AMP			500	DINK: I	1C ( AII -	DNK:				
					MAMP			• 500							
							•				_				
26	•	713879z			AMP=	DNR: A	MPM:	=POSI1	IVE: I	1ETAM=N	EGATIVE:				
		•			- AMP			500							
					MAMP		0 ,	500							
/ 27	, .	633410Z		NV.	AMP=	D110 - 4	MDM	-00011	• ************************************	4E T 334C	* 				
- 21		0334102		NV '	AMP=			≃PUSII '250	IAF: L	1E I AM=F	POSITIVE:				
			λV	/	MAMP			250	V						
			٠.												
28	*	713794Z		1	AMPM=POSI				ATIVE	: A500=	DNR	:			
	•				AMP			250							
					MAMP		0.	250							
29		714914Z													
دع		1 147144		•											

Open QC OK Blind QC OK

CUP ACCESSION PART-ID INST-ID		
	AMP=	DNR: AMPM=POSITIVE: METAM=NEGATIVE:
	AMP	8606 • 500
	MAMP	0 . 500
30 • 714220z	AMP=	DNR: AMPM=POSITIVE: METAM=NEGATIVE:
	AMP	8409 1 500
	MAMP	0 _500
31 • 714252Z	AMP=	DNR: AMPM=POSITIVE: METAM=NEGATIVE:
	AMP	2263 • 500
	MAMP	0 , 500
32 • 715025z	AUDU-DOG	SITIVE: METAM=NEGATIVE: A500= DNR:
32 • 7130232	AMPM=PUS	SITIVE: METAM=NEGATIVE: A500= DNR: 4272 v 250
	MAMP	0 250
. /	man	• 250
33 • 714098z	AMP=	DNR: AMPM=POSITIVE: METAM=POSITIVE:
14.4	AMP	>10000   500
	MAMP	>10000 • 500
		•
34 • 7153562 • •		SITIVE: METAM=NEGATIVE: A500= DNR:
	AMP	1085 250
	MAMP	0 , 250
35 * 714901z	· AMP=	DNR: AMPM=POSITIVE: METAM=NEGATIVE:
	AMP	7640 1 500
	MAMP	0 500
		•
36 * 714439Z	AMP=	DNR: AMPM=POSITIVE: METAM=NEGATIVE:
	AMP	3073 1 500
	MAMP	0 . 500
√37 • 714611z	AND	DUD- ANDV-DOOTTING METAN DOOTTING
257 # 7146112	AMP≔ AMP	DNR: AMPM=POSITIVE: METAM=POSITIVE: 4164 • 500
407	MAMP	_
Occ	CIAPI	>10000 · 500 69027 ~
38 • 714931z	AMPM=POS	ITIVE: METAM=NEGATIVE: A500= DNR:
•	AMP	6314 + 250
	MAMP	0 • 250
70 +105%		
39 *125% •	QAMP	= (374.7)  QMAMP = (368.0)

QC ID = 125%

# Batch Summary Report

Quest

Batch Dir: TXNAMMS202240

Acquisition Date: 25 Feb 2022 5:11 pm

Instrument Name: A73

Drug Class: Amphetamine

Operator:

Batch Name: TXNAMMS20224018

Original Method File: C:\MSDCHEM\1\DATA\TXNAMMS20224018

Ion Ratio Range: +/-20%

\AMPSINGLECAL.M

Retention Time Range: +/-2%

Original Data Path: C:\MSDCHEM\1\DATA\TXNAMMS20224018

Cutoff File Information						Quantit	ation Da	tabase	
Compound Name	Cutoff Conc.	File Name	Calc. Conc.	Sample Name	RT	Ratio 1	Ratio 2	ISTD Ratio1	ISTD Ratio 2

Run No	Compound Name	Cutoff Conc.	File Name	Calc. Conc.	Sample Name	RT	Ratio 1	Ratio 2	ISTD Ratio1	ISTD Ratio 2
1	Amp	0	001SP0004.d	651.89	UNX	2.72	78,20	39.52	72.27	
1	Methamp	0		649.88		3.55	27.41	22.34	25.10	
3	Amp	250	002CA0002.d	250	CAL	2.72	76.97	39.18	70.21	
3	Methamp	250		250		3.55	27.09	20.73	24.29	
3	Amp	250	002CA0002.d	250	CAL	2.72	76.97	39.18	70.21	
3	Methamp	250		250		3.55	27.09	20.73	24.29	
1	Amp	0	003SP0003.d	112.79	40% CTRL	2.72	74.72	37.57	72.48	
1	Methamp	0		111.57		3.55	26.71	22.24	25.08	
1	Amp	0	004SP0004.d	681.09	125% NRC	2.73	77,88	40.04	72.61	
1	Methamp	0		679.43		3.55	27.35	22.16	25.32	
4	Amp	0	005NE0005.d	0.03	NEG INT CTRL	2.75	0.00	0.00	72.02	
4	Methamp	0		8.0		3.55	0.00	0.00	24.83	
1	Amp	0	006SP0006.d	5715.2	692504Z	2.73	77.72	38.33	69.85	
1	Methamp	0		2.28		3.55	29.86	33.18	25.25	
1	Amp	0	007SP0007.d	4281.61	692274Z	2.73	79.33	38.97	75.04	
1	Methamp	0		1.98		3.55	30.32	24.52	25.18	
1	Amp	0	008SP0008.d	39096.33	660111Z-20	2.72	78.78	39.17	73.81	
1	Methamp	0		251337,28		3.55	27.78	21.97	25.04	
2	: Amp	0	009BL0096.d	10597.78	(DQ) Blank injection	2.70	150.00	100.00	0.00	
2	: Methamp	0		0		0.00	0.00	0.00	0.00	
1	. Amp	0	010SP0009.d	36896.96	660111Z-40	2.73	77.06	38.26	73.02	
1	. Methamp	0		240662.4		3.55	27.32	21.79	25.31	
1	Amp	0	011SP0010.d	1538.98	715166Z	2.73	78.41	38.44	73.98	
1	Methamp	0		2.21		3.55	43.50	22.60	25.19	
1	Amp	0	012SP0011.d	1055.48	693718Z	2.72	77.77	39.10	72.87	
1	Methamp	0		0.73		3.55	0.00	34.69	24.99	
1	l Amp		013SP0012.d	0	7125452	0.00	0.00	0.00	74.12	

KRYSTAL BARRIER Page 1 of 3 FEB 2 7 2022

Date of Printing: 02-26-2022

	Mathematical		_					
	Methamp	0	0		0.00	0.00	0.00	25.27
1	Amp	0 014SP0013.d	0.1	713645Z	2.74	300.00	233.33	71.54
1	Methamp	0	0.58		3.55	0.00	16.67	25.07
1	Amp	0 015SP0014.d	687.81	703716Z	2.72	77.64	39,14	72.95
1	Methamp	0	614.71		3.55	27.45	22.15	25.29
1	Amp	0 016SP0015.d	7304.69	704691Z	2.73	79.21	39.62	69.12
1	Methamp	0	2.84		3,55	33.67	0.00	25.26
1	Amp	0 017SP0016.d	3860.68	710084Z	2.73	77.75	38.27	69.69
1	Methamp	0	3.4		3.54	31.58	31.02	24.78
1	Amp	0 018SP0017.d	5776.52	699577Z	2.73	78.09	38.55	70.82
1	Methamp	0	2.42		3.55	36.44	40.68	24.88
1	Amp	0 019SP0018.d	0.34	701428Z	2.69	342.31	0.00	71.07
1	Methamp	0	0.7		3.54	0.00	0.00	24.46
1	Amp	0 020SP0019.d	0.25	710457Z	2.69	0.00	0.00	72.67
1	Methamp	0	0		0.00	0.00	0.00	25.04
1	Amp	0 021SP0020.d	0.08	7121812	2.75	0.00	0.00	72.70
1	Methamp	0	0		0.00	0.00	0.00	24.85
2	Amp	0 022BL0099.d	529.88	SB	2.71	150.00	800.00	250.00
2	Methamp	0	0		0.00	0.00	0.00	250.00
1	Amp	0 023SP0021.d	639.57	712674Z	2.73	78.43	39.27	73.47
1	Methamp	0	375.69		3.55	27.38	22.31	25.25
1	Amp	0 024SP0022.d	0.02	718546Z***	2.72	300.00	0.00	71.59
1	Methamp	0	0.59		3.55	0.00	21.43	24.92
1	Amp	0 025SP0023.d	454.92	713616Z	2.72	78.16	39.31	73.12
1	Methamp	0	3391.52		3.55	27.59	22.01	25.23
1	Amp	0 026SP0024.d	0.64	713985Z	2.73	172.73	257.58	71.35
1	Methamp	0	0.76		3.55	0.00	0.00	24.63
1	Amp	0 027SP0025.d	518.6	712593Z	2.73	77.92	39.13	72.53
1	Methamp	0	0.72		3.54	0.00	19.70	25.00
1	Amp	0 028SP0026.d	23167.65	709852Z	2.73	78.36	38.51	70.28
1	Methamp	0	9.67		3.55	29.08	55.66	24.93
2	Amp	0 029BL0096.d	353.25	(DQ) Blank injection	2.73	150.00	0.00	133.33
2	Methamp	0	0		0.00	0.00	0.00	133.33
1	Amp	0 030SP0027.d	76.03	713631Z	2.71	0.43	0.00	73.21
1	Methamp	0	0.55		3.55	0.00	35.29	25.09
1	Amp	0 031SP0028.d	5625.5	713879Z	2.73	77.65	38.43	68.32
1	Methamp	0	1.79		3.55	0.00	0.00	25.18
1	Amp	0 032SP0029.d	1329.27	633410Z	2.73	78.10	38.94	72.35
1	Methamp	0	6012.91		3.55	27.62	21.93	25.19
1	Amp	0 033SP0030.d	8229.84	713794Z	2.73	78.48	38.83	68.78
1	Methamp	0	1.93		3.55	31.33	0.00	25.52
1	Amp	0 034SP0031.d	8606.42	714914Z	2.73	78.78	38.99	69.22
1	Methamp	0	26.16		3.55	27.93	28.69	24.94
1	Amp	0 035SP0032.d	8409.17	714220Z	2.73	79.27	39.50	69.39
1	Methamp	0	3.2		3.55	33.82	86.76	25.02
1	Amp	0 036SP0033.d	2263.74	714252Z	2.73	77.30	38.05	73.32
1	Methamp	0	0.72		3.55	0.00	0.00	25.27
1	Amp	0 037SP0034.d	4272.19	715025Z	2.73	77.73	38.32	74,11

Page 2 of 3

Date of Printing: 02-26-2022

1	Methamp	0	1.91		3.55	44.09	20.97	25.18
1	Amp	0 038SP0035.d	10379.3	714098Z	2.73	78.53	38.89	71.18
1	Methamp	0	90100.6		3.56	27.47	21.31	25.12
2	Amp	0 039BL0096.d	529.88	(DQ) Blank injection	2.75	100.00	400.00	400.00
2	Methamp	0	0		3.54	24.21	25.26	400.00
1	Amp	0 040SP0036.d	1085.42	715356Z	2.73	78.70	39.31	73.70
1	Methamp	0	1.81		3.55	31.74	20.36	25.24
1	Amp	0 041SP0037.d	7640.55	714901Z	2.73	80.32	40.47	68.91
1	Methamp	0	2.51		3.55	33.87	33.87	25.53
1	Amp	0 042SP0038.d	3073.08	714439Z	2.73	77.25	38.27	72.69
1	Methamp	0	1.19		3.54	0.00	28.79	24.73
1	Amp	0 043SP0039.d	4164	714611Z	2.73	78.05	38.65	70.61
1	Methamp	0	69027.97		3.56	27.54	21.22	24.92
2	Amp	0 044BL0096.d	264.94	(DQ) Blank injection	2.70	500.00	0.00	400.00
2	Methamp	0	0		3.55	31.67	38.33	400.00
1	Amp	0 045SP0040.d	6314.26	7149317	2.73	78.81	39.07	69.26
1	Methamp	0	2.18		3.55	30.53	46.46	25.32
1	Amp	0 046SP0041.d	374.74	125% CTRL	2.73	77.48	39.61	71.69
1	Methamp	0	368.07		3.55	26.98	21.66	25.08
	End of Batch							



# **TXNAMMS2**

# Batch ID 022401\$

		A	AMPH	ETAM	INE/MI	HETAMINE / METHAMPHETAMINE	<b>CAMINE</b>	
		ГОР		80% of	80% of On-Column		NRC 125%	
	Cutoff	LOQ ULL		Log	Target*	40% Control	Control	125% Control
AMP	250	25	10000	20	100	85.27-127.91	524.51-786.77	269.65-404.48
MAMP	250	25	25 10000	20	100	83.87-125.81	523.94-785.92	269.77-404.66

\*Regulated Only

2 ml acceptable dilutions

	Lot Numbers	<b></b>	Difution	٠,
S.	A020322S	1	NEAT	
Cal 1	A082521C	1	7	
40%	21075902	(	4	
NRC 125	21075903	(	9	
Neg**	1092921	\	20	
125%	21065897	1	4	
**Interfere	"Interference Control	7	100	- 1

Negative (µL)	Sample (µL) Neg
	2000
	1000
	200
	200
	100
	20
	20
lition	Serial Dilutions
2 then '	1:2 then 1:100
10 then 1.40	1.40 140

Dilution Protocol	NEAT	1:2	NEAT	
Ö	OTN	Insurance	Clinical	

Agilent Autotune Ranges

>40%

219 abundance:

>2.4% 502 abundance:

70 isotope: **0.5 - 1.6%** 220 isotope: 3.2 - 5.4% 503 isotope: 7.9 - 12.3%

Air(28):<10 EMVolts <3000 water(18): <20

Peak Width Pw50: 0.5 - 0.7 amu

KRYSTAL BARRIER FEB 27 202

# Batch # TXNAMMS2 0224018

Calibrator I.S. Areas 2nd (if Necessary)

37620	62742

here	
Area	drug
al I.S.	Multi-
r Cal	a
Enter	fitis
E	<del>-</del>

st Drug	nd Drug
1st	2nd

125,483	10	31,371
75,239	9	18,810
HIGH		LOW

2 87 P	
.2	4
376	627

10% (2nd drug)

10% (1st drug)

50% (1st drug) 50% (2nd drug)

200% (1st drug) 200% (2nd drug)

< this area

< this area

KRYSTAL BARRIER FEB 2 LAND

Version 4.0

Post-Batch Name

: C:\msdchem\1\sequence\TXNAMMS20224018.S

Original Data Path : C:\MSDCHEM\1\DATA\

Last Modified on

: 25 Feb 2022 at 16:14 pm

Method: AMPSINGLECAL.M; Intelligent Sequencing: On First Blank: 96

Line	SampleType	Vial	Sample Name	Multiplier	
1)	BATCHDIR -	CZMMANXT	0224018		~
	Specimen	4	UNX	1.00	
	Calibrator	2	CAL	1.00	
	REQTSTDS	2	CILL	2.00	
	Specimen	3	40% CTRL	1.00	
	Specimen	4	125% NRC	1.00	
	Negative	5	NEG INT CTRL	1.00	
	Specimen	6	692504Z	1.00	
	Specimen	7	692274Z	1.00	
	Specimen	8	660111Z-20	20.00*	
11)		9	660111Z-40	40.00	
	Specimen	10	715166Z	1.00	
13)		11	693718Z	1.00	1200
				1.00	18 6 8
14)		12	712545Z		10 6
15)		13	713645Z	1.00	10101
	Specimen	14	703716Z	1.00	Page 18
	Specimen	15	704691Z	1.00	可 出 (201 201 201 201 201 201 201 201 201 201
	Specimen	16	710084Z	1.00	
	Specimen	17	699577Z	1.00	
20)		18	701428Z	1.00	
21)		19	710457Z	1.00	3 50
22)		20	712181Z	1.00	8 X 2 3
	PAUSE				JOSEPH KUBIAK OVA - RPCO From JUMENY
	Blank	99	SB	1.00	
25)		21	712674Z	1.00	18 18 19
26)		22	718546Z***	1.00	1 8 5
27)		23	713616Z	1.00	1
	Specimen	24	713985Z	1.00	
	Specimen	25	712593Z	1.00	1 × 1 1
	Specimen	26	709852Z	1.00	_ 11 _ 3/3
31)	Specimen	27	713631Z	1.00	B
	Specimen	28	713879Z	1.00	
	Specimen	29	633410Z	1.00	
	Specimen	30	713794Z	1.00	
	Specimen	31	714914Z	1.00	c Built/Vials  John Sequence  iffed Eyr  crite Somence  riffed By:
36)	Specimen	32	714220Z	1.00	
37)	Specimen	33	714252Z	1.00	[₹ \\ \angle \\
	Specimen	34	715025Z	1.00	Bull jon fic fic
39)		35	714098Z	1.00	in the state of th
	Specimen	36	715356Z	1.00	Seatence Built/Vials Verte (
41)		37	714901Z	1.00	8 1
42)		38	714439Z	1.00	S. S
43)	Specimen	39	714611Z	1.00	
44)	Specimen	40	714931Z	1.00	
45)	Specimen	41	125% CTRL	1.00	
					1/11/

(@) Indicates that Sample name has been truncated.

KRYSTAL BARRIER FEB 27 2022

FEB 2 8 2022

: C:\MSDCHEM\1\DATA\TXNAMMS20224018\001SP0004.d Data File

Operator

 $C:\msdchem\1\5975\atune.u$ 

Tune File Name

Tune Date Acq Method Name

3:20 pm 🗸 25 Feb 2022

Calibration date Acquisition date : C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M : 25 Feb 2022 4:13 am

: 25 Feb 2022 : UNX

Sample Name Misc Info Vial Number

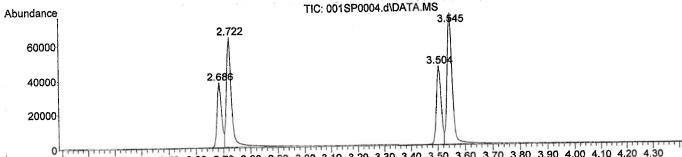
5:11 pm

FEB 2 8 2022

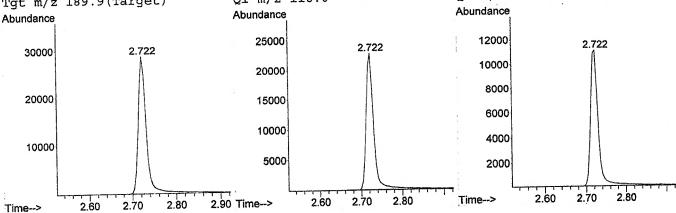
Mult: 1

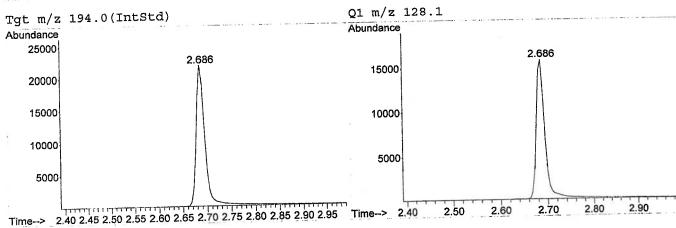
V 22,002 21,000				HENDERSON 1004	
1	Signal	RT	Limits	Response   QRatio	Limits
Amp D11		2.686	2.636- 2.744	28304*   20456   72.3	30273- 121090 57.4- 86.0
Amp	189.9 118.0 91.0	2.722	2.672- 2.781	36590 28613 78.2 14460 39.5	61.8- 92.6 30.7- 46.1

Concentration: 651.89 ng/mL \*\* ISTD AREA IS BELOW MINIMUM LIMIT \*\*



Time--> 2.10 2.20 2.30 2.40 2.50 2.60 2.70 2.80 2.90 3.00 3.10 3.20 3.30 3.40 3.50 3.60 3.70 3.80 3.90 4.00 4.10 4.20 4.30 Q2 m/z 91.0 Q1 m/z 118.0 Tqt m/z 189.9(Target)





Data File : C:\MSDCHEM\1\DATA\TXNAMMS20224018\001SP0004.d

Operator

C:\msdchem\1\5975\atune.u

Tune File Name Tune Date

25 Feb 2022 3:20 pm

Acq Method Name

C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M

Mult: 1

Calibration date Acquisition date

: 25 Feb 2022 4:13 am 5:11 pm

Sample Name

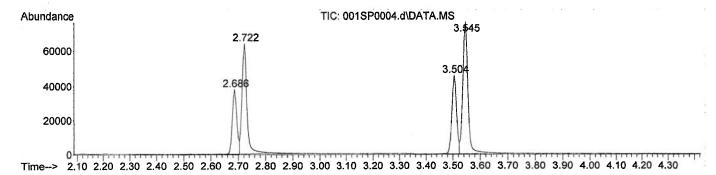
: 25 Feb 2022

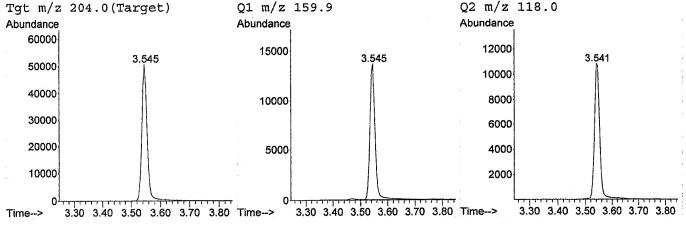
: UNX

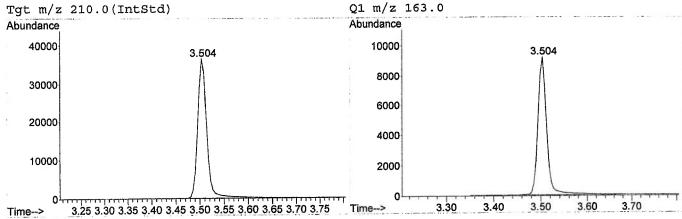
Misc Info Vial Number

Cmpnd	Signal	RT		Limits	Response	QRatio	Limits
Methamp	D11						
	210.0	3.504		3.434- 3.574	47381*		53855- 215418
- +	163.0				11894	25.1	19.9- 29.9
Methamp					•		
1	204.0	3.545	-	3.474- 3.616	64679		
1	159.9				17726	27.4	21.9- 32.9
	118.0				14452	22.3	17.2- 25.8

Concentration: 649.88 ng/mL \*\* ISTD AREA IS BELOW MINIMUM LIMIT \*\*







```
File
         :C:\MSDCHEM\1\DATA\TXNAMMS20224018\002CA0002.d
Operator :
Acquired : 25 Feb 2022 5:20 pm using AcqMethod AMPSINGLECAL.M
Sample Name: CAL
```

Misc Info : Vial Number: 2

AMPHETAMINES IN URINE

Calibration Last Updated: Fri Feb 25 17:27:07 2022

Reference Window: 4.00 Percent Non-Reference Window: 4.00 Percent Correlation Window: 0.03 minutes

Default Multiplier: 1.00

Default Sample Concentration: 0.00

Compound Information \_\_\_\_\_\_

1) Amp D11 (ISTD TR)

Ret. Time 2.69 min., Extract & Integrate from 2.39 to 2.99 min.

Signal Rel Resp. Pct. Unc. (rel) Integration

Tgt 194.00 \*\*\* METH DEFAULT \*\*\* Q1 128.10 70.20 20.0 \*\*\* METH DEFAULT \*\*\*

Lvl ID Conc (ng/mL) Response 500.000 37620

Qualifier Peak Analysis ON ISTD conc: 500.000 ng/mL Curve Fit: Linear, forced through origin 

( ) Amp

Ret. Time 2.72 min., Extract & Integrate from 2.52 to 2.92 min.

Rel Resp. Pct. Unc.(rel) Integration
\*\*\* METH DEFAULT \*\*\* Signal Tgt 189.90 77.00 20.0 39.20 20.0 Q1 118.00 \*\*\* METH DEFAULT \*\*\*

Q2 91.00 \*\*\* METH DEFAULT \*\*\* Lvl ID Conc (ng/mL) Response

Qualifier Peak Analysis ON

250.000

Curve Fit: Linear, forced through origin \_\_\_\_\_

(ISTD TR) 3) Methamp D11

Ret. Time 3.50 min., Extract & Integrate from 3.20 to 3.80 min.

Rel Resp. Pct. Unc. (rel) Integration Signal

\*\*\* METH DEFAULT \*\*\* Tgt 210.00 24.30 20.0 \*\*\* METH DEFAULT \*\*\* Q1 163.00

Lvl ID Conc (ng/mL) Response 500.000

Qualifier Peak Analysis ON ISTD conc: 500.000 ng/mL Curve Fit: Linear, forced through origin



4) Methamp () 7

Ret. Time 3.55 min., Extract & Integrate from 3.25 to 3.85 min.

 Signal
 Rel Resp.
 Pct. Unc.(rel)
 Integration

 Tgt
 204.00
 \*\*\* METH DEFAULT \*\*\*

 Q1
 159.90
 27.10
 20.0
 \*\*\* METH DEFAULT \*\*\*

 Q2
 118.00
 20.70
 20.0
 \*\*\* METH DEFAULT \*\*\*

Lvl ID Conc (ng/mL) Response 1 250.000 31546

Qualifier Peak Analysis ON Curve Fit: Linear, forced through origin

curve Fit: Linear, forced through origin

Data File : C:\MSDCHEM\1\DATA\TXNAMMS20224018\002CA0002.d

Operator

Page 5

Tune File Name

: C:\msdchem\1\5975\atune.u

Tune Date

Mult: 1 : 25 Feb 2022 3:20 pm

Acq Method Name

: C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M

Calibration date Acquisition date : 25 Feb 2022 5:27 pm

: 25 Feb 2022 5:20 pm

Sample Name

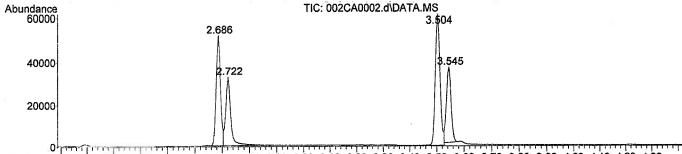
Misc Info

: CAL

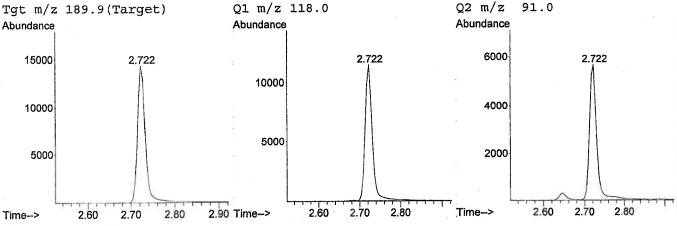
Vial Number : 2

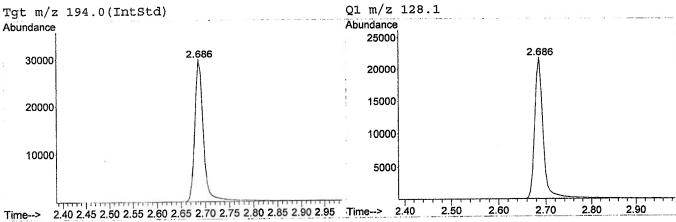
Cmpnd   Amp D11	Signal	RT	1	Limits	Response	QRatio	Limits
<u> </u>	194.0 128.1	2.686		2.632- 2.739	37620 26414	70.2	30273- 121090 56.2- 84.2
Amp	189.9 118.0 91.0	2.722		2.668- 2.777	17749 13662 6954	77.0 39.2	61.6- 92.4 31.4- 47.0

Concentration: 250.00 ng/mL CALIBRATOR



Time--> 2.10 2.20 2.30 2.40 2.50 2.60 2.70 2.80 2.90 3.00 3.10 3.20 3.30 3.40 3.50 3.60 3.70 3.80 3.90 4.00 4.10 4.20 4.30





: C:\MSDCHEM\1\DATA\TXNAMMS20224018\002CA0002.d Data File

Operator

C:\msdchem\1\5975\atune.u

Tune File Name

Mult: 1 : 25 Feb 2022 3:20 pm Tune Date

: C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M Acq Method Name

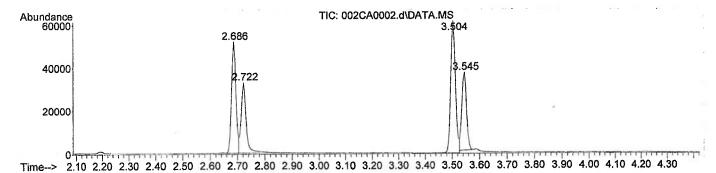
: 25 Feb 2022 5:27 pm Calibration date Acquisition date : 25 Feb 2022 5:20 pm

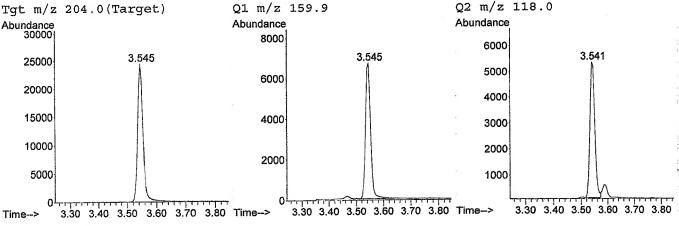
Sample Name : CAL

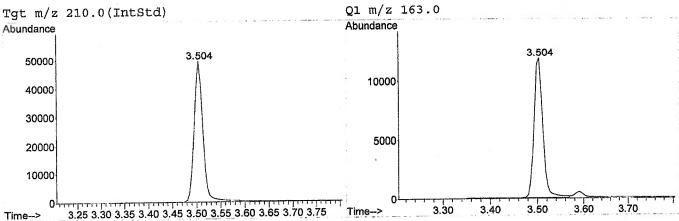
Misc Info Vial Number

<u> </u>	Signal	RT	Lim	its	Response	QRatio	Limi	ts
Methamp	D11 210.0 163.0	3.504	3.434-	3.574	62742 15237	24.3		- 215418 - 29.2
Methamr	204.0 159.9 118.0	3.545	3.474-	3.616	31546 8545 6538	27.1 20.7		- 32.5 - 24.8

Concentration: 250.00 ng/mL CALIBRATOR







: C:\MSDCHEM\1\DATA\TXNAMMS20224018\002CA0002.d Data File

Operator

C:\msdchem\1\5975\atune.u

Tune File Name Tune Date

3:20 pm 25 Feb 2022

Acq Method Name

Mult: 1

Calibration date

: C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M

Acquisition date

: 25 Feb 2022 5:27 pm

Sample Name

5:20 pm -: 25 Feb 2022

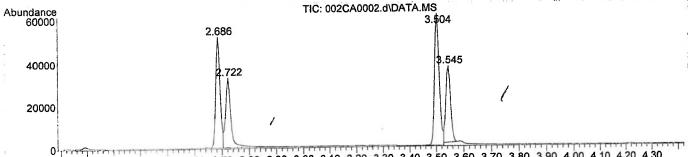
: CAL

Misc Info

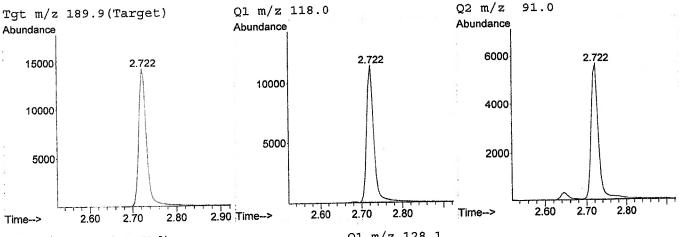
2 Vial Number

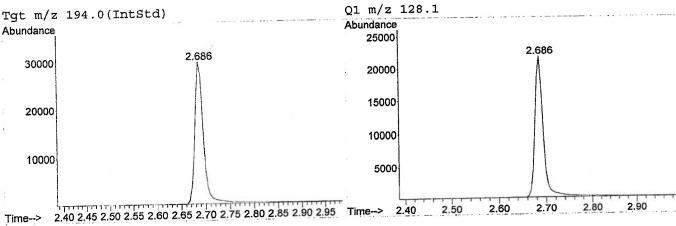
Cmpnd	Signal	RT	{	Limits	Response	QRatio	Limits
Amp D11	194.0 128.1	2.686		2.632- 2.739	37620 26414	70.2	18810- 75240 56.2- 84.2
Amp	189.9 118.0 91.0	2.722		2.668- 2.777	17749 13662 6954	77.0 39.2	61.6- 92.4 31.4- 47.0

Concentration: 250.00 ng/mL CALIBRATOR



Time--> 2.10 2.20 2.30 2.40 2.50 2.60 2.70 2.80 2.90 3.00 3.10 3.20 3.30 3.40 3.50 3.60 3.70 3.80 3.90 4.00 4.10 4.20 4.30





Printed on : 25 Feb 2022 5:27 pm

: C:\MSDCHEM\1\DATA\TXNAMMS20224018\002CA0002.d Data File

Operator

C:\msdchem\1\5975\atune.u Tune File Name

Mult: 1 Tune Date : 25 Feb 2022 3:20 pm

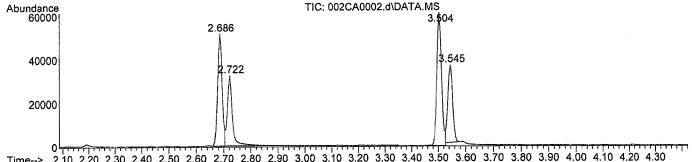
: C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M Acq Method Name : 25 Feb 2022 5:27 pm Calibration date

: 25 Feb 2022 5:20 pm Acquisition date : CAL

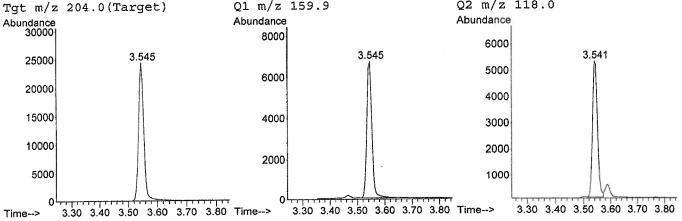
Sample Name Misc Info Vial Number : 2

Cmpnd	Signal	RT	1	Limits	Response	QRatio	Limits
Methamp		3.504		3.434- 3.574	62742 15237	24.3	31371- 125484 19.4- 29.2
Methamp   	204.0 159.9 118.0	3.545		3.474- 3.616	31546 8545 _6538	27.1 20.7	21.7- 32.5 16.6- 24.8

Concentration: 250.00 ng/mL CALIBRATOR



Time--> 2.10 2.20 2.30 2.40 2.50 2.60 2.70 2.80 2.90 3.00 3.10 3.20 3.30 3.40 3.50 3.60 3.70 3.80 3.90 4.00 4.10 4.20 4.30 Q1 m/z 159.9Q2 m/z 118.0



Q1 m/z 163.0 Tqt m/z 210.0(IntStd) Abundance Abundance 3.504 50000

3.504 10000 40000 30000 5000 20000 10000 3.60 3.40 3.50 3.70 3.25 3.30 3.35 3.40 3.45 3.50 3.55 3.60 3.65 3.70 3.75 3.30 Time-->

Printed on : 25 Feb 2022 5:27 pm



# Calibration Summary Report AMPHETAMINES IN URINE

Instrument : A73

Acquisition Method: C:\MSDCHEM\1\DATA\TXNAMMS20224018\AMPSINGLECAL.M

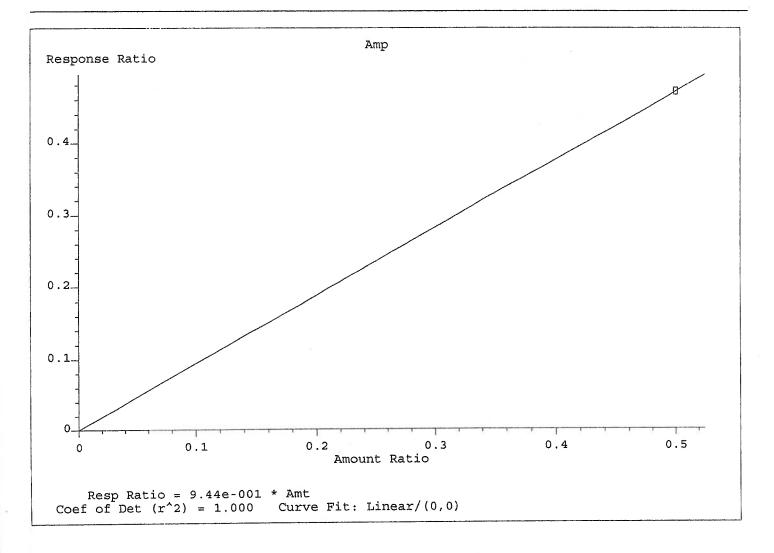
Calib Update Time : Fri Feb 25 17:27:07 2022

Data Path : C:\MSDCHEM\1\DATA\TXNAMMS20224018\

# Compound Information:

1)	Amp D11				(ISTD)	
				Response	100 10	
Lvl	File	Conc	R.T.	194.00	128.10	
1	002CA0002.d Average:	500.00	2.69 2.69	37620 37620	70.21 70.21	
				ISTD R	ange( 18810.00- 7524	0.00)
2)	Amp					

2)	Amp						
				Response			
Lvl	File	Conc	R.T.	189.90	118.00	91.00	Rf
1	002CA0002.d	250.00	2.72	17749	76.97	39.18	0.944
	Average:		2.72		76.97	39.18	0.944
	Correlation	Coefficient	= 1.0000		Rf Range	( 0.755-	- 1.132)





Instrument : A73

Acquisition Method: C:\MSDCHEM\1\DATA\TXNAMMS20224018\AMPSINGLECAL.M

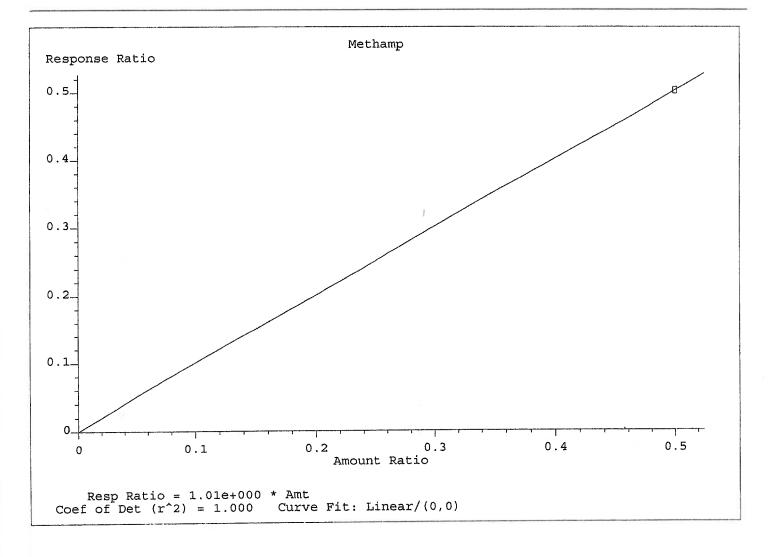
Calib Update Time: Fri Feb 25 17:27:07 2022

Data Path : C:\MSDCHEM\1\DATA\TXNAMMS20224018\

### Compound Information:

3)	Methamp D11			Dogoongo	(ISTD)		
Lvl	File	Conc	R.T.	Response 210.00	163.00		
1	002CA0002.d Average:	500.00	3.50	62742 62742 ISTD R	24.29 24.29 ange( 31371	.00-125484.00)	
4)	Methamp						

4)	Methamp						
				Response			
Lvl	File	Conc	R.T.	204.00	159.90	118.00	Rf
1	002CA0002.d	250.00	3.55	31546	27.09	20.73	1.006
	Average:		3.55		27.09	20.73	1.006
	Correlation	Coefficient	= 1.0000		Rf Range	( 0.804-	- 1.207)





: C:\MSDCHEM\1\DATA\TXNAMMS20224018\003SP0003.d Data File

Operator

: C:\msdchem\1\5975\atune.u

Tune File Name Tune Date

: 25 Feb 2022 3:20 pm

Aca Method Name

: C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M

Mult: 1

Calibration date

: 25 Feb 2022 5:27 pm

Acquisition date

: 25 Feb 2022 5:29 pm

Sample Name

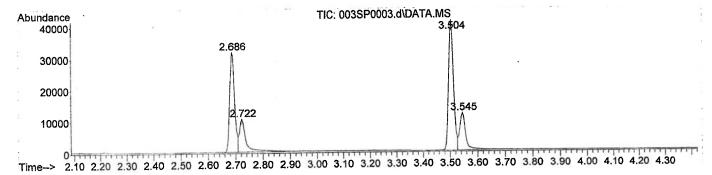
: 40% CTRL

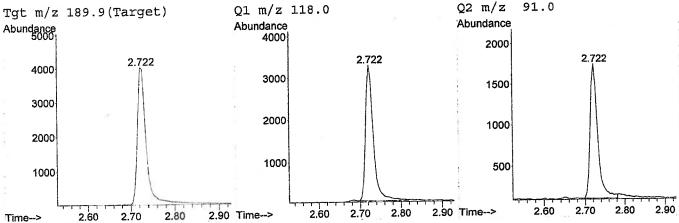
Misc Info

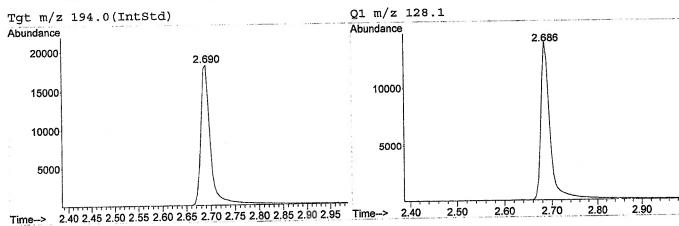
Vial Number : 3

;	Signal	RT	l	Limits	Response	QRatio	Limits
Amp D11	194.0	2.690		2.632- 2.739	26520 19223	72.5	18810- 75240 56.2- 84.2
Amp	189.9 118.0 91.0	2.722		2.668- 2.777	5645 4218 2121	74.7 37.6	61.6- 92.4 31.4- 47.0

Concentration: 112.79 ng/mL







: C:\MSDCHEM\1\DATA\TXNAMMS20224018\003SP0003.d Data File Operator C:\msdchem\1\5975\atune.u Tune File Name Mult: 1 : 25 Feb 2022 3:20 pm Tune Date : C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M Acq Method Name : 25 Feb 2022 5:27 pm Calibration date 5:29 pm 25 Feb 2022 Acquisition date 40% CTRL Sample Name Misc Info 3 Vial Number Limits Response | QRatio | Limits Cmpnd | Signal | RTMethamp D11 31371- 125484 3.434- 3.574 44493 3.504 210.0 19.4- 29.2 11160 25.1 163.0 Methamp 3.474- 3.616 9984 3.545 204.0 21.7- 32.5 26.7 2667 159.9 16.6- 24.8 2220 22.2 118.0 Concentration: 111.57 ng/mL TIC: 003SP0003.d\DATA.MS Abundance 40000 2.686 30000 20000 .545 10000 Time--> 2.10 2.20 2.30 2.40 2.50 2.60 2.70 2.80 2.90 3.00 3.10 3.20 3.30 3.40 3.50 3.60 3.70 3.80 3.90 4.00 4.10 4.20 4.30 Q2 m/z 118.0 Q1 m/z 159.9Tgt m/z 204.0(Target) Abundance Abundance Abundance 2500 2000 8000 3.545 3.545 3.545 2000 1500 6000 1500 1000 4000 1000 500 2000 500 3.30 3.40 3.50 3.60 3.70 3.80 Time-> 3.30 3.40 3.50 3.60 3.70 3.80 3.30 3.40 3.50 3.60 3.70 3.80 Time--> Q1 m/z 163.0 Tgt m/z 210.0(IntStd) Abundance Abundance 3.504 3.504 8000 30000 6000 20000 4000 10000 2000 3.60 3.70

Printed on: 25 Feb 2022 5:36 pm NVBOP - 086

3.40

3.30

Time-->

3.50

3.25 3.30 3.35 3.40 3.45 3.50 3.55 3.60 3.65 3.70 3.75

: C:\MSDCHEM\1\DATA\TXNAMMS20224018\004SP0004.d Data File

Operator

Tune File Name C:\msdchem\1\5975\atune.u

Tune Date

25 Feb 2022 3:20 pm

Acq Method Name

: C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M

Mult: 1

Calibration date

: 25 Feb 2022 5:27 pm

Acquisition date

: 25 Feb 2022 5:38 pm

Sample Name

: 125% NRC

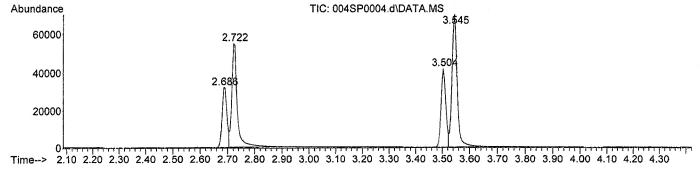
Misc Info

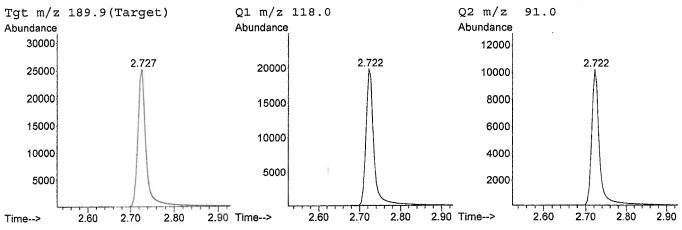
Vial Number

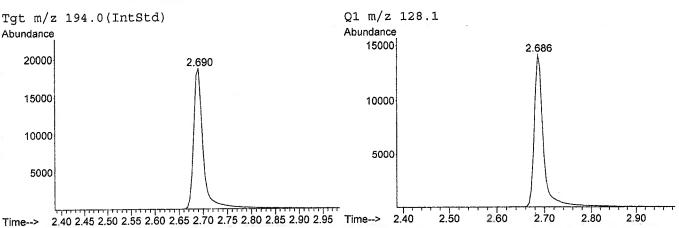
: 4

Cmpnd   Amp D11	Signal	RT	1	Limits		Response		QRatio		Limits
Amp Dri		2.690		2.632- 2.739		26459 19211		72.6		18810- 75240 56.2- 84.2
Amp	189.9	2.727	1	2.668- 2.777	1	34009	1	, _ , ~		30.2 01.3
	118.0 91.0					26487 13618		77.9 40.0		61.6- 92.4 31.4- 47.0

Concentration: 681.09 ng/mL









: C:\MSDCHEM\1\DATA\TXNAMMS20224018\004SP0004.d Data File

Operator

: C:\msdchem\1\5975\atune.u

Tune File Name Tune Date

: 25 Feb 2022 3:20 pm

5:38 pm

Mult: 1

: C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M Acq Method Name

Calibration date

: 25 Feb 2022 5:27 pm

Acquisition date : 25 Feb 2022 Sample Name

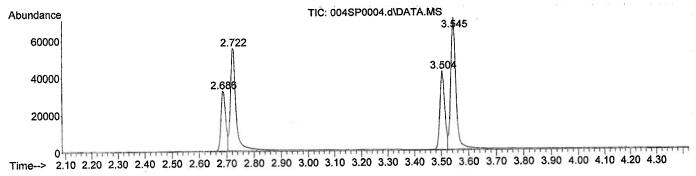
Misc Info

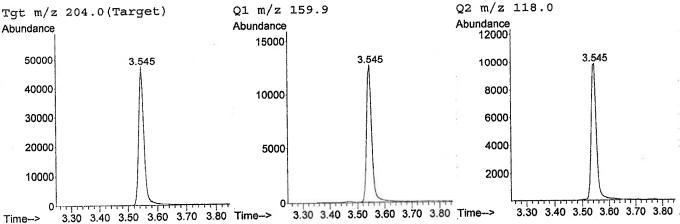
: 125% NRC

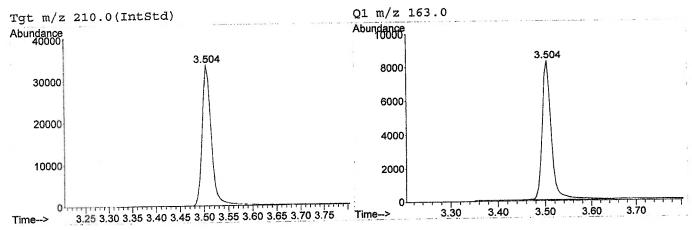
Vial Number

Cmpnd	Signal	RT	]	Limits	Response	QRatio	Limits
Methamp		3.504		3.434- 3.574	44113 11169	25.3	31371- 125484 19.4- 29.2
Methamp	•	3.545		3.474- 3.616	60278 16484 13356	27.3 22.2	21.7- 32.5 16.6- 24.8

Concentration: 679.43 ng/mL







Data File : C:\MSDCHEM\1\DATA\TXNAMMS20224018\005NE0005.d

Operator

G.\\_\_d\_b\_\_\1\romr\\_\_b\_\_\_

Tune File Name

: C:\msdchem\1\5975\atune.u

Tune Date

: 25 Feb 2022 3:20 pm Mult : 1

Acq Method Name

: C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M

Calibration date Acquisition date

: 25 Feb 2022 5:27 pm

Sample Name

: 25 Feb 2022 5:47 pm : NEG INT CTRL

Misc Info

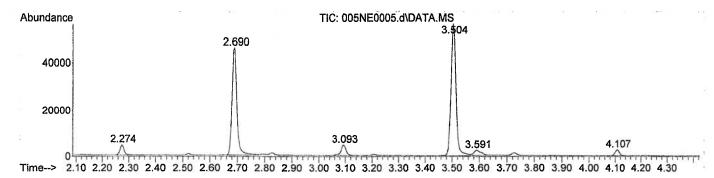
: 141

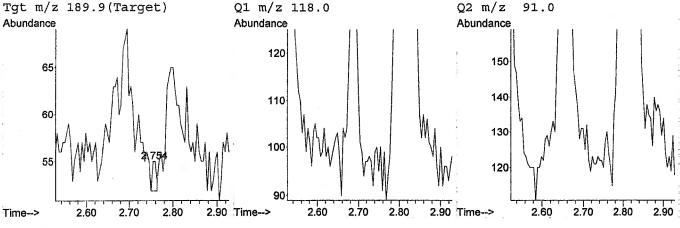
Vial Number

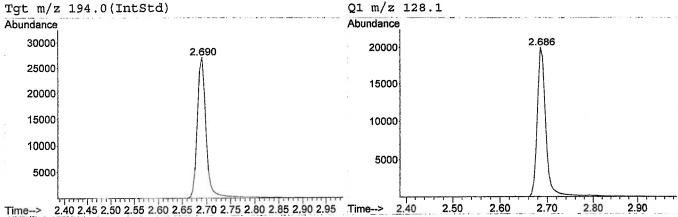
. 5

Cmpnd Amp D1	1 1	RT	Lir	nits	Response	QRatio	Limits	
-	194.0	2.690	2.632	2.739	34150 24595	72.0	18810- 75 56.2- 84	
Amp	189.9 118.0 91.0	2.754	2.668	2.777	2 0 0	0.0*	61.6- 92 31.4- 47	

Concentration: 0.03 ng/mL \*\* GOOD NEGATIVE: CONC. < 25 ng/mL LIMIT \*\*







: C:\MSDCHEM\1\DATA\TXNAMMS20224018\005NE0005.d Data File

Operator

C:\msdchem\1\5975\atune.u Tune File Name

25 Feb 2022 Tune Date

3:20 pm C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M

Mult: 1

Acq Method Name

Calibration date Acquisition date

25 Feb 2022 5:27 pm 5:47 pm 25 Feb 2022

Sample Name

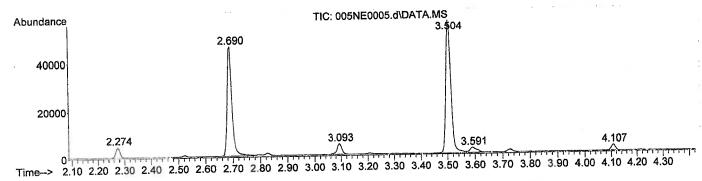
NEG INT CTRL

Misc Info

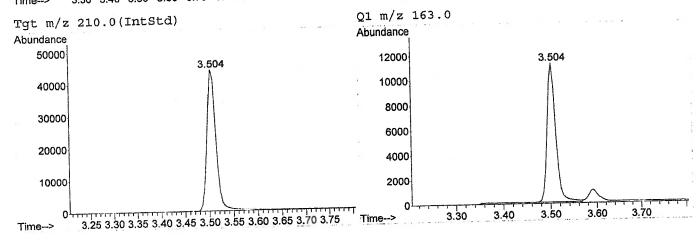
Vial Number 5

Cmpnd	Signal	RT	1	Limits	R	esponse	}	QRatio	Limits	3
Methamp		3.504		3.434- 3.574		56747 14089		24.8	31371- 19.4-	125484 29.2
Methamp	204.0 159.9 118.0	3.545		3.474- 3.616		92 0 0		0.0*	21.7- 16.6-	

0.80 ng/mL \*\* GOOD NEGATIVE: CONC. < 25 ng/mL LIMIT \*\* Concentration:



Q2 m/z 118.0 Q1 m/z 159.9 Tgt m/z 204.0(Target) Abundance Abundance Abundance 150 130 80 3.545 120 60 100 110 40 50 100 20 90 3.30 3.40 3.50 3.60 3.70 3.80 3.30 3.40 3.50 3.60 3.70 3.80 Time--> 3.30 3.40 3.50 3.60 3.70 3.80 Time-->



: C:\MSDCHEM\1\DATA\TXNAMMS20224018\006SP0006.d Data File Operator : C:\msdchem\1\5975\atune.u Tune File Name Mult: 1 : 25 Feb 2022 3:20 pm Tune Date : C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M Acq Method Name : 25 Feb 2022 5:27 pm Calibration date : 25 Feb 2022 Acquisition date 5:56 pm : 692504Z Sample Name Misc Info Vial Number Limits Response | QRatio | Cmpnd | Signal | RTLimits Amp D11 18810- 75240 34111 194.0 2.632- 2.739 2.690 23826 56.2-84.2 69.8 128.1 Amp 367910 2.668- 2.777 189.9 2.727 61.6- 92.4 77.7 118.0 285946 31.4- 47.0 38.3 91.0 141034 DANSON KAMUNYU Concentration: 5715.20 ng/mL TIC: 006SP0006.d\DATA.MS Abundance 2.727 600000 400000 200000 4.217 3.504 Time--> 2.10 2.20 2.30 2.40 2.50 2.60 2.70 2.80 2.90 3.00 3.10 3.20 3.30 3.40 3.50 3.60 3.70 3.80 3.90 4.00 4.10 4.20 4.30 Q2 m/z 91.0 Q1 m/z 118.0 Tqt m/z 189.9(Target) Abundance Abundance 300000 Abundance 2.722 2,727 250000 300000 100000 200000 150000 200000 50000 100000 100000 50000 2.60 2.70 2.80 2.90 2.90 Time--> 2.80 2.90 Time--> 2.60 2.70 2.80 2.70 2.60 O1 m/z 128.1 Tgt m/z 194.0(IntStd) Abundance Abundance 2.686 20000 30000 2.690 25000 15000 20000 10000 15000 10000 5000 5000 2.40 2.45 2.50 2.55 2.60 2.65 2.70 2.75 2.80 2.85 2.90 2.95 Time-> 2,60 2.70 2.80 2.40 2.50

Mult: 1

: C:\MSDCHEM\1\DATA\TXNAMMS20224018\006SP0006.d Data File

Operator

: C:\msdchem\1\5975\atune.u

Tune File Name : 25 Feb 2022 3:20 pm Tune Date

: C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M Acq Method Name

Calibration date Acquisition date : 25 Feb 2022 5:27 pm 5:56 pm

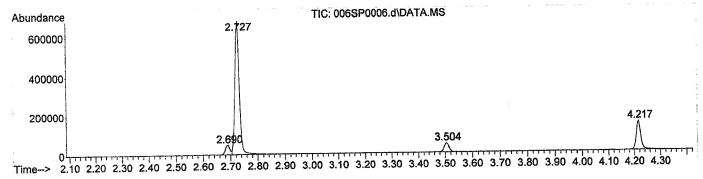
: 25 Feb 2022 Sample Name : 692504Z

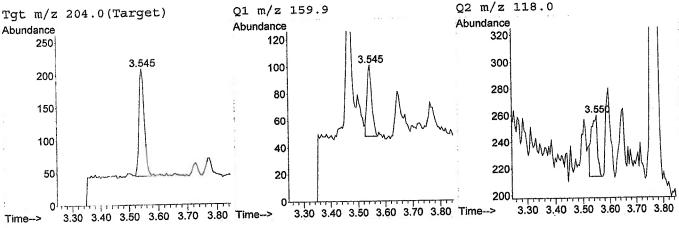
Misc Info

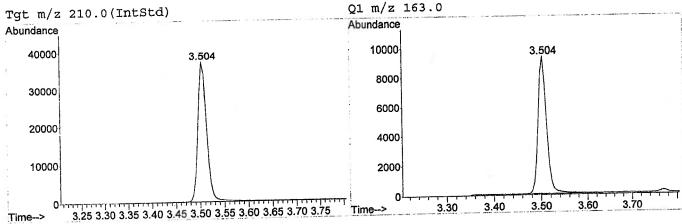
Vial Number : 6

		RT	Limits	Response   QRatio	Limits
Methamp		3.504	3.434- 3.574	46004   25.3	31371- 125484 19.4- 29.2
Methamp	204.0 159.9 118.0	3.545	3.474- 3.616	211 63 29.9 70 33.2*	21.7- 32.5 16.6- 24.8

2.28 ng/mL Concentration:







Data File C:\MSDCHEM\1\DATA\TXNAMMS20224018\024SP0022.d Operator

Tune File Name C:\msdchem\1\5975\atune.u

Tune Date : 25 Feb 2022 Mult : 1 3:20 pm

Acq Method Name : C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M

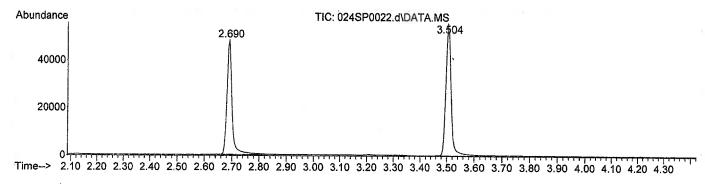
Calibration date : 25 Feb 2022 5:27 pm Acquisition date : 25 Feb 2022 8:40 pm : 718546Z\*\*\*

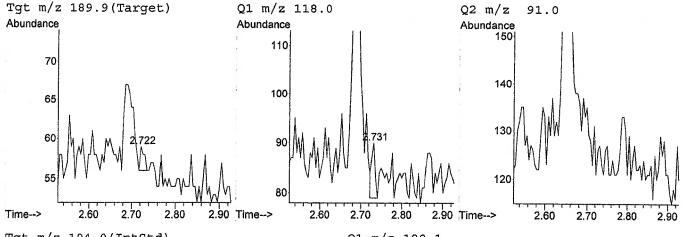
Sample Name Misc Info

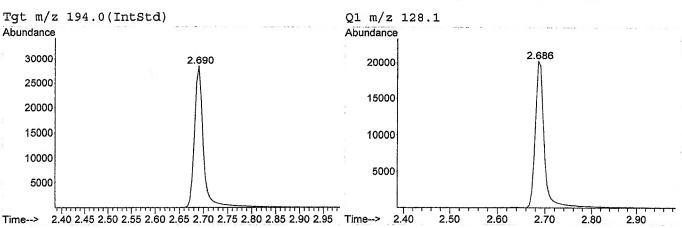
Vial Number : 22

Cmpnd Amp D11	Signal	RT	1	Lim	its	Response	QRatio	İ	Limits	5
Amp	194.0 128.1	2.690	2.	632-	2.739	37329 26724	71.6		18810- 56.2-	
	189.9 118.0 91.0	2.722	2.	668-	2.777	2 6 0	300.0* 0.0*		61.6- 31.4-	

Concentration: 0.02 ng/mL







Page 51

Data File : C:\MSDCHEM\1\DATA\TXNAMMS20224018\024SP0022.d

Operator

Tune File Name

: C:\msdchem\1\5975\atune.u

Tune Date : 25 Feb 2022 3:20 pm Mult : 1

Acq Method Name : C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M

Calibration date : 25 Feb 2022 5:27 pm Acquisition date : 25 Feb 2022 8:40 pm

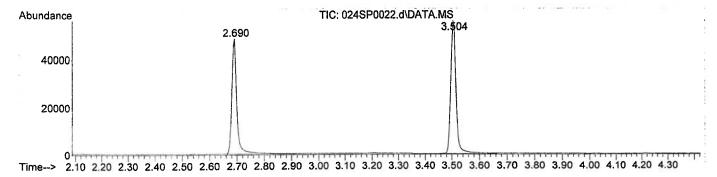
Sample Name : 718546Z\*\*\*

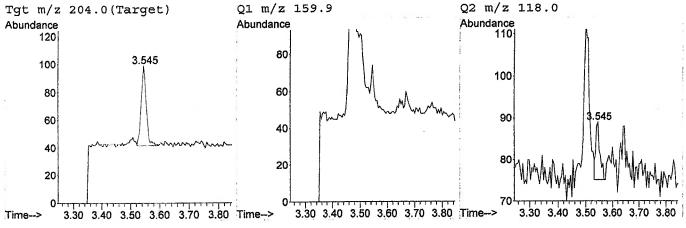
Misc Info

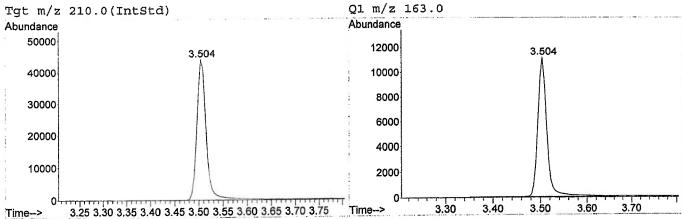
Vial Number : 22

- 1	Signal	RT	Limits	Response	QRatio	Limits
Methamp	D11		-			
	210.0	3.504	3.434-3.574	58976		31371- 125484
1	163.0			14694	24.9	19.4- 29.2
Methamp	· ·					
Ī	204.0	3.545	3.474-3.616	70		
İ	159.9		1	0	0.0*	21.7- 32.5
	118.0			15	21.4	16.6- 24.8

Concentration: 0.59 ng/mL









Mult: 1

Data File : C:\MSDCHEM\1\DATA\TXNAMMS20224018\046SP0041.d

Operator

Tune File Name : C:\msdchem\1\5975\atune.u

Tune Date : 25 Feb 2022 3:20 pm

Acq Method Name : C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M

Acq Method Name : C:\MSDCHEM\1\METHODS\AMPSIN

Calibration date : 25 Feb 2022 5:27 pm Acquisition date : 25 Feb 2022 11:59 pm

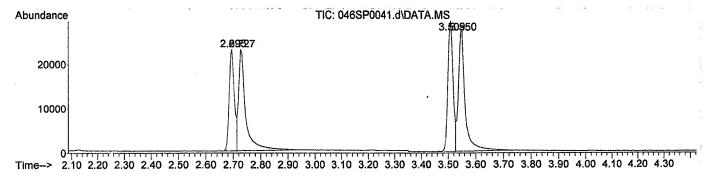
Sample Name : 125% CTRL

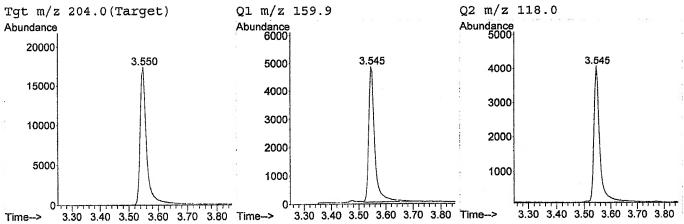
Misc Info

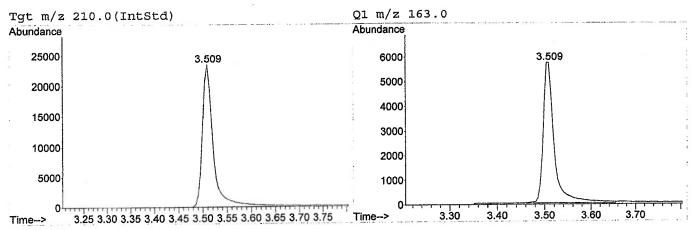
Vial Number : 41

Cmpnd   Methamp	Signal  D11	RT	-	Limits	Response	QRatio	1	Limits
	210.0   163.0	3.509		3.434- 3.574	36701 9205	25.1		31371- 125484 19.4- 29.2
Methamp	•		•		•			
1	204.0	3.550	1	3.474- 3.616	27168			
	159.9				7329	27.0		21.7- 32.5
	118.0				5885	21.7		16.6- 24.8

Concentration: 368.07 ng/mL







: C:\MSDCHEM\1\DATA\TXNAMMS20224018\046SP0041.d Data File Operator C:\msdchem\1\5975\atune.u Tune File Name Mult: 1 : 25 Feb 2022 3:20 pm Tune Date : C:\MSDCHEM\1\METHODS\AMPSINGLECAL.M Acq Method Name : 25 Feb 2022 5:27 pm Calibration date : 25 Feb 2022 11:59 pm Acquisition date : 125% CTRL Sample Name Misc Info : 41 Vial Number Limits Response | QRatio | Limits RTCmpnd | Signal | Amp D11 18810- 75240 22440 2.632- 2.739 2.695 194.0 56.2-84.2 16088 128.1 Amp 15870 2.668- 2.777 189.9 2.731 61.6- 92.4 77.5 12296 118.0 31.4- 47.0 39.6 6286 91.0 Concentration: 374.74 ng/mL TIC: 046SP0041.d\DATA.MS Abundance 3.50950 2.89527 20000 10000 Time--> 2.10 2.20 2.30 2.40 2.50 2.60 2.70 2.80 2.90 3.00 3.10 3.20 3.30 3.40 3.50 3.60 3.70 3.80 3.90 4.00 4.10 4.20 4.30 Q2 m/z 91.0 Q1 m/z 118.0Tgt m/z 189.9(Target) Abundance Abundance Abundance 2.727 2.727 8000 4000 2.731 10000 8000 6000 3000 6000 2000 4000 4000 1000 2000 2000 2.90 2.80 2.70 2.90 Time-> 2.60 2.80 2,60 2.70 2.80 2.90 Time--> 2,60 2.70 Time--> Q1 m/z 128.1 Tgt m/z 194.0(IntStd) Abundance Abundance 2.690 15000 10000 2.695 8000 10000 6000 4000 5000 2000 2.90 2.80 Time--> 2.40 2.45 2.50 2.55 2.60 2.65 2.70 2.75 2.80 2.85 2.90 2.95 Time--> 2.40 2.60

2.50

# **CERTIFICATION INFORMATION**

51030236 AREA/ROUTE/STOP: XXXXXXX

DESERT VIEW HOSPITAL

360 S LOLA LN PAHRUMP, NV 89048

276761

BURKINTAS, MICHAEL

Specimen ID:4840481

4840481 692504Z

02182022

02232022 02282022 09:54PM

Client Site Location;

REASON FOR TEST: NOT PROVIDED DONOR ID VERIFIED: PHOTO I.D.

FINAL

Seals Intact: Yes

\*\*\* POSITIVE/ABNORMAL REPORT \*\*\*

Tests Ordered: 443N (ETHANOL (BLOOD) .01%) 35190N (SAP 10-50/2000 W/NIT)

Urine Specimen Validity Testing

Acceptable Range

CREATININE

47.5 mg/dL

>/= 20 mg/dL

Нф

5.8

4.5-8.9

OXIDIZING ADULTERANTS

Negative

Urine Substance Abuse Panel				itial Level	MS Confirm Test Level
AMPHETAMINES AMPHETAMINE METHAMPHETAMINE BARBITURATES BENZODIAZEPINES COCAINE METABOLITES MARIJUANA METABOLITES METHADONE METHAQUALONE OPIATES PHENCYCLIDINE PROPOXYPHENE	Negative Negative Negative Negative Negative Negative Negative Negative Negative	POSITIVE	300 300 300 50 300 300 2000	ng/mL ng/mL ng/mL ng/mL ng/mL ng/mL ng/mL ng/mL ng/mL	500 ng/mL 500 ng/mL 200 ng/mL 200 ng/mL 150 ng/mL 15 ng/mL 200 ng/mL 200 ng/mL 200 ng/mL 25 ng/mL 200 ng/mL

Urine Quantitative Results

AMPHETAMINE

5715 ng/mL

Blood Alcohol

GC Confirm Test Level

Rejected for Testing: Fatal Flaw, Bottle A label/seal missing

CERTIFYING TECHNICIAN/SCIENTIST: KSDK02 >> REPORT CONTINUED ON NEXT PAGE <<

CONTINUED REPORT

51030236 AREA/ROUTE/STOP: XXXXXXX

DESERT VIEW HOSPITAL

360 S LOLA LN PAHRUMP, NV 89048

276761

BURKINTAS, MICHAEL

Specimen ID:4840481

4840481 692504Z

02182022

02232022 02282022 09:54PM

Client Site Location:

REASON FOR TEST: NOT PROVIDED DONOR ID VERIFIED: PHOTO I.D.

FINAL

SPECIMEN RECEIVED AND PROCESSED IN THE LENEXA DHHS CERTIFIED LABORATORY.

LAB

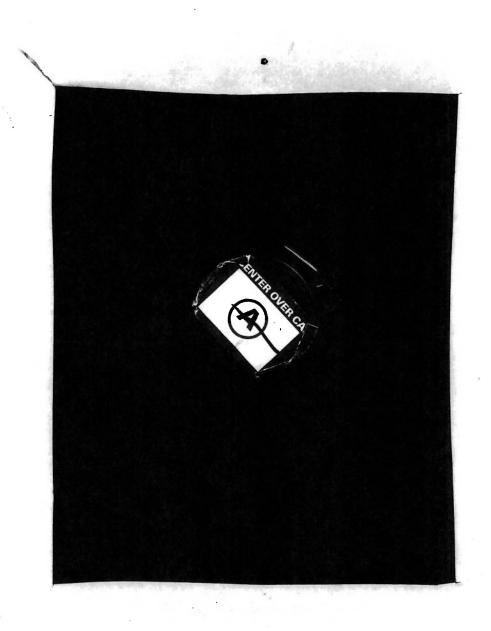
Quest Diagnostics-Lenexa

10101 Renner Blvd Lenexa KS 66219

>> END OF REPORT <<

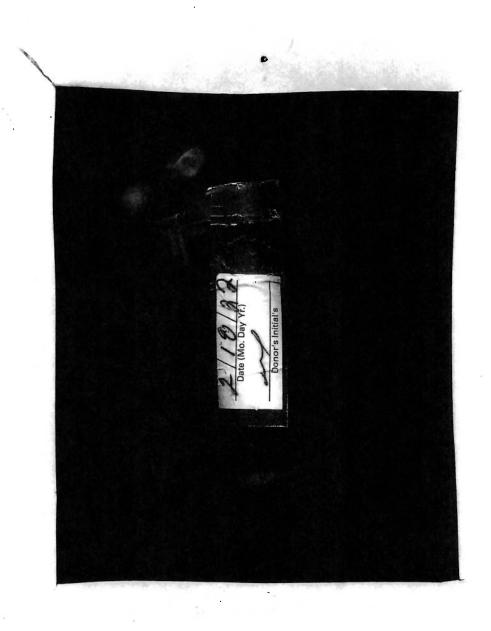
2 √

SPECIMEN STORAGE INFORMATION



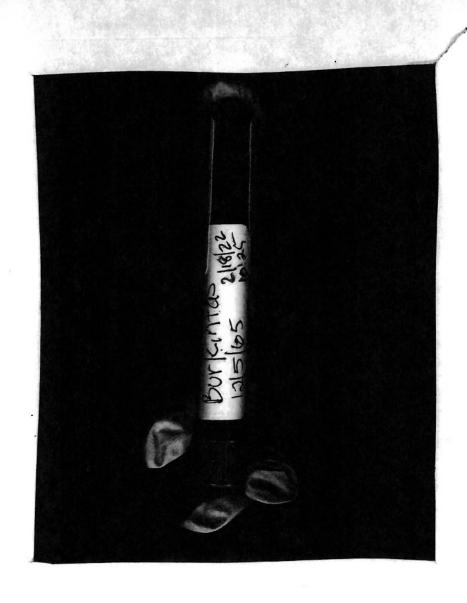














Accession # 6925042	Accession #	
Accession # 1092495 Z	Accession #	
Accession #	Accession #	
Accession #	Accession #	
Accession #	Accession #	

DATE	Released By Signature/Printed Name	Received By Signature/Printed Name	Purpose of Chain of Custody
FEB 2 4 2022	Temp Storage  Long Term Storage	SERRA GARDNER	TRANSFER
FEB 2 4 2022	SERRA GARDNER	PROCESSING TS	TEMP STORAGE

MANUAL FAT STORAGE LIST

AGE

02/24/2022

CHAIN OF CUSTODY LOG

FEB 2 4 2022 Sign. Sign. Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Sign. Name  Sign. Sign. Name  Sign. Name  Sign. Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Sign. Name  Name	inc.	DATE 1/24/2022	Hion	RELEASEL BY	_Sign.	RECEIVES BY	PURPOSEANSFER
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02/24/2022

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•			691218ZR1	400				
			691203ZR1					
			691240ZRi					
		4	671286ZRi					
			691309ZR1					
			691355ZR3	all l				
		7	691341ZR1					
			691276ZR1					
			691384ZR1					
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Ģ	1	737414ZR1	
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03/10/2022

### BOX Y014226 (Continued)

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PAGE 1

02/24/2022

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Н	8	369655ZB1	
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J	2	583758ZB1	
d	3	632689ZB1	
J	4	632776ZB1	
d	5	659201ZB1	X
J	6	649727ZB1	
J	7	649583ZB1	
J	8	617665ZB1	
K	1.	692539ZB1	
K	2	661931ZBi	
K	3	661950ZB1	
K	4	661923ZB1	
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N	1	692412ZB1	
N	2	692525ZB1	
N	3	692529ZB1	
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O	8	692495ZB1	
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Q	3	471584EB1	
Q	4	632917ZB1	THE REAL PROPERTY.
Q	5	661820ZB1	
Q	6	544047ZB1	444
Q	7	632812ZB1	

\*\* END \*\*

# PERSONNEL QUALIFICATIONS

## **CURRICULUM VITAE**

NAME:

Danson Kamunyu

**ADDRESS:** 

10101 Renner Blvd Lenexa, KS 66219

(913) 888-1770 – work

**EDUCATION:** 

Bachelor of Science, Major-Biology-2004

Washburn University, Topeka, KS

**EXPERIENCE:** 

Sep 2015 to

Present

Quest Diagnostics, Lenexa, KS Non-Negative Certifying Scientist

Responsibilities as a certifying scientist include reviewing and

certifying the screening, confirmation, and specimen validity data for

drugs of abuse.

Sep 2013 to

Sep 2015

Quest Diagnostics, Lenexa, KS

Negative Certifying Scientist

Responsibilities included certify/review negative Federal/Non-Federal urine,

hair and oral fluid samples.

Sept 2011 to

Quest Diagnostics, Lenexa, KS

Sept 2013

Forensic Scientist I

Responsibilities included preparing urine, oral fluid, and blood samples to be

tested for drugs of abuse by GC, GC/MS and LC/MS/MS.

July 2006 to

Quest Diagnostics, Lenexa, KS

Sept 2011 Laboratory Technologist

Responsibilities included performing urinalysis, blood hemoglobin A1C,

complete blood count, fibrinogen, pronthroping time, and partial thromboplastin

time.

CERTIFICATIONS: American Society for Clinical Pathologists Board of Registry in chemistry

State of Nevada Department of Health and Human Services

Specialty Technologist-Chemistry/Toxicology

#### Curriculum Vitae

### DAWN M. HAHN

Quest Diagnostics, Inc. 10101 Renner Boulevard Lenexa, KS 66219

(913) 577-1632; Fax: (913) 895-2622 E-mail: <u>dawn.m.hahn@questdiagnostics.com</u>

### **EDUCATION**

1984 Bachelor of Arts; Medical Technology

Northwestern College; Orange City, Iowa

2014 Masters of Business; Administration

John Hancock University, Chicago, Illinois

#### **EXPERIENCE**

September 2013 - Present

Director, Laboratory Operations and Responsible Person Quest Diagnostics, Inc.; Lenexa, KS

Responsibilities include: preparing and maintaining standard operating procedures for drug testing;, establish training protocol for personnel; ensure training is complete, ensure analytical methods are validated; establish acceptable performance limits on QC; ensure the laboratory follows HHS Guidelines for regulated testing; ensure all appropriate corrective action is implemented for any PT or inspection issue assisting; assisting in maintaining toxicology budget; and interfacing with inspection teams

September 2010 -September 2013 Laboratory Operations Manager and Responsible Person Quest Diagnostics, Inc.; Lenexa, KS

Responsibilities include: preparing and maintaining standard operating procedures for drug testing;, establish training protocol for personnel; ensure training is complete, ensure analytical methods are validated; establish acceptable performance limits on QC; ensure the laboratory follows HHS Guidelines for regulated testing; ensure all appropriate corrective action is implemented for any PT or inspection issue assisting; assisting in maintaining toxicology budget; and interfacing with inspection teams

November 2005 – September 2010 Manager of Toxicology

Quest Diagnostics, Inc.; Lenexa, KS

August 2006 -Present Responsible Person, Laboratory Manager

Quest Diagnostics, Inc.; Lenexa, KS

November 2005 -

Alternate Responsible Person

August 2006 Quest Diagnostics, Inc.; Lenexa, KS (formerly LabOne, Inc.)

Dawn M. Hahn Curriculum Vitae Page 2 of 4

November 2000 -

Alternate Responsible Person

November 2005

LabOne, Inc.; Lenexa, KS

July 1999 – November

Director of Toxicology

2005

LabOne, Inc.; Lenexa, KS

November 1997 -

Manager of Toxicology

June 1999

LabOne, Inc.; Overland Park, KS

January 1995 -

SAT Lab Coordinator

November 1997

LabOne, Inc.; Overland Park, KS

February 1990 -

GC/MS Operator/Certifying Scientist Forensic Drug

December 1994 Testing Laboratory

LabOne, Inc.; Overland Park, KS

October 1987 -

Generalist, Blood Laboratory

February 1990

Home Office Reference Laboratory; Overland Park, KS

November 1984 -

**Medical Technologist** 

September 1987

Terrell Community Hospital; Terrell, TX

June 1984 -

**Medical Technologist** 

November 1984

Newburn Memorial Hospital; Jacksonville, TX

### PROFESSIONAL CERTIFICATIONS AND MEMBERSHIPS

**Diplomate** 

American Board of Forensic Toxicology (ABFT)

Forensic Drug toxicology

Inspector

National Laboratory Certification Program (Team Leader)

Inspector

College of American Pathologists

Forensic Urine Drug Testing Program

Member

Society of Forensic Toxicologists (SOFT)

Member

Midwest Association for Toxicology and Therapeutic Drug

Monitoring

Vice President 2005 - 2006 President 2006 - 2007

Lab Supervisor

New York State Department of Health

Lab Supervisor Nevada State Department of Health

Lab Technical Supervisor College of American Pathologists (CAP)

Medical Technologist American Society of Clinical Pathologists (ASCP)

### PROFESSIONAL MEETINGS National Laboratory Certification Program, NLCP Workshop -December 2020 Virtual Society of Forensic Toxicologists, Annual Meeting, Virtual September 2020 Society of Forensic Toxicologists, Annual Meeting, San Antonio, TX October 2019 Society of Forensic Toxicologists, Annual Meeting, October 2018 Minneapolis, MN Society of Forensic Toxicologists, Annual Meeting, Boca Raton, FL January 2018 Society of Forensic Toxicologists, Annual Meeting, Dallas, TX October 2016 October 2015 Society of Forensic Toxicologists, Annual Meeting, Atlanta, GA Society of Forensic Toxicologists, Annual Meeting, October 2014 Grand Rapids, MI July 2012 Society of Forensic Toxicologists, Annual Meeting, Boston, MA Society of Forensic Toxicologists, Annual Meeting September 2011 San Francisco, CA Society of Forensic Toxicologists, Annual Meeting, Richmond, VA October 2010 Society of Forensic Toxicologists, Annual Meeting, October 2009 Oklahoma City, OK October 2008 Society of Forensic Toxicologists, Annual Meeting, Phoenix, AZ Society of Forensic Toxicologists, Annual Meeting, RTP, NC October 2007 Midwest Association for Toxicologists and Therapeutic Drug April 2007 Monitoring Annual Meeting, Indianapolis, IN Society of Forensic Toxicologists, Annual Meeting, Nashville, TN May 2006 Society of Forensic Toxicologists, Annual Meeting, May 2005 Washington, D.C. Society of Forensic Toxicologists, Annual Meeting, Portland, OR August 2004 Society of Forensic Toxicologists, Annual Meeting, Dearborn, MI October 2003

Dawn M. Hahn Curriculum Vitae Page 4 of 4

October 2002 Midwest Association for Toxicology & Therapeutic Drug Monitoring

Annual Meeting; Kansas City, MO

May 2000 National Laboratory Certification Program, NLCP Workshop

Research Triangle Park, NC

April 1999 Society of Forensic Toxicologists, Annual Meeting,

Salt Lake City, UT

	PUBLICATIONS AND PRESENTATIONS
2003	William Seiter, Russell Robinson, Tiffany Porter, Barbara Rowland, Dawn Hahn, Michael Lehrer, Lance Presley. Opiate Prevalence in Oral Fluid. Poster Presentation, SOFT, Oct. 2003 Annual Meeting; Portland, OR.
2003	Lance Presley, Michael Lehrer, William Seiter, Dawn Hahn, Barbara Rowland, Melissa Smith, Keith Kardos, Dean Fritch, Sal Salamone, R. Sam Niedbala, Edward Cone. <u>High Prevalence of 6-acetylmorphine in Morphine-Positive Oral Fluid Specimens</u> , Forensic Science International, 133: 22 – 25 (2003).
October 1997	Dawn M. Hahn, Alan E. Davis; <u>Semi-Automated Urine</u> <u>Extraction by a Hamilton 2200 Microlab Extraction Unit;</u> Society of Forensic Toxicologists, Oral Presentation, Annual Meeting; Salt Lake City, UT

References available upon request.

### **CURRICULUM VITAE**

NAME:

M. SHANE MORRIS

ADDRESS:

10101 Renner Blvd Lenexa, KS 66219

800-877-7484

**EDUCATION:** 

Bachelor of Science, Cellular Biology University of Kansas, Lawrence, KS 1997

**EXPERIENCE:** 

Jan 2015 to

Laboratory Manager

Present

Quest Diagnostics, Lenexa, KS

Responsible for daily operations of forensic urine, oral fluid and

hair drug testing laboratory.

Dec 2021 to

Responsible Person

Present

Quest Diagnostics, Lenexa, KS

Feb 2012 to Dec 2021

Alternate Responsible Person Quest Diagnostics, Lenexa, KS

Nov 2010 to Jan 2015

Non-Negative Certification Supervisor

Quest Diagnostics, Lenexa, KS

Responsibilities include evaluation of non-negative certifying scientists, coordination of area procedures and certifying data for

drugs of abuse.

Dec 2009 to Nov 2010 Non-Negative Certifying Scientist, Forensic Drug Testing

Quest Diagnostics, Lenexa, KS

Responsibilities as certifying scientist involve reviewing/certifying the screening, confirmation (GC/MS) and specimen validity data

for drugs of abuse

June 2008 to

**Technical Supervisor** 

Nov 2009 Oncimmune LLC, DeSoto, KS

Supervise laboratory, which includes scheduling, writing SOPs, performance reviews, staffing, insuring CLEA guidelines are followed, as well as resolving technical issues with ELISA assays.

Aug 2007 to June 2008

Research Scientist, Research & Development

Quest Diagnostics, Lenexa, KS

M. Shane Morris Curriculum Vitae Page 2 of 2

Non-Negative Certifying Scientist, Forensic Drug Testing June 2004 to LabOne, Inc./Quest Diagnostics, Lenexa, KS Aug 2007 GCMS Operator, Forensic Drug testing Laboratory April 2003 to Clinical Reference Lab, Lenexa, KS May 2004 **Laboratory Technologist** December 2001 to April 2003 LabOne, Inc., Lenexa, KS Lead Tech in Research and Development July 1997 to Osborn Laboratories, Olathe, KS Dec 2001

### TRAINING, CONTINUING EDUCATION AND CONFERENCE PARTICIPATION:

September 2020	S.O.F.T. Annual Meeting and Workshops,	Remote
October 2019	S.O.F.T. Annual Meeting and Workshops,	San Antonio, TX
October 2018	S.O.F.T. Annual Meeting and Workshops,	Minneapolis, MN
September 2018	SAPAA. Annual Conference,	Kansas City, MO
January 2018	S.O.F.T. Annual Meeting and Workshops,	Boca Raton, FL
October 2016	S.O.F.T. Annual Meeting and Workshops,	Dallas, TX
October 2015	S.O.F.T. Annual Meeting and Workshops,	Atlanta, GA
October 2014	S.O.F.T. Annual Meeting and Workshops,	Grand Rapid, MI
October 2013	S.O.F.T. Annual Meeting and Workshops,	Orlando, FL
July 2012	S.O.F.T. Annual Meeting and Workshops,	Boston, MA
October 2011	S.O.F.T. Annual Meeting and Workshops,	San Francisco, CA

### **CERTIFICATIONS/MEMBERSHIPS:**

- American Board of Forensic Toxicology (ABFT)
   Forensic Drug Toxicology Diplomate
- Member Society of Forensic Toxicologists (SOFT)
- Member Midwest Association for Toxicology and Therapeutic Drug Monitoring
- Inspector National Laboratory Certification Program (NLCP)
- State of Nevada Department of Health and Human Services Specialty Technologist Chemistry/Toxicology

Kenneth Reine Curriculum Vitae Page 1 of 2

### **CURRICULUM VITAE**

NAME:

Kenneth Reine

ADDRESS:

10101 Renner Blvd Lenexa, KS 66219 800-877-7484

EDUCATION:

Bachelor of Science – Microbiology-Aug 1990 Louisiana State University, Baton Rouge, LA

**EXPERIENCE:** 

Dec 2021 to

Laboratory Manager

Present

Quest Diagnostics, Lenexa, KS

Responsible for daily operations of forensic urine, oral fluid and

hair drug testing laboratory.

Sep 2019 to Present Alternate Responsible Person

Quest Diagnostics, Lenexa, KS

May 2015 to Dec 2021 Non-Negative Certification Supervisor

Quest Diagnostics, Inc., Lenexa, KS

Responsibilities include evaluation of non-negative certifying scientists, coordination of area procedures and certifying data for drugs of abuse.

Oct 2013 to May 2015 Non-Negative Certifying Scientist, Team Lead

Ouest Diagnostics, Inc., Lenexa, KS

Responsibilities as certifying scientist, lead involve reviewing and certifying the screening, confirmation, and specimen validity data for drugs of abuse; provide technical leadership, training and direct workflow in the certification area; consult with clients and physicians

regarding testing and results.

July 2011 to Oct 2013 Non-Negative Certifying Scientist Ouest Diagnostics, Inc., Lenexa, KS

Responsibilities as certifying scientist involve reviewing and certifying the screening, confirmation, and specimen validity data for drugs of abuse.

Kenneth Reine Curriculum Vitae Page 2 of 2

April 2010 to Jul 2011

GCMS Analyst, Team Lead Ouest Diagnostics, Inc., Lenexa, KS

Responsibilities include operating and maintaining GC/MS instruments, reviewing positive and negative federal/non-federal urine, blood, oral fluid, and hair samples.

Jul 2004 to Apr 2010

Clinical Reference Laboratory, Lenexa, KS **Confirmation Analyst Supervisor** 

Supervise toxicology confirmation department, which includes extraction and GC/MS. Daily functions involve scheduling, performance reviews, staffing, GC/MS validation, instrument maintenance as well as resolving technical issues within the department. (1.5 years)

Positive Certifying Scientist- perform duties of PCS & NCS as workflow dictated for regulated and non-regulated batches (1 year) GC/MS analyst - perform operation and maintenance of instrumentation, initial review of batches and bench level PCS duties for non-regulated batches only. (~3 years)

Extractions- perform extraction/derivatization of both regulated and non-regulated batches. (0.5 years)

July 1998 to July 2004

Dallas County Institute of Forensic Sciences, Dallas, TX **Drug Chemist II** 

Perform qualitative and quantitative analysis on suspected controlled substances, poisons, and other drugs of abuse providing court testimony as needed. Identify and quantify by Gas Chromatography/Mass Spectrometry, Infrared Spectrophotometry, Atomic Absorption Spectroscopy, Enzyme-Linked Immunosorbent Assay, Gas Chromatography, and Gas Chromatography/Mass Spectrometry.

Aug1990 to July 1998

Louisiana State Police Crime Laboratory, Baton Rouge, LA Forensic Scientist II

Perform qualitative and quantitative analysis on suspected controlled substances or dangerous drugs according to laboratory policies and procedures, providing court testimony as needed. Identify and quantify by Gas Chromatography/Mass Spectrometry, Fourier Transform Infrared Spectrophotometry, Ultraviolet Spectrophotometry, and Microcrystalline analysis.

### **CERTIFICATIONS/MEMBERSHIPS:**

State of Nevada Department of Health and Human Services Specialty Technologist-Chemistry/Toxicology

## EXHIBIT 3 Case No. 22-063-RPH-S Michael Burkintas, RPh.

### Dena M. McClish

From:

Di Maulo, Christopher < Christopher. Di Maulo @uhsinc.com>

Sent:

Thursday, March 17, 2022 11:36 AM

To:

Dena M. McClish

Cc:

Davila, Susan; Stolzman, Bonnie; Rayfield, Carol; Huntington, Matthew

Subject:

Desert View Investigation [Sent securely via TLS]

<u>WARNING</u> - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hi Dena.

Mr. Burkintas was terminated on March 3, 2022 as a result of the positive drug screen.

He did not provide any verbal or written statements regarding the drug screen since all pharmacy employees were drug tested in response to the drug diversion event.

Ms. Crain was not drug tested as she was suspended immediately once she confessed her actions regarding the drug diversion and she did not go back to the hospital after that point.

The previous pharmacist-in-charge (Elliott Asarch) voluntarily resigned from his position at Desert View Hospital for another employment opportunity.

The pharmacy department and other hospital employees did not notice any suspicious activities with Ms. Crain's transactions outside of the identified discrepancies that occurred between the movement of controlled substances between the Pyxis CII Safe and the patient care area Pyxis Med Stations.

### Sincerely,

Christopher Di Maulo, PharmD. | Assistant Director - Pharmacy Operations Acute | <a href="mailto:christopher.dimaulo@uhsinc.com">christopher.dimaulo@uhsinc.com</a> | Office (610) 382-3356 | Cell (201) 615-0462 | Universal Health Services, Inc. | UHS of Delaware, Inc. | 367 South Gulph Road, King of Prussia, PA 19406 | <a href="https://www.uhsinc.com">www.uhsinc.com</a>

From: Dena M. McClish < dmcclish@pharmacy.nv.gov >

Sent: Thursday, March 17, 2022 10:14 AM

To: Di Maulo, Christopher < Christopher. Di Maulo @uhsinc.com >

Subject: [External] RE: Desert View Investigation [Sent securely via TLS]

WARNING: This email is from an external source. DO NOT CLICK links or attachments unless you recognize the sender and know the content is safe. REPORT any suspicious emails by clicking the "REPORT SPAM" button in Outlook.

Thank you sir, this brings me to the next questions... Mr. Burkintas: 1) What date was he terminated? 2) Did he provide any verbal or written statements regarding the positive drug screen to anyone? 3) Were all pharmacy employees drug tested in response to the drug diversion event?—If so, did that include Ms. Crain and what was her result?

4) Was RPh Asarch's termination voluntary? 5) Outside of Ms. Crain's transactions, were there any other suspicious or discrepant transactions?

## EXHIBIT 4 Case No. 22-063-RPH-S Michael Burkintas, RPh.

### Dena M. McClish

From:

Dena M. McClish

Sent:

Wednesday, March 30, 2022 1:58 PM

To:

Michael Burkintas

Subject:

RE: NV Board of Pharmacy case no 22-063

Thank you Mr. Burkintas, as I'm sure you understand, we cannot take an allegation or suspicion of drug use lightly. Since you are stating that this was a false positive test, it would be quite beneficial for you to get additional testing to confirm that statement. To be clear, I am not requiring you to go get tested independently at this time, but I am strongly encouraging it as it would be beneficial for your case to show a negative test as soon as possible after the positive one.

In addition, I am asking that you notify me and/ or Mr. Wuest prior to returning to work in a pharmacy setting.

Dena M McClish, Investigator

Nevada State Board of Pharmacy 1140 N Town Center Dr Ste 300 Las Vegas, NV, 89144

Office: 702.486.6420 ext 154

Cell: 702.494.8672 Fax: 702.486.7903

E-mail: dmcclish@pharmacy.nv.gov

Web Page: www.bop.nv.gov



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This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

From: Michael Burkintas

Sent: Wednesday, March 30, 2022 12:28 PM

To: Dena M. McClish <dmcclish@pharmacy.nv.gov>
Subject: Re: NV Board of Pharmacy case no 22-063



Hello Dena,
These are the OTC meds and supplements that I take.
Loratadine/Pseudoephedrine
Chlorpheniramine
Phenylephrine
GHR (see attached)
T-Max (see attached)
ThermoRip (see attached)
I hope that this is helpful
Thank You,
Mike Burkintas

----Original Message----

From: Dena M. McClish <a href="mailto:dmcclish@pharmacy.nv.gov">dmcclish@pharmacy.nv.gov</a>>

To:

Sent: Thu, Mar 24, 2022 11:55 am

Subject: NV Board of Pharmacy case no 22-063

Good afternoon Mr. Burkintas,

As you know we have received information surrounding the circumstances of your termination from DVH and I'd like to get some information from you as well. Please give me a call at your earliest convenience or at least respond to this email. Please let me know your side of the story and anything you feel we may need to know to assist us in making a determination in this case to include any intentions of rehabilitation or other treatment.

Thank you,

Dena M McClish, Investigator

Nevada State Board of Pharmacy 1140 N Town Center Dr Ste 300 Las Vegas, NV, 89144

Office: 702.486.6420 ext 154

Cell: 702.494.8672 Fax: 702.486.7903

E-mail: dmcclish@pharmacy.nv.gov

Web Page: www.bop.nv.gov



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This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

## PipingRock GHR Complex

- GHR Complex (1,480 mg)
- Gluten-Free & Non-GMO
- Quick-Release Capsules

As a leader in Sports Nutrition, PipingRock has crafted the ultimate GHR Complex for wide-ranging nutritional support. This cutting-edge formula features a 1,480 mg GHR Complex, with a 610 mg L-Arginine Base and other key amino acids in convenient quick-release capsules. It's gluten-free and non-GMO with no preservatives, norwiding hald convent to halo you converse.

# Supplement Facts

Serving Size: 2 Quick Release Capsules

Servings Per Container: 90

	Amount Per Serving	% Daily Value (DV)
Vitamin C (as Ascorbic Acid)	100 mg	111%
Vitamin B-6 (as Pyridoxine HCI)	15 mg	882%
GHR Complex	1,480 тд	*
L-Arginine Base	610 mg	*
L-Ornithine Alpha-Ketoglutarate (OKG)	340 mg	*
L-Omithine HCI	220 mg	*
Glycine	220 mg	*
L-Lysine HCI	90 mg	*



Our Testestorone Support Formula is specially designed for men! Our quick-release capsules include time-tested ingredients like Horny Goat Weed and Maca that have been used by men for centuries. So grab a bottle today!

## **Supplement Facts**

Serving Size: 2 Vegetarian Capsules

Servings Per Container: 45

	Amount % Daily Per Value Serving (DV)	% Daily Value (DV)
Maca (Lepidium meyenii) (root) (from 150 mg of 4:1 extract)	600 mg	*
fribulus Extract (Tribulus terrestris) (fruit) (Standardized o contain 45% saponins)	100 mg	<b>*</b> ¢
Horny Goat Weed Extract (Epimedium sagittatum) aerial) (Standardized to contain 10% icariins)	500 mg	*
ohimbe Extract (Pausinystalia yohimbe) (bark) Standardized to contain 2% Yohimbine Alkaloids)	40 mg	*
-Arginine HCI	40 mg	*

## What are Thermogenics?

The word "thermogenics" means heat producing.

Thermogenics are ingredients designed to support a healthy metabolism alongside diet and exercise.\*\* There are many standalone thermogenic ingredients that are used for support. However, the best formulas have multiple ingredients from various sources. Our ThermoRip Fat Burner is just that!

# Get Optimal Fuel with Thermo Rip!

### (<u>P</u>) Value Amount % Daily Serving 1,185 ξE Green Tea Extract (Camellia sinensis) (leaf) (Standardized L-Tyrosine (Free Form), Caffeine (Pharmaceutical Grade) heating units), Black Pepper Extract (Piper nigrum) (fruit) (270 mg), Apple Cider Vinegar, Acetyl L-Carnitine HCl, to 95% Polyphenols, 75% Catechins, and 45% EGCG), Cayenne Pepper (Capsicum annuum) (fruit) (40,000 Supplement Facts (Standardized to contain 95% Piperine) Servings Per Container: 60 Serving Size: 2 Capsules Thermo Rip® Complex

## EXHIBIT 5 Case No. 22-063-RPH-S Michael Burkintas, RPh.

### Michael Burkintas

DOB: Sex: M | Report Prepared: 04/20/2022

Date Range: 04/20/2017 - 04/20/2022

### Demographics

### Linked Records

Name DOB ID Gender Address
Michael Burkintas 1 M MONEY ST PAHRUMP NV 89048

### Search Criteria

First Name Last Name DOB
Michael Burkintas

### Risk Indicators

NARXCARE SCORES

OVERDOSE RISK SCORE

ADDITIONAL RISK INDICATORS (0)

Narcotic

000

000

Sedative 000

(Range 000-999)

Stimulant 000

This Narx Care report is based on search criteria supplied and the data entered by the dispensing pharmacy. For more information about any prescription, please contact the dispensing pharmacy or the prescriber. Narx Care scores and reports are intended to aid, not replace, medical decision making. None of the information presented should be used as sole justification for providing or refusing to provide medications. The information on this report is not warranted as accurate or complete.

\*Per CDC guidance, the MME conversion factors prescribed or provided as part of the medication-assisted treatment for opioid use disorder should not be used to benchmark against dosage thresholds meant for opioids prescribed for pain. Buprenorphine products have no agreed upon morphine equivalency, and as partial opioid agonists, are not expected to be associated with overdose risk in the same dose-dependent manner as doses for full agonist opioids. MME = morphine milligram equivalents. LME = Lorazepam milligram equivalents. MG = dose in milligrams:

### Summary.

Sedatives Buprenorphine Narcotics\* (excluding buprenorphine) Summary Current Qty: 0 Current Qty: n Total Prescriptions: Current Qty: 0 Current mg/day: 0.00 Current mg/day: 0.00 Current MME/day: 0.00 **Total Prescribers:** 30 Day Avg mg/day: 0.00 30 Day Avg mg/day: 0.00 30 Day Avg MME/day: 0.00 Total Pharmacies:

FIII Date	ID	Written	Sold	Drug	Qty	Days	Prescriber	Rx#	Pharmacy	Refill	Daily Dose *	Pymt Type	PMP
01/06/18	1	01/06/18	01/06/18	Testosterone Cypionate Powder	2.00	60	Da Rod	2450901	Dru (7765)	0/0		Private Pay	NV
11/07/17	1	11/06/17	11/07/17	Testosterone Cyp Micro Powder	2,00	60	Da Rod	2368874	Dru (7785)	0/0		Private Pay	NV
11/07/17	1	11/06/17	11/07/17	Chononic Gonad 5 Million Unit	0.00	60	Da Rod	2368866	Dru (7765)	0/0		Private Pay	NV
09/06/17	1	09/06/17	09/06/17	Testosterone Cyp Micro Powder	2.00	60	Da Rod	2280521	Dru (7765)	0/0		Private Pay	NV
09/06/17	1	09/06/17	09/06/17	Chorionic Gonad 5 Million Unit	0.00	60	Da Rod	2280514	Dru (7765)	0/0		Private Pay	NV
07/06/17	1	07/06/17	07/06/17	Testosterone Cyp Micro Powder	2.00	60	Da Rod	2192526	Dru (7765)	0/0		Private Pay	NV
07/06/17	1	07/06/17	07/06/17	Chorionic Gonad 5 Million Unit	0.00	60	Da Rod	2192521	Dru (7765)	0/0		Private Pay	NV
05/08/17	1	05/08/17	05/08/17	Testosterone Cyp Micro Powder	2,00	60	Da Rod	2112134	Dru (7765)	0/0		Private Pay	NV
05/08/17	1	05/08/17	05/08/17	Chorionic Gonad 5 Million Unit	0.00	60	Da Rod	2112117	Dru (7765)	0/0		Private Páy	NV

1.0		100	THE PARTY
Pr	-	~	**
	IIVI		

Name	Address	City	State	Zipcode	Phone
Dagoberto J Rodriguez, Md 🧸	5640 W Atlantic Blvd	Margate	FL	33063	(954) 708-2976

Pharmacies					
Name	Address	City	State	Zipcode	Phone
Drug Depot, Inc (7765)	34911 Us Highway 19 N Ste 600	Palm Harbor	FL	34684	(888) 547-2654

### Disclaimer

Report contents are based on data entered by dispensers and their staff, and may contain errors. The Board of Pharmacy recommends independent verification with dispensers when prudent or necessary. Willful disclosure of prescription information may be subject to disciplinary action, civil penalties or criminal action.

**NVBOP - 142** 

## EXHIBIT 6 Case No. 22-063-RPH-S Michael Burkintas, RPh.

### AGREEMENT NOT TO PRACTICE PHARMACY UNTIL NEXT SCHEDULED HEARING IN CASE NO. 22-063

- 1. My name is Michael Burkintas, RPH, and I am a licensed pharmacist in the State of Nevada. My Nevada pharmacist's certificate of registration number is 15419.
- The Nevada State Board of Pharmacy ("Board") has investigated and filed a Notice of Intended Action and Accusation ("Accusation") on or about April 25, 2022. The allegations included a positive amphetamine test result which led to my termination at Desert View Hospital Alliance.
- 3. By signing below, I agree that:
  - a. I will not practice as a pharmacist, or in any capacity, at a place of employment licensed or registered by the Board, where there is access to dangerous drugs and/or controlled substances, during the continuation of the Board hearing of the Accusation in case no. 22-063.
  - b. I understand that violation of this written agreement constitutes my consent in having my pharmacist registration number 15419 summarily suspended.

Dated this 13 day of JULy, 2022.

MICHAEL BURKINTAS, RPH

## EXHIBIT 7 Case No. 22-063-RPH-S Michael Burkintas, RPh.

**Attorney Timesheet for Peter Keegan and Courtney Lee** 

MICHAEL BURKINTAS, RPH. - CASE NO. 22-063-RPH-S

DATE TIME

April 21, 2022 1.6

Courtney Lee - reviewed investigative file with Executive Secretary David Wuest and Deputy Executive Secretary Yenh Long; legal research; discuss investigation with Board staff including Investigator Dena McClish, determined to proceed with drafting accusation.

April 22, 2022 1.1

Courtney Lee – Draft Accusation and submit for review and Executive Secretary signature.

July 13, 2022 0.9

Courtney Lee – Communications with Michael Burkintas, draft Agreement Not to Practice Pharmacy, send to Burkintas for signature.

August 5, 2022 1.1

Courtney Lee – Receive and review Notice of Representation from Kevin Murphy, Esq. as well as Answer of Notice of Defense filed on behalf of Burkintas. Communications confirming continuance of September hearing.

September 23, 2022 0.3

Courtney Lee – Receive and review Initial Discovery Production

December 6, 2022 0.2

Courtney Lee – Receive and review Supplemental Discovery Production

December 20, 2022 0.8

Courtney Lee – Draft stipulation after discussions with Board Executive Staff, submit to Kevin Murphy for review.

December 22, 2022 0.5

Courtney Lee – Receive and review Quest Toxicity Litigation Packet regarding drug screening for Michael Burkintas

December 28, 2022 0.5

Peter Keegan – Assume responsibility for case from Courtney Lee. Email correspondence with Kevin Murphy and discussion with Board's Executive staff concerning case status.

December 29-30, 2022 0.6

Peter Keegan – review email correspondence from Kevin Murphy requesting another continuance, discuss with Board Executive staff, prepare stipulation to continue and email to Kevin Murphy.

January 16-18, 2023 0.3

Peter Keegan – Emails with Kevin Murphy regarding rescheduling of continued case based upon Board changing March meeting date. Resolve and agree.8 to reschedule hearing for June 14, 2023.

March 1, 2023 0.3

Peter Keegan – Receive and review 2nd supplemental discovery production

May 19, 2023 0.3

Peter Keegan – Receive and review 3rd supplemental discovery production

May 23, 2023 1.6

Peter Keegan – Review Accusation, investigation, and emails with Kevin Murphy in preparation for June 14, 2023 hearing.

May 24, 2023 0.5

Peter Keegan – Telephone conference with Kevin Murphy regarding upcoming June 14, 2023, hearing and status of settlement negotiations. Discuss exhibit preparation and exchange.

May 26, 2023 1.8

Peter Keegan – Prepare exhibits, timesheets. Emails with Investigator Dena McClish regarding preparations.

June 7, 2023 0.5

Peter Keegan – Zoom conference with Investigator Dena McClish in preparation for June 14, 2023, hearing.

June 13, 2023 1.0

Peter Keegan - Prepare to prosecute Case No. 22-063-RPH-S before Nevada Board of Pharmacy.

June 14, 2023 1.5

Peter Keegan - Prosecute Case No. 22-063-RPH-S before Nevada Board of Pharmacy.

**TOTAL 15.4 hours x \$59.97/hour = \$923.54** 

### Investigation hours

### Case No 22-063 RPh Burkintas **Investigator Dena McClish**

Date	Duties	Hours
3/16/2022	Init case review, phone, email	1
3/24/2022	Recvd info from hospital, internal discuss	1.5
3/29/2022	PMP review, phone interview, emails	1.25
4/21/2022	ROI, case review in South	2

Total 5.75 Hourly wage 46.41 Total billing 266.8575

### Timesheet for Kristopher Mangosing -

### Michael Burkintas Case No.22-063-RPH-S

DATE TIME

5/3/2022 0.25

Prepared 21 day notice for mailing.

8/9/2022 0.25

Prepared 21 day notice for mailing.

8/30/2022 0.5

Prepared discovery request

9/27/2022 0.25

Prepared 21 day notice for mailing.

12/13/2022 0.25

Prepared 21 day notice for mailing

1/13/2023 0.25

Sent Stipulation and Order continuing hearing by certified mail

5/12/2023 0.25

Prepared 21 day notice for mailing.

5/23/2023 0.25

Prepared documents for Board Book

**TOTAL POSTAGE \$8.10 X 5 = 40.50** 

TOTAL 2.25 hours x \$34.86/hour = \$78.44

**TOTAL \$118.94** 

### Timesheet for Darlene Nases -

### MICHAEL BURKINTAS - CASE NO. 22-063-S

DATE TIME

4/25/2022 0.50 Certified and mailed out NIAA

Certified Mailing Cost: \$9.86

• TOTAL .50 hours x \$34.86/hour = \$17.43

• Total Expenses for Certified Mailings: \$9.86

### **TOTAL TIME & COST SUMMARY**

### Case No. 21-063-CS-S- Dr. Wesley Robertson

Total	\$1,336.63
Certified Mailing Postage	\$9.86
Board Coordinator Darlene Nases – 0.5 hours @34.86/hr =	\$17.43
Certified Mailing Postage	\$40.50
Board Coordinator Kristopher Mangosing – 2.25 @34.86/hr =	\$78.44
Investigator Dena McClish – 5.75 hours @\$46.41/hr	\$266.86
Attorney Peter Keegan – 12.5 hours @\$59.97/hr =	\$923.54

### IN THE MATTER OF:

### MICHAEL BURKINTAS, RPh.

CASE NO.: 22-063-RPH-S

HEARING DATE: JUNE 14, 2023

**KEVIN C. MURPHY** Attorney for Respondent



### IN THE MATTER OF MICHAEL BURKINTAS CERTIFICATE OF REGISTRATION NO.: 15419

### BEFORE THE NEVADA STATE BOARD OF PHARMACY

CASE No.: 22-063-RPH-S

HEARING DATE: JUNE 14, 2023

Title	Page	Document	I.D.	REC'D
Ex. A.	RESP	"Mr. Burkintas' Resume."	X	X
	0001-0002			
Ex. B.	RESP	"Character References."	X	X
	0003-0012			
Ex. C.	RESP	"May 7, 2022, Negative Drug Screen Result."	X	X
	0013			
Ex. D.	RESP	"Employment Evaluations."	X	X
	0014-0016			
Ex. E.	RESP	"Letters of Professional Recommendation."	X	X
	0017-0022			
Ex. F.	RESP	"Mr. Burkintas' Medications and Supplements."	X	X
	0023-0027			

### Michael Burkintas

Pharmacist Pahrump, NV 89048 hayata@verizon.net 775-537-0931

I have been a pharmacist in retail settings for 28 years and hospital setting for 6 and ½ years. I have active registrations in Nevada and Pennsylvania.

### Work Experience

Staff Pharmacist

Desert View Hospital / Universal Health Services Inc. - Pahrump, NV October 2015 to 03-07-2022

performs clinical and professional pharmaceutical work in the compounding and dispensing of drugs and sterile IV supplies. Monitor drug therapy and provide clinical dosage adjustment as required. Interview patients and family to

determine home medication usage and possible interaction with treatment.

ACLS Certified

**BLS** Certified

### Staff Pharmacist

CVS/pharmacy – various locations in Pennsylvania; Las Vegas, Elko and Pahrump, NV April 2002 to May 2014

Responsibilities

Fill and verify prescriptions, council patients, resolve insurance issues, manage workflow, ensure State, Federal and DE Acontrol drug regulations are followed, control inventory. Administer immunizations.

Skills Used

Immunization certified, CPR certified.

### Manager

Public Drug Stores - Beaver, PA October 1991 to April 2002

Council patients, fill prescriptions, control inventory, order schedule 2 controlled substances and schedule employees.

### Assistant Manager

Olson's Pharmacy - Beaver Falls, PA May 1989 to October 1991

### Intern and Pharmacist

C. G. Huy Pharmacy - Pittsburgh, PA September 1983 to August 1990

### Assistant Manager

Thrift Drug - Butler, PA
August 1988 to May 1989
Intern, Graduate Intern and Pharmacist

### Education

BS in Pharmacy University of Pittsburgh, School of Pharmacy - Pittsburgh, PA September 1983 to May 1988 Milton Hershey School - Hershey, PA. June 1983

### Skills

Management experience, Inventory Control, CPR certified, ACLS Certified, Immunization Certified.

### Certifications/Licenses

Registered Pharmacist - Nevada State Board of Pharmacy Registered Pharmacist - Pennsylvania State Board of Pharmacy CPR/BLS ACLS Immunization Certification

### Additional Information

I am a Shriner clown and do what I can to support the Shriners Hospital for Children.

1.	Name:	
d	D	ONALD FORSE
	Date:	
	<i></i>	94 10,2023
2.	In wha	t capacity do you know Mr. Burkintas?
	(a)	Personal
	(b)	Professional
3.	How lo	ong have you known Mr. Burkintas?
	a. 4	vears/months
4.		the personal qualities which you have known Mr. Burkintas to possess. (If possible, see one or two supportive examples).
		Honestv I have never observed Michael cheating or telling a lie.
	b.	Trustworthiness
		-Micheal was my pharmacist for several years and relied on his guidance.
	c.	Responsibility We traveled many times together. You could depend on Mike to be present and on time!
	d.	Morality
		Michael has always had a high standard of morals. It's his way of life
	e.	Ethicality
		I am not aware of anything Michael has done that was not ethical.
	f.	Other

5.	State your assessment of Mr. Burkintas's relationship with family, friends, business associates, and the community at large, with particular examples if possible. (Example: On numerous occasions, John Doe has put himself before others. He is selfless and whenever someone needs anything, he is there).					
	When My wife and I visited Las Vegas, Mike always altered his schedule to join us.  Also, I know he has done this for several others. He is always willing,  to help!					
6.	Are you personally aware of any hardships that Mr. Burkintas is/has undergone which you think contributed to this offense, please list them below:					
	Yes					
	If yes, please describe below.					
7.	Are you planning on employing Mr. Burkintas in the future?					
	Yes					
8.	Are you planning on working with Mr. Burkintas in the future?					
	Yes					
9.	State your assessment of Mr. Burkintas's past contribution to the community, and pharmaceutical					
	profession, with particular examples in the space provided. (Examples: Community Service, Volunteer Work, Church Attendance, School Activities, Sports, etc. ie. Jane Doe has been a					
	volunteer Sunday school instructor for our young adults at our church for several years. Or John					
	Doe has volunteered at the local Salvation Army helping to provide meals to indigent/homeless persons for the last five years.)					
	Michael devotes a fair portion of his time helping others via the Shriner's charities.					

### 10. Please rate Mr. Burkintas in terms of the following qualities:

Please note: If the choice does not apply to your relationship with Mr. Burkintas, choose "Not Applicable."

	Outstanding	Excellent	Good	Average	Poor	Not Applicable
Ability to work well with others						X
Tenacity; perseverance toward goals						X
Ability to meet deadling	es					
Maturity and judgment	X					
Accountabili accepts responsibility own actions	X,					
Clear verbal and written communicati	ion					
Ability to we without supe vision						X
Overall ratin	ag 📈					

Please add anything additional that you feel the BOP should know about Mr. Burkintas.
I BELIEVE THAT MICHAEL WOULD BE A GREAT ASSET TO ANY TEAM. ALTHOUGH HE IS BEST TRAINED TO BE A PHARMACIST, HE WOULD SUCCEED IN ALMOST ANY FIELD. HE POSSESSES A HIGHLY DESIRABLE BLEND OF TRAINING, INTELLIGENCE, PERSONALITY, DEPENDABILITY AND MORAL STANDARDS!
Do you declare under penalty of perjury of the laws of the State of Nevada, and the United States  Constitution, that the foregoing is true and correct to the best of your knowledge?  Yes  No
Signature: Signature:
Signature: Donald Roas

1.	Name:
	Beverly J. Gray
	Date:
	august 27, 2022
2.	In what capacity do you know Mr. Burkintas?
	(a.) Personal
	b. Professional
3.	How long have you known Mr. Burkintas?
	a. 12 years months
1.	Circle the personal qualities which you have known Mr. Burkintas to possess. (If possible, describe one or two supportive examples).
	a) Honesty
	Mike is the most honest person I know
	(b) Trustworthiness
	I would trust him with my life.
	(c) Responsibility
	Mike is very responible person.
	d Morality
	Ethicality
	(f) Other
	animals rescue. He is a mason a Shriner He plays a clown for the Shriners for all the parades.
	animal rescue. He is a mason & a Shriner He plays
	a clown for the Shriners for all the parades.

5.	State your assessment of Mr. Burkintas's relationship with family, friends, business associates,
	and the community at large, with particular examples if possible. (Example: On numerous
	occasions, John Doe has put himself before others. He is selfless and whenever someone needs
	anything, he is there).
	mike is a very selfless person whenever or
	when I husband was alive to was always there to
	help us physically on financially.
	surp we proporting
_	
6.	
	contributed to this offense, please list them below:
	□ Yes
	If yes, please describe below.
	if yes, please describe below.
14.	Are you planning on employing Mr. Burkintas in the future?
	□ Yes
,	
8. 8.	Are you planning on working with Mr. Burkintas in the future?
0.	☐ Yes
	☑ No
g	State your assessment of Mr. Burkintas's past contribution to the community, and pharmaceutical
٠.	profession, with particular examples in the space provided. (Examples: Community Service,
	Volunteer Work, Church Attendance, School Activities, Sports, etc. ie. Jane Doe has been a
	volunteer Sunday school instructor for our young adults at our church for several years. Or John
	Doe has volunteered at the local Salvation Army helping to provide meals to indigent/homeless
	persons for the last five years.)
	He is a mason of also a Shriner, He plays a Clown
	in the different parades, he sells one on polatous for
	the Shriners He is a given not only to his friends but
	Alle March To March Barrer of aller

## 10. Please rate Mr. Burkintas in terms of the following qualities:

Please note: If the choice does not apply to your relationship with Mr. Burkintas, choose "Not Applicable."

	Outstanding	Excellent	Good	Average	Poor	Not Applicable
Ability to work well with others	V	С		С	o	5
Tenacity; perseverance toward goals	0/	a	O	Э	a	
Ability to meet deadlines		С	Ü	J	٥	٥
Maturity and judgment	6/	ā		Ľ	٦	3
Accountability accepts responsibility f own actions	/	С	Ü	С	ב	9
Clear verbal and written communication	n t	a	۵	٥	۵	ם
Ability to work without supervision	/	ם	0	С	С	С
Overall rating	iz	۵	С	٥	D	ū

Please add anything additional tha	t you feel the BOP should know about Mr. Burkintas.
Do you declare under penalty of p	perjury of the laws of the State of Nevada, and the United States
Constitution, that the foregoing is	true and correct to the best of your knowledge?
If I es	□ No
	Signature: Benefit & Hand
	Signature: Buesly J. Gray
Are you willing to testify regardir	ng the above opinions and information?
✓Yes	□ No
	Signature: Beverly J. Gray

## 08/21/2022

I met Michael Burkintas 5 years ago through a mutual friend while visiting Las Vegas from Arizona. When I decided to move to Pahrump, Nevada, I reached out to him, and he offered to show me around the area. The last day of my move, I had to return a rental truck to the local dealer but did not have a ride back to my new home. At that time taxi service in Pahrump was nearly non existent. So, I called Mike. He generously offered to pick me up and take me home. Since then he has let me borrow tools, hang shelves and move items around my home.

In February of this year, I accidentally took too much blood pressure medication. I immediately called Mike. He calmed me down. He told me that what I took was not an excessive dose and to take my blood pressure every 15 minutes and to call him back if it starts to drop. He called me about an hour later to see how I was.

I am glad to continue to be friends.

I declare under penalty of perjury of the laws of the State of Nevada and the United States Constitution that the foregoing is true and correct to the best of my knowledge. I am willing to testify regarding the above opinions and information.

9-1-22

William Tilghman

I have lived with Michael Burkintas for 32 years. I have been disabled for over 22 years. Michael has supported me physically and emotionally throughout our many years together.

Michael is a Shriner and does what he can to help support the Shriners Hospital for Children. He has participated with the Pahrump Mason Lodge in their effort to provide children's identification, and giving tablet computers to local schools to promote reading. When he was working, he donated to Tails of Nye County, a group that spays and neuters feral cats.

Michael has never abused controlled substances. Even now, when his body is failing from arthritis and degenerating knees and ankles, He avoids taking anything but ibuprofen.

I declare under penalty of perjury of the laws of the State of Nevada and the United States Constitution that the foregoing is true and correct to the best of my knowledge. I am willing to testify regarding the above opinions and information.

Cother Harasida 8-15-2022

Exhibit C. "May 7, 2022, Negative Drug Screen Result."



## **Test Results**

Date Results Transmitted: 2022-05-07 12:49 PM

Transmitted By: JAJ

Participant/Donor: Michael Burkintas

SSN/EID: \*\*4768

**CCF/Specimen ID:** 0234113751

Specimen Type: URINE

Company: NATIONAL DRUG SCREENING Location: NATIONAL DRUG SCREENING

Lab Account Number: 379856

Reason for Test: OTHER

Date Specimen Collected: 2022-05-05

Laboratory: LabCorp

Collection Site: LABCORP - PAHRUMP, NV (E

Collection Site Phone: 7757519229

Program: NONDOT

Date MRO Received CCF Copy 2:

Date Test Verified by MRO: 2022-05-07

## **Test Results**

Panel - 5 PANEL LOOK ALIKI	E - 789888 - 379856 8534380008	
Drug	Results	
Amphetamines	NEGATIVE	
Cocaine	NEGATIVE	
Marijuana	NEGATIVE	
Opiates	NEGATIVE	
Phencyclidine (PCP)	NEGATIVE	

## MY DETERMINATION/VERIFICATION IS: NEGATIVE

Certified	Medical	Review	Officer
-----------	---------	--------	---------

Janelle Jaworski M.D.

ignature

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Maunslims

9501 NORTHFIELD BLVD, DENVER, CO 80238 | Phone: 877-585-7366 | Fax: 855-253-5666

mroresultsonline.com

## **EMPLOYEE INFORMATION**

Employee: Michael Burkintas

Institution Name: 006-Acute Desert View Hospital

Job Title: 520- PHARMACIST

Manager: May, Robert

Department: 006:8290-Pharmacy

## **ASSESSMENT SUMMARY**

Assessment Status: Review

**Assessor: Robert May** 

Assigned Effective Date: 07/04/2020

Due Date: 08/30/2020

Overall Rating: 3 - Meets

Overall Score: 2.875

## **ASSESSMENT DETAIL**

Service Excellence/Great

3 - Meets Expectations

Behavioral Criteria:

Rater: May, Robert

Rated Date: 07/29/2020

Comment:

Michael greets staff and co-workers when they address him first. He is able to communicate verbally when asked specific

questions.

## Desert View Hospital Employee | 2018 Performance Review

**Employee Name: MICHAEL BURKINTAS** 

**Department: PHARMACY** 

Position: PHARMACIST-FULL TIME

Supervisor Name: HELEN LOSASSO

Employee's focus on Service Excellence and Great:

Micheal is our full time pharmacist. He staffs six- 12 hour shifts per pay period. He assumed the full time position fall 2017. He is well spoken of. Michael interacts with patients and medical staff.

Employee's accomplishments during past year:

He is developing stronger clinical skills. Micheal supervises technicians, maintains appropriate inventory. He interviews patients and completes med-rec interviews in a timely manner.

**Maintains BLS** 

As he has moved from per-diem to full time position has has taken much responsibility for appropriate inventory and day-to-day operations

## Goal(s) for coming year:

- Participate in Antimicrobial Stewardship, complete three ASP patient reviews per month
- Maintain order review turn around time to less than 5 minutes per order 90% of time
- · Identify and report at lease two suspected adverse drug event per month
- Increase intervention documentation
- . Complete CAI proficiency and hazardous drug handling proficiency. (Physical CAI aseptic technique is completed, didactic needs to be completed still
- Obtain ACLS certification

### Areas for Improvement:

Become more familiar and comfortable with operations of the pharmacy department Continue to expand clinical skills

## **Supervisor's Comments:**

Michael is a stable member of out team. He is very quiet, and possibly underestimated. In addition to the hospital, Michael is an active member of the Pahrump community. Since starting at DVH, Michal has made the difficult transition from retail pharmacy to hospital His clinical skills have developed, and my goal would be for those skills to pharmacy. increase

## Desert View 2016 Hospital Employee Performance Review

Employee Name: Mike Bukintas

Department: Pharmacy

Position: Pharmacist

Supervisor Name: Helen Losasso

## Employee's strengths:

- Careful
- Knowledgeable
- Reliable

Employee's accomplishments during past year:

Mike is transitioning from community pharmacy to hospital pharmacy. He has become competent with Healthland.

He is becoming comfortable dosing vancomycin

He has also established an organization method for filing patient orders that makes it much easier to locate a specific order if the need arises

## Goal(s) for coming year:

- Professional Develop and implement one Pharmacy process that improves patient outcomes or increases satisfaction of pharmacy customers
- Personal Continue personal development with The Shrine Clowns and make a film

Supervisory support requested / needed to achieve goal(s):

• I will work with Mike as he develops/ implements his pharmacy process.

Supervisor's Comments: meets expectation

I am glad Mike has joined our department. I appreciate the challenge of transitioning from community to hospital practice. I am grateful for his flexibility in scheduling.

I expect Mike to continue to grow and be a great assess to the organization

**Exhibit E. "Letters of Professional Recommendation."** 

## To Whom it may concern:

I am writing this letter to give a little professional in site into one Mr. Michael Burkintas. The purpose of this letter is to let you know my firsthand accounts on his professionalism

I have seen and experienced. I started working at Desert View Hospital in the emergency room in November 2019.as an emergency room technician. Michael Burkintas was a licensed pharmacy at Desert View Hospital, I got know him through his work there. He always seemed very knowledgeable about medications, effects, side effects and proper dosages. During codes different members of the interdisciplinary teams are called pharmacy, X-ray, respiratory and other register nurses from the floor to help assist in the code. On many different occasions he was involved in the codes, from mixing IV medications, dose medications on the fly as needed per doctor request. He was very proficient and professional, at no point did he ever seem altered, distant or under the influence. He always seems to ask the right question prior to dose medication mixing -ex: allergies, patients' weight and so on.

Outside of emergency situations he was always professional, polite, and kind to all co-workers. He dressed professional with a button up shirt, tie, and slacks.

In the community outside the hospital setting, he is pilar of the county being a head Mason and member of the Shriner Club.

I understand the importance of these allegations. I also understand this was a lifetime of schooling, training, and experience for him, this is his livelihood. I hope this letter shines a little light on the professionalism of Michael Bukintas, so that this can be cleared up and be reinstated and more on.

Sincerely

Jon Adams

BSN, EMT-P

	JON ADAMS	
	Date:	
	08/30/2022	
2.	In what capacity do you know Mr. Burkintas?	
	a. Personal	
	b. Professional	
3.	How long have you known Mr. Burkintas?  a.248 0m years/months	
4.	Circle the personal qualities which you have known Mr. Burkintas to possess. (If possible, describe one or two supportive examples).	
	T BELIEVE MICHAEL ON A DAILY	
	(b) Trustworthiness BASES SHOWED ALL OF THESE	
	QUALITIES, I NEVER SAW HIM  (c.) Responsibility SHOW ANYTHING BUT THESE QUALITIES  DAILY PROFESSIONAL WORK	ス
	d. Morality	
	©. Ethicality	
	(f.) Other	
	FRIGNDLY, KIND & KNOWLEDABLE	

1. Name:

5.	State your assessment of Mr. Burkintas's relationship with family, friends, business associates,
	and the community at large, with particular examples if possible. (Example: On numerous
	occasions, John Doe has put himself before others. He is selfless and whenever someone needs
	anything, he is there).
	I KNOW HE TOOK TIME AWAY FROM HIS COMMUNIT
	TIME & FAMILY WHEN WAS ASKED & SCHOOVLE
	OVERTIME WORK 5-6 DAYS AWEEK THIS TOOV
	AWAY FROM HIS PREE MASION & SHRINER CLUB
	WORK
6.	Are you personally aware of any hardships that Mr. Burkintas is/has undergone which you think
	contributed to this offense, please list them below:
	V.
	Yes
	If yes, please describe below.
	OTHER MOT BEING EMPLOYEED AND NOT
	HAVWE A PAT CHECK COMING IN I KNOW
	HE HAD TO DIP INTO HIS SAVINGS TO
	DE ABLE TO PAY THE BILLS
7.	Are you planning on employing Mr. Burkintas in the future?
٠.	
	Yes
0	Annual to the state of the Posting in the County
δ.	Are you planning on working with Mr. Burkintas in the future? Yes
	No
9	State your assessment of Mr. Burkintas's past contribution to the community, and pharmaceutical
٠.	profession, with particular examples in the space provided. (Examples: Community Service,
	Volunteer Work, Church Attendance, School Activities, Sports, etc. ie. Jane Doe has been a
	volunteer Sunday school instructor for our young adults at our church for several years. Or John
	Doe has volunteered at the local Salvation Army helping to provide meals to indigent/homeless
	Persons for the last five years.)  I KNOW HE STATED HE IS A FLEE MASION
	SHIRNERS CLUB

## 10. Please rate Mr. Burkintas in terms of the following qualities:

Overall rating

OVISTANDING

Please note: If the choice does not apply to your relationship with Mr. Burkintas, choose "Not Applicable."

	Outstanding	Excellent	Good	Average	Poor	Not Applicable
Ability to work well with others						
Tenacity; perseverance toward goals	<b>✓</b>					
Ability to meet deadline	s					
Maturity and judgment	<b>/</b>					
Accountability accepts responsibility own actions						
Clear verbal and written communicatio	n					
Ability to wor without super-vision	/					

Please add anything additional that you feel the BOP should know about Mr. Burkintas.

PLEASE SEE ATTACHE	D LETTER/
Do you declare under penalty of perjury of the la Constitution, that the foregoing is true and correct Yes	tws of the State of Nevada, and the United States ct to the best of your knowledge?  No
	Signature:
Are you willing to testify regarding the above option Yes	inions and information?

**Dotty Edwards** 

2004 N Fairway Drive

St. George, UT.84780

To whom it may concern:

I met Michael Burkintas in 2014 while working at a CVS Pharmacy in Pahrump Nevada. In 2015 he joined our Pharmacy team at Desert View Hospital. It was here I worked closely with him as his pharmacy technician. He was great to work with and always paid close attention to the safety of our patients by watching his physician orders as well as verifying patient home meds for the nurses.

Michael was very aware of the rules and regulations that are necessary to keep in compliance with the state and federal boards. While he had to address a lot of protocol with doctors and nurse he was very professional and enjoyed being part of this important team.

He was a very competent pharmacist overseeing my compounding and filling of medicine cart, code carts, OR trays as well as making and checking IV. Michael was especially careful with the narcotics. The narcotic count had to be correct or we stayed until we found the error. We followed our protocol whenever meds were dispensed. Once the hospital went to Pixas machines Michael was trained as the manager of these machines. He was called back to the hospital often to correct problems.

He was always on time and stayed till his work was done. I never saw him be unethical with the pharmacy charting or drugs. I never saw him act unprofessional or put his Pharmacy license at risk. He donates a lot of his time to the Shriners where he loved to go ride in parades to help children.

Working at Desert View Hospital was difficult at times, due to a poor communication with CEO and Director of Nursing. As any workplace Michael tried to work with Corporate and nursing staff to solve problems.

Please do not hesitate to call me if you need to discuss this further.

Sincerely

Dotty Edwards Dotty Edwards

7752535204

Exhibit F. "Mr. Burkintas' Medications and Supplements."

## Michael Burkintas medication, vitamin and supplement list.

## Ozempic

Amlodipine Carvedilol Cephalexin

Ciprofloxicin Loratidine/psoudoephrine

Chlorpheniramine

Gvapenesin/dextromethorphan

L-Argenine Beta Carotene Melatonin

Glucosamine/chondroitin/msm

Vitamin C Vitamin E

Super B complex Potassium iodide

Levothyroxine Ibuprophen Acetaminophen

Pepto bismol Selenium

L-lysine

Black cherry extract Eye Vision Guard

## Glipizide

Allopurinol Dicyclomine

Amoxicillin/Clavulanate

Famotidine Phenylephrine Diphenhydramine

**DHEA** 

Coenzyme Q10 5-Hydroxytryptophan Alpha Lipoic Acid

Calcium/magnesium/zinc

Vitamin D3
Folic acid
vitamin B12

Century multi-vitamin for men

Sitagliptin Asprin

Eye vites areds2

Lecithin

Chromium picolinate

Coconut oil Tadalifil GHR

## **Supplement Facts**

Serving Size: 1 Quick Release Softgel

Servings Per Container: 200

	Amount Per Serving	% Daily Value (DV)
Vision Shield™ Lutein (from Marigold Petal Extract)	20 mg	*
Vision Shield™ Zeaxanthin (from Marigold Petal Extract)	1 mg	*
Bilberry Extract (Vaccinium uliginosum) (fruit)	2.2 mg	*

**Other ingredients:** Sunflower Oil and/or Safflower Oil, Gelatin, Vegetable Glycerin, Sunflower Lecithin, Yellow Beeswax, Annatto Extract Color, Titanium Dioxide Color

**Directions:** For adults, take 1 quick release softgel 2 times daily, preferably with meals.

**WARNING:** If you are pregnant, nursing, taking any medications or have any medical condition, consult your doctor before use. Avoid this product if you are allergic to daisy-like flowers. If any adverse reactions occur, immediately stop using this product and consult your doctor. If seal under cap is damaged or missing, do not use. Keep out of reach of children. Store in a cool, dry place.



<sup>\*</sup> Daily Value (DV) not established.

## PipingRock GHR Complex

- GHR Complex (1,480 mg)
- Gluten-Free & Non-GMO
- Quick-Release Capsules

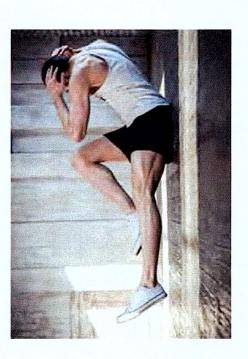
As a leader in Sports Nutrition, PipingRock has crafted the ultimate GHR Complex for wide-ranging nutritional support. This cutting-edge formula features a 1,480 mg GHR Complex, with a 610 mg L-Arginine Base and other key amino acids in convenient quick-release capsules. It's gluten-free and non-GMO with no preservatives, providing hold connect to help you converse.

## Supplement Facts

Serving Size: 2 Quick Release Capsules

Servings Per Container: 90

	Amount Per Serving	% Daily Value (DV)
Vitamin C (as Ascorbic Acid)	100 mg	111%
Vitamin B-6 (as Pyridoxine HCI)	15 mg	882%
GHR Complex	1,480 mg	*
L-Arginine Base	610 mg	*
L-Ornithine Alpha-Ketoglutarate (OKG)	340 mg	*
L-Ornithine HCI	220 mg	*
Glycine	RESP 0028	*
L-Lysine HCI	90 mg	*



Our Testestorone Support Formula is specially designed for men! Our quick-release capsules include time-tested ingredients like Horny Goat Weed and Maca that have been used by men for centuries. So grab a bottle today!

## Supplement Facts

Serving Size: 2 Vegetarian Capsules

Servings Per Container: 45

	Amount % Daily Per Value	% Daily Value
	Serving	(00)
Maca (Lepidium meyenii) (root) (from 150 mg of 4:1 extract)	600 mg	*
Tribulus Extract (Tribulus terrestris) (fruit) (Standardized to contain 45% saponins)	100 mg	*
Horny Goat Weed Extract (Epimedium sagittatum) (aerial) (Standardized to contain 10% icariins)	500 mg	*
Yohimbe Extract (Pausinystalia yohimbe) (bark) (Standardized to contain 2% Yohimbine Alkaloids) RE	40 mg RESP 0026	*
L-Arginine HCI	40 mg	*

## What are Thermogenics?

The word "thermogenics" means heat producing.

Thermogenics are ingredients designed to support a healthy metabolism alongside diet and exercise.\*\* There are many standalone thermogenic ingredients that are used for support. However, the best formulas have multiple ingredients from various sources. Our ThermoRip Fat Burner is just that!

# Get Optimal Fuel with Thermo Rip!

## Value (e) Amount % Daily Serving 1,185 mg heating units), Black Pepper Extract (Piper nigrum) (fruit) ESP 0027 Green Tea Extract (Camellia sinensis) (leaf) (Standardized L-Tyrosine (Free Form), Caffeine (Pharmaceutical Grade) (270 mg), Apple Cider Vinegar, Acetyl L-Carnitine HCI, to 95% Polyphenols, 75% Catechins, and 45% EGCG), Cayenne Pepper (Capsicum annuum) (fruit) (40,000 Supplement Facts (Standardized to contain 95% Piperine) Servings Per Container: 60 Serving Size: 2 Capsules Thermo Rip® Complex

## **Kristopher Mangosing**

From:

Joe Dodge

Sent:

Thursday, June 1, 2023 8:49 AM

To:

Kristopher Mangosing

Subject:

Partell Board Meeting supplemental documents

**Attachments:** 

Partell Board Meeting Documents.pdf

Follow Up Flag:

Follow up

Flag Status:

Flagged

HI Kris,

Please include the attached documents in the board book if possible.

Thanks,

Joe Dodge, Pharm D Inspector

Nevada State Board of Pharmacy 1140 N. Town Center Dr Ste 300 Las Vegas, NV, 89144

Office: 702.486.6420 Ext 157

Fax: 702.486.7903

E-mail: j.dodge@pharmacy.nv.gov Web Page: www.bop.nv.gov

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The observations of objectionable conditions and practices listed on the front of this form are reported:

- 1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
- To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgement, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filithy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 02/26/2018-03/08/2018 1431 Harbor Bay Parkway Alameda, CA 94502-7070 FEI NUMBER (510)337-6700 Fax:(510)337-6702 3011769075 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Eric L. Sparks, PharmD, Pharmacy Manager FIRM NAME STREET ADDRESS One Way Drug LLC dba Partell Specialty Pharmacy 5835 S. Eastern Ave. Suite 101 CITY, STATE AND ZIP CODE TYPE OF ESTABLISHMENT INSPECTED Las Vegas, NV 89119 Producer of Sterile and Non-Sterile Drugs

THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

## OBSERVATION 1

The filter intended to render final product sterile is not adequate to accomplish sterilization and/or is not pharmaceutical grade.

Specifically,

a. Your firm uses the Vacuum Filter, Stericup (Millipore) sterile filter, when compounding large volume batches of sterile finished product.

The Stericup does not appear to be pharmaceutical grade and the labeling for the Stericup states "Do not use these systems in direct patient care applications."

There is no integrity testing method for the Vacuum Filter, Stericup (Millipore) sterile filter. The firm releases finished drug product without determining the suitability of the filter. Examples of products, where the Stericup has been used as the sterilizing filter are Coenzyme Q10, Ascorbic acid, and Vitamin B Complex.

b. There is no assurance that the bubble point testing of filters used to render drug product sterile is adequate to ensure the integrity of such filters. Your firm was unable to confirm what required minimum pressure is used when performing integrity testing on sterilizing filters. There is a discrepancy with the required minimum pressure written in the bubble point test log and the manufacturers requirement. For example, the log states '38psi' required for the PES-50 filter, yet the manufacturer requires 50 psi. Your firm does not document the actual value in the Formula Worksheet and simply enters "PASS or FAIL".

## **OBSERVATION 2**

SEE
REVERSE
OF THIS
PAGE

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Lucila B. Nwatu, Investigator/CSO
Juanita P. Versace, Microbiologist

03/08/2018

ORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

Page 1 of 6

## DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 02/26/2018-03/08/2018 1431 Harbor Bay Parkway Alameda, CA 94502-7070 FEI NUMBER (510)337-6700 Fax:(510)337-6702 3011769075 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Eric L. Sparks, PharmD, Pharmacy Manager STREET ADDRESS One Way Drug LLC dba Partell Specialty Pharmacy 5835 S. Eastern Ave. Suite 101 CITY, STATE AND ZIP CODE TYPE OF ESTABLISHMENT INSPECTED Las Vegas, NV 89119 Producer of Sterile and Non-Sterile Drugs

The cycle parameter (temperature, pressure, and time) used for heat sterilization of product interned to be sterile are not verified to be lethal to heat-resistant microorganisms.

## Specifically,

- a. Your firm performs all compounding and filling operations for terminally sterilized pellet products in an unclassified Biosafety Cabinet, located in an unclassified room. Pellet products include:
- Estradiol, 10mg, 12.5mg, 15mg, 20mg, 25mg, 35mg, 40mg, 50mg, 55mg Pellets
- · Naltrexone, 200mg Pellets
- Pregnenolone, 50mg, 100mg Pellets
- Progesterone, 50mg Pellets
- Testosterone/Anastrozole 120/8mg; 180/12mg; 200/20mg; 60/1mg; 60/4mg Pellets
- Testosterone/Estradiol 60/6 mg Pellets
- Testosterone 100 mg, 200 mg, 25 mg, 37.5 mg, 40 mg, 50 mg, 55 mg, 80 mg Pellets
- Testosterone/ Finasteride 60/5 mg, 80/8mg Pellets
- Testosterone/ Finasteride/Anastrozole 120/10/4 mg Pellets
- b. Your firm uses the Hirayama HV-25 Autoclaves for both terminal sterilization and sterilization of containerclosures, such as stoppers and final product vials. Effectiveness of Steam Sterilization is verified using Sporview Self-Contained Biological Indicators. The manufactured recommends incubation conditions of 55°C to 60° C for a minimum of 24 hours. Biological Indicator dry block incubator is not calibrated to ensure the temperature can maintain 55-60°C for 24 hours. The dry block does not contain a visual thermometer to monitor the temperature during BI incubation.
- c. Your firm conducts terminal sterilization on sealed vials containing pellet products, using an autoclave cycle of 121°C for 20 minutes. There is no adequate scientific justification for the autoclave cycle used to terminally sterilize implantable pellets, including consideration of heat penetration into the container closure and the pellets themselves. There is no assurance that 121°C for 20 minutes is adequate for pellets in sealed containers.

OBSERVATION 3

EMPLOYEE(S) NAME AND TITLE (Print or Type)

DATE ISSUED

Lucila B. Nwatu, Investigator/CSO

Juanita P. Versace, Microbiologist

03/08/2018

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

Page 2 of 6

### DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 02/26/2018-03/08/2018 1431 Harbor Bay Parkway Alameda, CA 94502-7070 FEI NUMBER (510)337-6700 Fax:(510)337-6702 3011769075 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Eric L. Sparks, PharmD, Pharmacy Manager FIRM NAME STREET ADDRESS One Way Drug LLC dba Partell Specialty Pharmacy 5835 S. Eastern Ave. Suite 101 CITY, STATE AND ZIP CODE TYPE OF ESTABLISHMENT INSPECTED Las Vegas, NV 89119 Producer of Sterile and Non-Sterile Drugs

The final containers/closures used for drug product intended to be sterile have not been sterilized or depyrogenated.

Specifically,

- a. Your firm does not depyrogenate the non-sterile stoppers and vials before conducting filling operation for all aseptically filled drug products.
- b. Your firm does not depyrogenate the non-sterile stoppers and vials before conducting filling operation for all terminally sterilized pellet drug products.

## **OBSERVATION 4**

Disinfecting agents and cleaning pads or wipes used in the ISO 5 area are not sterile.

Specifically,

To clean and disinfect the ISO- 5 Laminar Air Flow Hood (LAFH), the firm uses non-sterile PolySat Wipers, non-sterile Alpha Wipe Dry Wipes, non-sterile Opti-cide 3, non-sterile Spor-Klenz, and sterile 70% Isopropyl Alcohol spray.

## **OBSERVATION 5**

The use of sporicidal agents in the cleanrooms and/or ISO 5 areas is inadequate.

Specifically,

Your firm has not established sufficient contact time for all disinfectants use in the cleanroom. Your film failed to follow manufacturer's recommended contact times for the disinfectants used in the controlled environments. For example, for non-sterile sporicidal agent Spor-Klenz, the manufacturer recommends a contact surface time of

	EMPLOYEE(S) SIGNA	TYRE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
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FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

Page 3 of 6

## DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702

DATE(S) OF INSPECTION 02/26/2018-03/08/2018

Industry Information: www.fda.gov/oc/industry

FEI NUMBER 3011769075

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric L. Sparks, PharmD, Pharmacy Manager

One Way Drug LLC dba Partell Specialty Pharmacy

5835 S. Eastern Ave. Suite 101

STREET ADDRESS

CITY, STATE AND ZIP CODE

TYPE OF ESTABLISHMENT INSPECTED

Las Vegas, NV 89119

Producer of Sterile and Non-Sterile Drugs

30 minutes. Your daily cleaning/disinfecting log for controlled environments and procedure, does not indicate contact times. Pharmacy Lab Manager and Technicians confirmed that after spraying Spor-Klenz ion the surface, the solution is immediately removed. Demonstration of the effectiveness of the cleaning operations was not assessed due to lack of established contact times.

## **OBSERVATION 6**

You produced hazardous drugs without providing adequate cleaning of utensils to prevent cross-contamination.

Specifically,

Your firm uses non-dedicated glassware and utensils to weigh and mix non-sterile hazardous and non-hazardous ingredients, in preparation for aseptic filling operations. Examples of hazardous ingredients used in your facility include Testosterone Cypionate and Alprostadil.

## **OBSERVATION 7**

Non-sterilized or non-depyrogenated tools or temporary container were used in sterile production.

Specifically,

Your firm uses glassware and utensils to weigh and mix non-sterile ingredients, in preparation for aseptic filling operations. Your firm does not adequately clean the glassware and utensils to prevent cross-contamination. Glassware, spatulas, and mixing bars are washed in a dishwasher using Reverse Osmosis water. Your firm has not conducted any testing (microbial and analytical) of the water generated through your reverse osmosis (RO) system. The glassware is placed in an oven for approximately 20 minutes at 90°C. There is no assurance that these conditions sterilization or depyrogenation these materials prior to use in compounding sterile drug products.

## **OBSERVATION 8**

Environmental monitoring in your aseptic processing areas is not adequate.

REVERSE OF THIS

EMPLOYEE(S) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (Print or Type)

Lucila B. Nwatu, Investigator/CSO

DATE ISSUED

Juanita P. Versace, Microbiologist

03/08/2018

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

Page 4 of 6

## DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

1431 Harbor Bay Parkway Alameda, CA 94502-7070 (510)337-6700 Fax:(510)337-6702 DATE(S) OF INSPECTION 02/26/2018-03/08/2018

FEI NUMBER 3011769075

Industry Information: www.fda.gov/oc/industry

DISTRICT OFFICE ADDRESS AND PHONE NUMBER

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Eric L. Sparks, PharmD, Pharmacy Manager

One Way Drug LLC dba Partell Specialty Pharmacy

STREET ADDRESS

5835 S. Eastern Ave. Suite 101

CITY, STATE AND ZIP CODE TYPE OF ESTABLISHMENT INSPECTED Las Vegas, NV 89119

Producer of Sterile and Non-Sterile Drugs

## Specifically,

- a. Review of the last biannual Environmental Monitoring report, dated 11/30/17, revealed that Micrococus species and Aspergillus was detected when viable air sampling was conducted in the ISO-5 Laminar Air Flow Hood. As a corrective action, your firm performed cleaning three times in the controlled environment, and air sampling was repeated. An investigation was not conducted and a root cause was not determined.
- b. Monthly surface sampling is part of the firm's Environmental Monitoring program. Surface samples are taken with a EnviroTest Media Paddles, immediately after spraying sterile 70% Isopropyl Alcohol on the surface.

## **OBSERVATION 9**

Inadequate pressure differentials between higher quality air rooms and lower quality air rooms were observed. .

## Specifically,

- a. Sterile drug filling is conducted inside the ISO 5 core of Laminar Air Flow Hood (LAFH). The evaluation of unidirectional airflow (e.g., smoke studies) for microbiological contamination was not performed under dynamic conditions in the ISO 5 LAFH, which is located in an ISO 7 environment.
- b. During filling operations, we observed that the doors from the ISO 8 compounding room to the ISO 7 Ante room, and the door from the ISO 7Ante-Room to the ISO 7 aseptic filling room, did not stay consistently closed. We heard multiple alarms during the aseptic filling due to loss in pressure. The firm cannot assure continuous positive pressure during filling operations.

## **OBSERVATION 10**

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically,

REVERSE

EMPLOYEE(S) SIGNATURE

EMPLOYEE(S) NAME AND TITLE (Print or Type)

DATE ISSUED

PREVIOUS EDITION OBSOLETE

Lucila B. Nwatu, Investigator/CSO Juanita P. Versace, Microbiologist

03/08/2018

INSPECTIONAL OBSERVATIONS

Page 5 of 6

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DISTRICT OFFICE ADDRESS AND PHONE NUMBER		DATE(S) OF INSPECTION				
1431 Harbor Bay Parkway		02/26/2018- 03/08/2018				
Alameda, CA 94502-7070		FEI NUMBER				
(510)337-6700 Fax:(510)337-6702						
Industry Information: www.fda.gov/oc/industry	311	3011769075				
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED						
To: Eric L. Sparks, PharmD, Pharmacy Manager FIRM NAME	Toronto London					
	STREET ADDRESS					
One Way Drug LLC dba Partell Specialty Pharmacy CITY, STATE AND ZIP CODE	5835 S. Eastern Ave.	BLISHMENT INSPECTED				
Las Vegas, NV 89119		Producer of Sterile and Non-Sterile Drugs				
<ul> <li>a. Your firm conducts Media Fill in liquid filled bags versus vials. A commercially purchased kit containing 100 ml flexible container of TSB (Tryptic Soy Broth), 20 ml vial of TSB, and a 3 ml ampule of red TSB, are used to conduct media fills. The content of the ampule is injected into the 20 ml vial of TSB. 1 ml of this solution is injected into the 100 ml TSB bag. This procedure is repeated 19 times. This does not simulate their filling process. The bag is not representative of the container/closures used during routine production.</li> <li>b. When filling large batch size sterile products, the firm uses a fluid dispensing pump. For example, the fluid dispensing pump is used during filling of Methylcobalamin, 12.5mg/ml injection, whose batch size is 3000ml into 50 ml vials or 500ml into 5 ml vials. This pump is not included during the media fill simulation.</li> </ul>						
You have a sterility failure as evidence of production under insanitary conditions. Your firm conducted an inadequate Sterility OOS investigation. Review of OOS Sterility failure investigation revealed Bacillus species was detected in TM#3 (20 vials, Lot # 20171128@27). The firm's corrective action includes cleaning and disinfecting the controlled environment three times. Demonstration of the effectiveness of the cleaning operations was not assessed because environmental and personnel monitoring was not performed afterward.  *DATES OF INSPECTION 2/26/2018(Mon), 2/27/2018(Tue), 2/28/2018(Wed), 3/01/2018(Thu), 3/02/2018(Fri), 3/05/2018(Mon), 3/06/2018 (Tue), 3/07/2018(Wed), 3/08/2018(Thu)						
EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TO	LE (Print or Type)	DATE ISSUED			
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OF THIS TO MAN	Lucila B. Nwatu, Investig Juanita P. Versace, Micro		03/08/2018			
1,100		<b>5</b>				



Partell Pharmacy 5835 S. Eastern Avenue #101 Las Vegas, Nevada 89119 (702)791.3800

March 8, 2018

To whom it may concern:

Pharmacy Manager

The letter is meant to confirm the position of Partell Specialty Pharmacy on the topic of sterile products and sterile product compounding. The company's management and ownership have decided to voluntarily recall all compounded sterile products that have been shipped to customers. Additionally, the company has agreed to destroy all sterile products stored on site and has officially exited the business of sterile product compounding.

CEO - Owner

Eric Sparks, PharmD
Partell Specialty Pharmacy
5835 S. Eastern Avenue, Suite 101
Las Vegas, NV 89119
Fax: (702) 791-3630

March 29, 2018

Food and Drug Administration 1431 Harbor Bay Parkway Alameda, CA 94502-7070 Fax: (510) 337-6702

Re: 483 Report dated 03/08/2018

Dear FDA District Office:

With respect to the 483 Report of our pharmacy, based on dates of inspection 2/22/2018 to 03/08/2018, please be advised that Partell Specialty Pharmacy, during the FDA inspection ceased all sterile compounding activities, and is no longer filling any prescriptions for sterile compounded medications. All such inquiries are being referred to sterile compounding pharmacies in and around Las Vegas.

Additionally, Partell Specialty Pharmacy has initiated a voluntary recall of all of its sterile compounded prescriptions. We have been in regular communication regarding same with FDA's recall coordinators at Division of Pharmaceutical Quality Operations.

Sincerely yours,

Eric Sparks, PharmD



April 30, 2018

Dear Mr. Seidlinger,

Per your request I am submitting to you this letter which confirms that Partell Pharmacy is no longer engaged in the business of sterile product compounding. I understand, as does the rest of the company, that Partell Pharmacy is not permitted to reengage in any form of sterile product compounding unless we first notify the Nevada Board of Pharmacy and then subsequently undergo inspection and receive final approval. If the company does decide to engage the business in the future we will alert the Board of Pharmacy and discuss the necessary inspection.

Sincerely

Robert Seik

CEO - Partell Pharmacy

BIO-IDENTICAL HORMONE REPLACEMENT THERAPY

MENOPAUSE

PREMENSTRUAL SYNDROME

ADULT HORMONE DEFICIENCY

ANTI-AGING MEDICINE

HUMAN GROWTH HORMONE

ERECTILE DYSFUNCTION

PROFESSIONAL NUTRACEUTICAL FORMULAS

DERMATOLOGY

PEDIATRICS

**AUTISM** 

PAIN MANAGEMENT

**FIBROMYALGIA** 

DENTISTRY

HEPATITIS C

INFERTILITY

VETERINARY MEDICINE

8751 W. Charleston Blvd. #120 Las Vegas, NV 89117 - Phone: 702.685.3800 Fax: 702-685-3636 5835 S. Eastern Ave. #101 Las Vegas, NV 89119 - Phone: 702.791.3800 Fax: 702-791-3630

## **WARNING LETTER**

## One Way Drug LLC dba Partell Specialty Pharmacy

MARCS-CMS 573455 - MARCH 13, 2019

Product:	
Drugs	

## Recipient:

Robert A. Seik

CEO & Owner

One Way Drug LLC dba Partell Specialty Pharmacy

5835 S. Eastern Avenue, Suite 101

Las Vegas, NV 89119

**United States** 

## **Issuing Office:**

Division of Pharmaceutical Quality Operations IV

19701 Fairchild

Irvine, CA 92612-2506

**United States** 

**(949)** 608-2900

## WARNING LETTER

VIA UNITED PARCEL SERVICE

SIGNATURE REQUIRED

February 4, 2019

Robert A. Seik

CEO & Owner

One Way Drug LLC dba Partell Specialty Pharmacy

Las Vegas, NV 89119

Dear Mr. Seik:

From July 17, 2017, to July 19, 2017, U.S. Food and Drug Administration (FDA) investigators inspected your facility, One Way Drug LLC, dba Partell Specialty Pharmacy ("West"), located at 8751 W. Charleston Blvd, Suite 120, Las Vegas, NV 89117. Additionally, from February 26, 2018, to March 8, 2018, U.S. FDA investigators inspected your facility, One Way Drug LLC, dba Partell Specialty Pharmacy ("East"), located at 5835 S. Eastern Ave, Suite 101, Las Vegas, NV 89119. During the inspections, the investigators noted that drug products you produced failed to meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a] for exemption from certain provisions of the FDCA. The investigators noted serious deficiencies in your practices for producing drug products, which put patients at risk.

FDA issued a Form FDA 483 to your West facility on July 19, 2017, and to your East facility on March 8, 2018. FDA acknowledges receipt of your responses, dated August 8, 2017, November 7, 2017, March 8, 2018, and March 29, 2018. We acknowledge your statements in your March 29, 2018, letter that, "Partell Specialty Pharmacy ceased all sterile compounding activities...and is no longer filling any prescriptions for sterile compounded medications" and that, "Partell Specialty Pharmacy has initiated a voluntary recall of all its sterile compounded prescriptions." Based on these inspections, it appears that you produced drug products that violate the FDCA.

## A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].[1] Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A.

In addition, for a compounded drug product to qualify for the exemptions under section 503A, bulk drug substances used to compound it must: (I) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (II) if such a monograph does not exist, be components of drugs approved by the Secretary; or (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appear on a list developed by the Secretary through regulation ("503A bulks list") (section 503A(b)(1)(A)(i) of the FDCA).

## B. Failure to Meet the Conditions of Section 503A

During the inspection, the FDA investigators noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the investigators noted:

1. At your West facility, your firm did not receive valid prescriptions for individually-identified patients for a portion of the drug products you produced.

2. At your West facility, your firm compounded drug products using calendula, comfrey, dimethylaminoethanol bitartrate, saw palmetto, and turmeric. At your East facility, your firm compounded drug products using hydroxytryptophan, indole-3-carbinol, L-carnosine, pimobendan, saw palmetto, and theanine. Drug products compounded using calendula, comfrey, dimethylaminoethanol bitartrate, hydroxytryptophan, indole-3-carbinol, L-carnosine, pimobendane, saw palmetto, theanine, and turmeric are not eligible for the exemptions provided by section 503A(a), because they are not the subjects of applicable USP or NF monographs, are not components of an FDA-approved human drug, and do not appear on the 503A bulks list.[2]

Therefore, you compounded drug products that do not meet the conditions of section 503A and are not eligible for the exemptions in that section from the FDA approval requirement of section 505 of the FDCA, the requirement under section 502(f)(1) of the FDCA that labeling bear adequate directions for use, and the requirement of compliance with CGMP under section 501(a)(2)(B) of the FDCA. In the remainder of this letter, we refer to your drug products that do not qualify for exemptions under section 503A as the "ineligible drug products."

Specific violations are described below.

## C. Violations of the FDCA

## **Adulterated Drug Products**

FDA investigators noted that drug products at your East and West facilities were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, at your West facility, the investigators observed a vacuum cleaner being used to clean a powder press used in non-sterile drug production. In addition, at your East facility, the investigators observed that:

- 1. Your firm used a non-pharmaceutical grade filter to sterilize drug products. Specifically, labeling for the "(b)(4)" states, "Do not use these systems in direct patient care applications."
- 2. Your firm had no assurance that post-use filter integrity testing of filters, used to sterilize drug products, was performed according to the specifications of the filter manufacturer.
- 3. Your firm's production of implantable pellets intended to be sterile was inadequate. Specifically, pellets were processed in an unclassified area and then (b)(4) in a sealed container using an (b)(4) which lacks assurance of adequate heat penetration into the container closure and pellets themselves. Furthermore, biological indicators used to verify the adequacy of the (b)(4) were not properly incubated to ensure reliable results.
- 4. Your firm used a non-sterile cleaning agent as well as non-sterile cleaning wipes as part of your disinfection program for the aseptic processing areas. In addition, your firm did not ensure a sufficient contact time for the sporicidal agent used to disinfect the aseptic processing areas.
- 5. Your firm did not adequately clean or depyrogenate glassware and utensils used to produce drug products intended to be sterile. Additionally, non-dedicated glassware and utensils were used to weigh and mix hazardous and non-hazardous drug components in preparation for aseptic filling operations. Furthermore, your firm used non-depyrogenated stoppers and vials in the production of drug products intended to be sterile.

- 6. Your firm performed environmental sampling immediately after cleaning, which could potentially bias the results.
- 7. Your firm failed to perform adequate smoke studies under dynamic conditions to demonstrate unidirectional airflow within the ISO 5 area. Therefore, your products intended to be sterile were produced in an environment that may not provide adequate protection against the risk of contamination.
- 8. Your firm failed to maintain adequate pressure differentials between areas of higher quality air and lower quality air.
- 9. Your media fills were not performed under the most challenging or stressful conditions. Therefore, there is a lack of assurance that your firm can aseptically produce drug products within your facility.

Furthermore, the manufacture of the ineligible drug products is subject to FDA's CGMP regulations, Title 21, Code of Federal Regulations (CFR), parts 210 and 211. The FDA investigators observed significant CGMP violations at your West facility, causing the ineligible drug products to be adulterated within the meaning of section 501(a)(2)(B) of the FDCA. The violations included, for example:

- 1. Your firm failed to have, for each batch of drug product, appropriate laboratory determination of satisfactory conformance to final specifications for the drug product, including the identity and strength of each active ingredient, prior to release (21 CFR 211.165(a)).
- 2. Your firm failed to clean, maintain, and, as appropriate for the nature of the drug, sanitize and/or sterilize equipment and utensils at appropriate intervals to prevent malfunctions or contamination that would alter the safety, identity, strength, quality, or purity of the drug product beyond the official or other established requirements (21 CFR 211.67(a)).

It is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

## **Misbranded Drug Products**

The ineligible drug products you compounded are intended for conditions not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses.[3] Accordingly, these ineligible drug products are misbranded under section 502(f)(1) of the FDCA. It is a prohibited act under section 301(k) of the FDCA to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

## D. Corrective Actions

We have reviewed your responses to the Form FDA 483s issued at both of your facilities. Regarding your West facility, FDA is aware that this site in no longer operational. Regarding your East facility, we acknowledge your statements in your March 29, 2018, letter that, "Partell Specialty Pharmacy ceased all sterile compounding activities...and is no longer filling any prescriptions for sterile compounded medications" and that, "Partell Specialty Pharmacy has initiated a voluntary recall of all its sterile compounded prescriptions."

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A, including the condition on receipt of a prescription for an identified individual patient prior to compounding and distributing drug products.

Regarding observations related to the conditions of section 503A of the FDCA, some of your corrective actions appear to be adequate. Specifically, in your letter dated March 8, 2018, you agree to "cease to use for compounded prescription products the following items until a USP monograph is available for each one:" indole-3-carbinol, L-carnosine, pimobendan, and saw palmetto. However, you have not addressed the compounding of drug products using calendula, comfrey, dimethylaminoethanol bitartrate, hydroxytryptophan, and theanine. As explained above, drug products compounded using these bulk drug substances are not eligible for the exemptions provided by section 503A(a), because they are not the subjects of an applicable USP or NF monograph, are not components of FDA-approved human drugs, and do not appear on the 503A bulks list.

Should you continue to compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations. Before doing so, you must comply with the requirements of section 505 and 502(f)(1) and fully implement corrections that meet the minimum requirements of the CGMP regulations. [4]

In addition to the issues discussed above, you should note that CGMP requires the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products. See section 501 of the FDCA. If you choose to contract with a laboratory to perform some functions required by CGMP, it is essential that you select a qualified contractor and that you maintain sufficient oversight of the contractor's operations to ensure that it is fully CGMP compliant. Regardless of whether you rely on a contract facility, you are responsible for assuring that drugs you produce are neither adulterated nor misbranded. [See 21 CFR 210.1(b), 21 CFR 200.10(b)].

FDA strongly recommends that if you decide to resume production of sterile drugs, your management first undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

## E. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

If you decide to resume sterile operations, you should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen (15) working days of receipt of this letter, please notify this office in writing if you have taken any specific steps to correct the violations cited in this letter. If you intend to resume production of sterile drugs in the future, please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above violated the FDCA,

include your reasoning and any supporting information for our consideration. In addition to taking appropriate corrective actions, you should notify this office 15 days prior to resuming production of any sterile drugs in the future.

Your written notification should refer to unique identifier CMS 573455 and sent to:

CDR Steven E. Porter, Jr.

Director, Division of Pharmaceutical Quality Operations IV

19701 Fairchild Road

Irvine, CA 92612

If you have questions regarding the contents of this letter, please contact William V. Millar, Compliance Officer at (510) 337-6896, or by email at william.millar@fda.hhs.gov (mailto:william.millar@fda.hhs.gov).

Sincerely,

/S/

CDR Steven E. Porter, Jr.

Director, Division of Pharmaceutical Quality Operations IV

[1] We remind you that there are conditions other than those discussed in this letter that must be satisfied to qualify for the exemptions in section 503A of the FDCA.

[2] On June 9, 2016, FDA issued a final guidance titled, Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act. This guidance describes FDA's interim regulatory policy for State-licensed pharmacies, Federal facilities, and licensed physicians that compound human drug products using bulk drug substances that do not otherwise meet the conditions of section 503A(b)(1)(A)(i) while the 503A bulks list is being developed. Specifically, the guidance sets out the conditions under which FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician for compounding a drug product using a bulk drug substance that is not the subject of an applicable USP or NF monograph or a component of an FDA-approved drug, until the substance is identified in a final rule as included or not included on the 503A bulks list. These conditions include that the substance may be eligible for inclusion on the 503A bulks list, was nominated with adequate support for FDA to evaluate it, and has not been identified by FDA as a substance that appears to present significant safety risks pending further evaluation. Dimethylaminoethanol bitartrate, indole-3-carbinol, L-carnosine, pimobendan, and saw palmetto were nominated for inclusion on the 503A bulks list; however, they were not nominated with adequate support for FDA to evaluate the substances. Calendula, comfrey, hydroxytryptophan, theanine, and turmeric were not nominated for the 503A bulks list. For additional information, see the guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf).

[3] Your ineligible drug products are not exempted from the requirements of section 502(f)(1) of the FDCA by regulations issued by the FDA (see, e.g., 21 CFR 201.115).

<b>⊙</b> More Warning Letters (/inspections-complia	ance-enforcement-and-criminal-investigations/compilance-acti	ons-and-activities/warning-letters)

Partell Pharmacy 5835 South Eastern Avenue Suite 101 Las Vegas, NV March 27, 2019

CDR Steven E. Porter, Jr.
Director, Division of Pharmaceutical Quality Operations IV
U.S. Food and Drug Administration
19701 Fairchild Road
Irvine, CA 92612
Reference#CMS 573455

Dear CDR Steven E. Porter, Jr.:

Partell Pharmacy no longer compounds any sterile products. At this time there are no future plans to revisit sterile compounding.

The pharmacy does not and will not compound using the following bulk ingredients until a USP monograph is available for each one:

L-Carnosine, Indole-3-carbinol, L-carnosine, pimobendan, saw palmetto, calendula, comfrey, dimethylaminoethanol bitartrate, hydroxytryptophan, and theanine.

Sincerely,

Jeffrey S. Lang, Pharm D

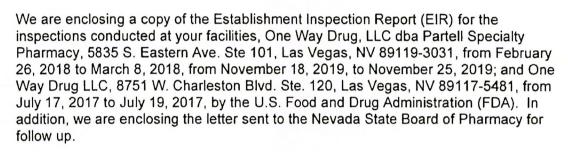
Pharmacy Manager



June 16, 2020

Robert A. Seik, CEO, Owner One Way Drug, LLC dba Partell Specialty Pharmacy 5835 S. Eastern Ave. Ste 101 Las Vegas, NV 89119-3031

Dear Mr. Seik:



When the agency considers an inspection to be "closed" under 21 CFR 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the agency in accordance with the Freedom of Information Act (FOIA) and 21 CFR Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, please contact William V. Millar, Compliance Officer, at (503) 671-9711 Ext. 30, or by email at william.millar@fda.hhs.gov..

Sincerely,

CDR Steven E. Porter, Jr.

Director, Division of Pharmaceutical Quality Operations IV

SP:wm

Division of Pharmaceutical Quality Operations IV 19701 Fairchild Road, Irvine CA 92612-25006 Telephone: (949) 608-2900 Fax: (949) 608-4417 www.fda.gov



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FEI 3011769075, 3010839113

CMS WA 168903, 206036, 306483

Enclosure: EIR and State Referral Letter

Cc: Nevada State Board of Pharmacy (cover letter only)

**Dave Wuest** 

**Executive Secretary** 

985 Damonte Ranch Pkwy Ste 206

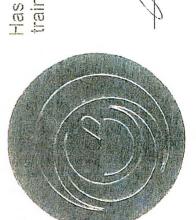
Reno, Nevada 89521

## Sterility Assurance Training

# Certificate of Completion

Presented to

## Jeff Lang, PIC



Has completed 30 hours of live presentations and hands-on training in Sterility Assurance at PCCA in Houston, Texas – May 8-11, 2023

Matt Martin-PharmD, BCSCP PCCA Director of Clinical Services

Jeff M. J. J. J. J. J. J. J. J. J. Jerra Banwarth, RPh, FAPC
PCCA Education and Training Manager

This certificate does not convey any CE hours.



## ASSOUR TECHNIQUE COMIDOUNGING

# Certificate of Completion

Presented to

## Chris Peters, PharmD

Attended Aseptic Technique Compounding Training at PCCA in Houston, Texas - October 23-25, 2019.

Megan Jeffrey Liotta, MS Quality and Regulatory Affairs

Keisha Lovoi, RPh Compounding Training Consultant

This certificate does not convey any CE hours.





MyRx Request	Ela Fil Ibry			
Advanced Options * RE	QUESTOR LAST NAME SOrelle			
MyRx History				
Prescriber First Name \$	Prescriber Last Name   Role	DEA   Date F	Requested © Sta	itus #
Jonathan	Sorelle	Physician (MD DO)	FS0191166	08 13/2022 10.20 AM
Jonathan	Sorollo	Physician (MD DO)	F\$0191166	08/13/2022 10 18 AM
Jonathan	Sorette	Physician (MD DO)	FSD191166	D8/13/2022 10 14 AM
Jonathan	Sorelle	Physician (MD DO)	FS0191166	08/13/2022 ID 13 AM
Jonathan	Sorolle	Physician (MD DO)	FS0191166	09/23/2016 04 52 PM



STATE LICENSE SERVICING 1751 Route 17A, Suite 3 Florida, NY 10921 Tel. 845/544-2482 Fax. 845/544-2481 statelicenseservicing.com

Date:

12/14/2022

To:

Nevada State Board of Pharmacy

Re:

VistaPharm, Inc.

License # WH02256

Facility Address: 13701 66th Street North, Largo, FL 33771

Dear Sir/Madam:

Please be advised that I represent VistaPharm, Inc. as their Attorney-in-Fact for licensing purposes. Please find enclosed a completed application as well as check/money order #\_\_\_ for your fee in the amount of \$ NIA . As required, the following documents are also being submitted:

A Change of DR

If you have any questions or need any additional documentation, please contact our Compliance Department at compliance@slsnysupport.com

Kind regards,

Jennifer Schneider VP, Client Services

### **NEVADA STATE BOARD OF PHARMACY**

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - 775-850-1440

## **Designated Representative Application**

Rev (05/12/2022)

An application for a license, or a licensee with a license, to conduct a pharmacy or to operate as a wholesaler shall designate at least one natural person to serve as the representative of the pharmacy or wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a pharmacy or wholesaler unless the Board determines that the designated natural person meets the following qualifications per NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler):

- 1. Is at least 21 years of age;
- 2. Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.

The designated representative of a pharmacy or a wholesaler:

- 1. Must be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
- 2. Must be employed full-time in a managerial level position with the pharmacy or wholesaler;
- Must be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
- 4. May serve in this representative capacity for only one pharmacy or wholesaler at a time

A pharmacy or wholesaler that is required to designate a natural person as its representative shall not open or operate the pharmacy or wholesaler unless that representative is actually employed full-time in the operation of the pharmacy or wholesaler and is physically present at the site of the pharmacy or wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. If the natural person designated as the representative of a pharmacy leaves the employ of the pharmacy or wholesaler, thus leaving the pharmacy or wholesaler without a representative in violation of this section, the pharmacy or wholesaler shall:

- 1. Immediately cease conducting business until another qualified natural person is approved by the Board to serve as the representative of the pharmacy or wholesaler; and
- 2. Not later than 48 hours after that person leaves its employ, notify the Board that the person designated as the representative of the pharmacy or wholesaler has left the employ of the pharmacy or wholesaler.

Before a pharmacy or wholesaler, that is in violation of NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler) because the natural person designated as the representative of the pharmacy or wholesaler left the employ of the pharmacy or wholesaler, may continue conducting business:

- 1. The pharmacy or wholesaler must designate, on a form provided by the Board, a new natural person to serve as the representative of the pharmacy; and
- 2. The Board must approve the natural person so designated.

## **NEVADA STATE BOARD OF PHARMACY**

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

## **Designated Representative Application**

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information				
Name of Pharmacy/Wholesaler VistaPharm, LLC				
Pharmacy/Wholesaler License # (if applicable) WH02256				
Physical Address 13701 66th Street North				
City Largo	State FL			
Mailing Address (if different from physical address) $\frac{\text{c/o State}}{\text{City Florida}}$	State NY		Suite 3	
Telephone (845) 544-2482 Website www.vista	apharm.com			
Licensing Company Email VLL@slsny.com				
Section 2: Personal Information				
First Marcelino Middle	$\sim$ 1	Last Rodriguez Carras	quillo	
Alias(es, nicknames, name changes, etc.) Marcelin	10 Rodriguez			
Date of Birth SSN or ITIN		Sex ■M □ F □	□x	
Mailing Address Grand Ave Apt.				
City Pinellas Park		State FL Zip 3	3782	
Telephone Email mcr	rodriguez@paipharma.co	om		
Are you a citizen of the United States? ■ Yes □ No				
Section 3: Military Service (NRS 622.120)			Yes	No
1. Have you ever served on active duty in the Armed Forces of under conditions other than dishonorable? (Mark "Yes" if disc		arated from such service		X
2. Have you ever been assigned to duty for a minimum of 6 co component of the Armed Forces of the United States and sepa than dishonorable? (Mark "Yes" if discharged honorably.)				*
3. Have you ever served the Commissioned Corps of the Unite Corps of the National Oceanic and Atmospheric Administration commissioned officer while on active duty in defense of the United Conditions other than dishonorable? (Mark "Yes" if discharged	n of the United States in the nited States and separated	e capacity of a		X
			1	
Section 4: Federally Mandated Requirement (NRS 425.520, I	NRS 639.129)		Yes	No
Section 4: Federally Mandated Requirement (NRS 425.520, I 1. Are you the subject of a court order for the support of a c		ition 2.)	Yes	X

School Name University of Puerto Rico, Rio Piedras Campus				мм/үү-мм/үү) 84 - 1990
Address 6, 2526, 601 Av. Universidad	San Juan	Country Puerto Rico	State	00925
Diploma/Degree obtained, if any BS Chemistry				
School Name Jose Campeche				мм/үү - мм/үү) 80 - 1984
Calle Emilio Buitrago	San Lorenzo	Country Puerto Rico	State	Zip
Diploma/Degree obtained, if any High School Diploma				
School Name			From - To (	MM/YY – MM/YY)
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (I	MM/YY – MM/YY)
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (f	MM/YY – MM/YY
Address	City		State	Zip
Diploma/Degree obtained, if any				

From - To (MM/YY - MM/YY) 08/2021 - Present	Grand Ave, Apt	City Pinellas Park	State FL	Zip 33782
From - To (MM/YY - MM/YY) 02/2018 - 08/2021	Martin Luther King St N	St. Petersburg	State FL	Zip 33716
From - To (MM/YY - MM/YY) 05/2004 - 02/2018	Address Sabanera del Rio,	City Country Gurabo Puerto Rico	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY - MM/YY)	Address	City	State	Zip

pharmacies (NAC 639.5005) or record keeping related to, pre-	wholesalers (NAC 639.593	of that he or she has been employeds) in a capacity related to the disp with the most current, list your ho	ensing and distribut	ion of, and
above. Business Name				MM/YY – MM/YY)
VistaPharm, LLC			11/2022	- Present
Business Address		City	State FL	Zip 33771
13701 66th Street North	L must	Largo		Employed Hours
Phone (727) 530-1633	Site Quality Leade	er, Designated Representative	~ 40 hrs	
and provide mitigation strategies for any	compliance risks. Development a	of the Quality Management System (QMS). C nd implementation of site's inspection readi eraction with third parties to include FDA au	ness plans (e.g. FDA, DEA.	vs to identify, evaluat Direct the activities o
Business Name			From - To (I	MM/YY – MM/YY)
VistaPharm, Inc.			02/2018	- 11/2022
Business Address 13701 66th Street North		City Largo	State FL	<sup>Zip</sup> 33771
Phone (727) 530-1633	Title Director of Quality	Control	Number of ~ 9,877	Employed Hours hrs
of over 30 associates). Lead the implem	entation of Empower III CDS, inclu	and test methods execution for Raw Materia ding the implementation of new HPLC and G aboratory work center and daily huddle mee	iC systems, assuring the re etings	stability testing (team equired validation and
Business Address		City	State	Zip
Phone	Title		Number of	Employed Hours
Description of Duties				
Business Name			From - To (	MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title		Number of	Employed Hours
Description of Duties				
Business Name			From - To (	MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title		Number of	Employed Hours
Description of Duties				
	Continue on next	page if additional space is needed.		

usiness Name			From - To (MI	M/YY – MM/YY)
usiness Address		City	State	Zip
none	Title		Number of Er	nployed Hours
escription of Duties				
usiness Name			From - To (M	M/YY – MM/YY)
Susiness Address		City	State	Zip
hone	Title		Number of E	nployed Hours
Description of Duties				
Business Name			From - To (M	M/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title		Number of E	mployed Hours
Description of Duties				
Business Name			From - To (N	IM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title		Number of E	mployed Hours
Description of Duties				
Business Name			From To (N	MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title	•	Number of	Employed Hours
Description of Duties				
	Property and Property		itional space is peeded	
Mal	ke copies of this page OR use	a separate piece of paper if add	itional space is needed.	

Sect	tion 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1.	Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		1
2.	If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?  N/A		
3.	Have you ever had a civil or criminal record expunged or sealed by a court order?		1
1.	Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		1
5.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		1
5.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		~
7.	Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		~
8.	Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		~
9.	Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		~
10.	Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		~

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

eason/Charge laintiff/Defendant/Clain lame of Business/Indust	cry/Entity	Governing,	licensing, Arresting Presi		ration/Bankruptcy	
aintiff/Defendant/Clain ame of Business/Indust	cry/Entity			Lawsuit/Arbit	ration/Bankruptcy	
ame of Business/Indust	cry/Entity			Lawsuit/Arbit	ration/Bankruptcy	
me of Business/Indust	cry/Entity					
Provide explar	nation below:					

Date

Original Signature (electronic, copies or stamps not accepted)

I, Marcelino Rodriguez Carrasquillo	, certify that as the designated representative for
VistaPharm, LLC	
that I (initial that you have read and meet the fo	ollowing requirements) (NAC 639.5005, NAC 639.5935):
related to the dispensing and distribution of the dispensing and distribution of the dispensing and distribution of the dispension of the	ast 6,000 hours in a pharmacy or with a wholesaler in a capacity of, and recordkeeping related to, prescription drugs. It is a ware of the actual daily operations of the pharmacy or wholesaler a managerial level position with the pharmacy or wholesaler; it is of the pharmacy or at the facility of the wholesaler during regular of the representative is authorized, including sick leaves, vacation we capacity for only one pharmacy or wholesaler at a time.
Marcelino Rodriguez Carrasquillo	
Print Name (First, Last)	12 December 2022

Designated Representative Application (Applicant's Initials

Date

Original Signature (electronic, copies or stamps not accepted)

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Marcelino Rodriguez Carrasqillo	
Print Name (First, Last)	12 Pecember 2022
Maril 1	12 Pecember WLL
Original Signature (electronic, copies or stamps not accepted)	Date
Please have this section completed in the presence of a Notary P	ublic.
State of Florida ss. County of	Pihellas
foregoing application and know the contents thereof; that the state and contain a full and true account of the information requested; knowledge that misrepresentation or failure to reveal information denial or revocation of the license, registration, permit, certificate	that I executed this statement with the requested may be deemed sufficient cause for
Original Signature Marcelino Rodriguez Carrasqillo	Date
Subscribed and Sworn to before me this 13th day of Decemb	er
Symm	
Notary Public Signature	
10/10/10	M. CRAVEN

Comm# HH235899 Expires 3/19/2026

## June 2023 Temporary Licenses since the last Board Meeting

Name	License Type	
Darlene Lawson	Pharmacist	
Ryan Fennick	Pharmacist	
Michael Choe	Pharmacist	
Dustin Hirsh	Pharmacist	
Joseph McDonald	Pharmacist	
Ilirjana Amzovski	Pharmacist	
Crystal Isaacs	Pharmacist	
Kristina Wallace	Pharmacist	
Annie Chhay	Pharmacist	
Mariam Ayoub	Pharmacist	
Can Ergenekan	Pharmacist	
Helga Jorge	Pharmacist	
Derek Hendry	Pharmacist	
Amy Moore	Pharmacist	
Roman Kulchitskiy-Gust	Pharmacist	
David Joseph	Pharmacist	
Connor Aldridge	Pharmacist	
Hitesh Patel	Pharmacist	
Timothy Young	Pharmacist	
Connor Wilson	Pharmacist	
Doris Glasu	Pharmacist	
Adonis Ducre	Pharmacist	
Johanna Lopez	Pharmacist	
Yassmine Sianaki	Pharmacist	
Desiree Hamler	Pharmacist	

2023 - NVBOP Business Address Change Only				
Date of Request	Business Name	License Number	New Location Address	
5/2/2023	Lincare Inc	MP00297	2177 W Williams Ave Fallon, NV 89406	