

TEXAS FORENSIC SCIENCE COMMISSION

Justice Through Science

FINAL REPORT ON SELF-DISCLOSURE
NO. 21.41, NMS LABS (SEIZED DRUGS)

January 21, 2022



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I. COMMISSION BACKGROUND

A. History and Mission of the Texas Forensic Science Commission

The Texas Forensic Science Commission (“Commission”) was created during the 79th Legislative Session in 2005 with the passage of HB-1068. The Act amended the Texas Code of Criminal Procedure to add Article 38.01, which describes the composition and authority of the Commission.¹ During subsequent legislative sessions, the Texas Legislature further amended the Code of Criminal Procedure to clarify and expand the Commission’s jurisdictional responsibilities and authority.²

Texas law requires the Commission to “investigate, in a timely manner, any allegation of professional negligence or professional misconduct that would substantially affect the integrity of the results of a forensic analysis conducted by a crime laboratory.”³ The Commission is also required to develop and implement a reporting system through which a crime laboratory must report professional negligence or professional misconduct and require crime laboratories that conduct forensic analyses to report professional negligence or professional misconduct.⁴

The term “forensic analysis” is defined as a medical, chemical, toxicological, ballistic, or other expert examination or test performed on physical evidence, including DNA evidence, for the purpose of determining the connection of the evidence to a criminal action.⁵ The statute excludes certain types of analyses from the “forensic analysis” definition, such as latent fingerprint analysis, a breath test specimen, and the portion of an autopsy conducted by a medical examiner or licensed

¹ See, Act of May 30, 2005, 79th Leg., R.S., ch. 1224, § 1 (2005).

² See e.g., Acts 2013, 83rd Leg., R.S., ch. 782 (S.B. 1238) §§ 1-4 (2013); Acts 2015, 84th Leg., R.S., ch. 1276 (S.B. 1287) §§ 1-7 (2015); TEX. CODE CRIM. PROC. art. 38.01 § 4-a(b) (2010).

³ TEX. CODE CRIM. PROC. art. 38.01 § 4(a)(3) (2019).

⁴ *Id.* at § 4(a)(1)-(2) (2019). Additionally, pursuant to the Forensic Analyst Licensing Program Code of Professional Responsibility, member of crime lab management shall make timely and full disclosure to the Texas Forensic Science Commission of any non-conformance that may rise to the level of professional negligence or professional misconduct. See, 37 Tex. Admin. Code § 651.219(c)(5) (2018).

⁵ TEX. CODE CRIM. PROC. art. § 38.35(a)(4) (2015).

physician.⁶ The statute does not define the terms “professional negligence” and “professional misconduct.” The Commission has defined those terms in its administrative rules.⁷

The Commission has nine members appointed by the Governor of Texas.⁸ Seven members are scientists or medical doctors and two are attorneys (one prosecutor nominated by the Texas District and County Attorney’s Association and one criminal defense attorney nominated by the Texas Criminal Defense Lawyer’s Association).⁹ The Commission’s Presiding Officer is Jeffrey Barnard, MD. Dr. Barnard is the Chief Medical Examiner of Dallas County and Director of the Southwestern Institute of Forensic Sciences in Dallas.

B. Investigative Process

The Commission’s administrative rules set forth the process by which it decides whether to accept a complaint or self-disclosure for investigation as well as the process used to conduct the investigation.¹⁰ The ultimate result is the issuance of a final report. The rules also describe the process for appealing final investigative reports as well as any resulting disciplinary action.¹¹

D. Jurisdiction Applicable to this Self-Disclosure

The forensic discipline discussed in this final investigative report, seized drugs analysis, is subject to the accreditation authority of the Commission. The disclosing laboratory in this matter,

⁶ For complete list of statutory exclusions see TEX. CODE CRIM. PROC. art. 38.35 (a)(4)(A)-(F) and (f) (2015).

⁷ “Professional misconduct” means the forensic analyst or crime laboratory, through a material act or omission, deliberately failed to follow the standard of practice that an ordinary forensic analyst or crime laboratory would have followed, and the deliberate act or omission would substantially affect the integrity of the results of a forensic analysis. An act or omission was deliberate if the forensic analyst or crime laboratory was aware of and consciously disregarded an accepted standard of practice required for a forensic analysis. “Professional negligence” means the forensic analyst or crime laboratory, through a material act or omission, negligently failed to follow the standard of practice that an ordinary forensic analyst or crime laboratory would have followed, and the negligent act or omission would substantially affect the integrity of the results of a forensic analysis. An act or omission was negligent if the forensic analyst or crime laboratory should have been but was not aware of an accepted standard of practice. 37 Tex. Admin. Code § 651.302 (7) and (8) (2020).

⁸ TEX. CODE OF CRIM. PROC. art. 38.01 § 3 (2019).

⁹ *Id.*

¹⁰ *See*, 37 Tex. Admin. Code § 651.304-307 (2019).

¹¹ *Id.* at § 651.309; *Id.* at § 651.216.

NMS Labs, LLC (“NMS”), is accredited by the Commission, the American Board of Forensic Toxicology (“ABFT”), and the ANSI-ASQ National Accreditation Board (“ANAB”) under the International Organization for Standardization (“ISO”) accreditation standard 17025: 2017.¹²

E. Limitations of this Report

The Commission’s authority contains important statutory limitations. For example, no finding by the Commission constitutes a comment upon the guilt or innocence of any individual.¹³ The Commission’s written reports are not admissible in civil or criminal actions.¹⁴ The Commission has no authority to subpoena documents or testimony. The information gathered in this report has not been subject to the standards for admission of evidence in a courtroom. For example, no individual testified under oath, was limited by either the Texas or Federal Rules of Evidence (*e.g.*, against the admission of hearsay) or was subject to cross-examination under a judge’s supervision.

III. BACKGROUND AND FACTS

A. Legalization of Hemp and Impact on Forensic Laboratories

On December 20, 2018, the Agriculture Improvement Act of 2018 legalized the industrial production of hemp nationwide while simultaneously removing hemp from the Controlled Substances Act. Legislators reclassified hemp as an agricultural product and charged the United States Department of Agriculture (USDA) with publishing regulations governing the industry. The legislation delegated to states and Indian tribes through their departments of agriculture broad authority to regulate and limit the production and sale of hemp products within their own borders.

¹² ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories. *See*, <http://www.txcourts.gov/fsc/accreditation/> for a list of accredited laboratories.

¹³ TEX. CODE OF CRIM. PROC. art. 38.01 § 4(g) (2019).

¹⁴ *Id.* at § 11 (2019).

Under the Texas Hemp Bill (HB-1325) and many similar bills adopted in state legislatures across the country, marijuana and Δ 9-tetrahydrocannabinol, or Δ 9-THC (excluding the limited Δ 9-THC in hemp), remain illegal substances. What changed under Texas law, similar to the federal legislation, is that “hemp” is now *excluded from* the definition of “controlled substance” and “marijuana.”¹⁵

Hemp and marijuana both come from the cannabis plant. Different parts of the plant have different Δ 9-THC concentrations and various factors may impact whether a particular plant sample exceeds the statutory Δ 9-THC limit of 0.3%. For example, if a hemp farmer waits too long to harvest, the Δ 9-THC in the crop may exceed the legal threshold. Before hemp was legalized, laboratories simply reported a positive result if cannabinoids were present. When no cannabinoids were detected, the laboratory reported no controlled substance. The laboratories were not required to *quantitate* Δ 9-THC, i.e., to *identify the amount of* Δ 9-THC as distinguished from other cannabinoids. Laboratories offering analysis in Texas must now establish that the quantity of Δ 9-THC in any particular evidentiary sample *exceeds the statutory threshold* of Δ 9-THC for hemp. However, a full quantitative analysis is expensive and time-consuming, and thus laboratories have sought to implement methods that accurately and reliably distinguish hemp from marijuana without performing a full quantitation.

The United States Drug Enforcement Administration (DEA) was the first to deploy a “decision point” gas chromatography/mass spectrometry (GC/MS) assay as part of their analytical scheme to differentiate hemp from marijuana. In addition to GC/MS, the DEA also uses a 4-AP color test, the purpose of which is to allow an analyst to quickly identify by observing a color

¹⁵ Hemp is defined as “the plant *Cannabis sativa* L. and any part of that plant, including the seeds of the plant and all derivatives, extracts, cannabinoids, isomers, acids, salts of isomers, whether growing or not, with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.”

change (or lack thereof) which samples contain Δ 9-THC greater than cannabidiol (“CBD”). After the DEA released its method, various laboratories across the country adopted methods for differentiating hemp from marijuana that are similar—though not necessarily the same as—the DEA’s method. In Texas, use of a GC/MS assay for differentiating hemp from marijuana was the subject of an inter-laboratory study facilitated by Sam Houston State University (“SHSU”) and the Commission. A sample analytical protocol for the qualitative identification of marijuana using GC/MS was published in September 2020 and is attached as **Exhibit A**. Participants in the inter-laboratory study presented data and related observations at various meetings including the American Academy of Forensic Sciences (“AAFS”) Annual Meeting in 2021. A retrospective data review following the inter-laboratory study will be presented at the AAFS Annual Meeting in 2022.

B. NMS Hemp/Marijuana Differentiation Method

NMS uses a gas chromatography mass spectrometry (GC/MS) detection method to analyze plant material and liquids.¹⁶ The hemp-marijuana differentiation (“HMD”) assay is performed in scan mode, with quantitation performed on a target ion. Identification is based on the full scan spectrum. The laboratory adopted an administrative cutoff of 1% Δ 9-THC for reporting purposes, which is well above the statutory threshold of 0.3%. The use of administrative cutoffs higher than the statutory threshold of 0.3% is a common safeguard used by forensic laboratories in Texas and nationwide.

¹⁶ Though NMS subsequently added a 4-AP color test to its analytical scheme, the laboratory was not using color tests as part of its HMD method when the issues described in this report were identified.

C. CBD to Δ 9-THC Conversion Using NMS HMD Method

It is a commonly known phenomenon that CBD can be converted to Δ 9-THC when an underivatized sample is analyzed at the high temperature necessary for GC/MS analysis. In other words, a plant or liquid item of evidence containing CBD can arrive at the laboratory with a certain amount of Δ 9-THC, and that amount can be *increased* by the high heat used in the testing process. During qualification of two new GC/MS instruments in the laboratory's DFW and El Paso locations, analysts noted a number of samples that resulted in a total Δ 9-THC concentration *less* than 1% on one instrument and *greater* than 1% on another instrument. These samples contained large amounts of CBD (>14%).

Upon discovery of the issue, NMS temporarily paused testing using the HMD method. The seized drugs technical director then conducted a series of experiments to: 1) determine what the likely explanation for the discrepancy between instruments was; 2) assess the potential impact on previously reported casework; and 3) provide a recommendation on the most prudent course of action moving forward.

The laboratory's initial hypothesis was that the CBD to Δ 9-THC conversion was attributable to the differences in the length of time and number of samples analyzed since the last injection port maintenance. Injection port maintenance decreased the amount of Δ 9-THC artifactually formed from CBD.¹⁷ Production of Δ 9-THC as an artifact (inside the instrument) using their method increased with higher sample volume, demonstrating the need for vigilance in injection port maintenance especially for instruments running a high volume of samples. During this time period, the number of exhibits tested using the HMD method rose dramatically from 350

¹⁷ As a precaution, at an analyst's discretion, samples with large amounts of CBD and small amount of Δ 9-THC were run on a low temperature method to confirm the presence of Δ 9-THC. However, the laboratory observed confirmable, artifactual formation of Δ 9-THC on the low temperature method when the amount of CBD present was around 10% and the injection port needed maintenance.

exhibits in 2019 to nearly 6,000 exhibits in 2020. The samples tested also showed increases in CBD concentration throughout the same time period, as products with higher CBD concentration products entered the market.

NMS also observed that in some samples run during the experimentation period, the amount of $\Delta 9$ -THC formed was higher than what was originally observed during method validation in 2019. During validation under the NMS test conditions, CBD concentrations of less than or equal to 20% were associated with significant artifactual $\Delta 9$ -THC formation. Those samples then required additional evaluation before reporting. However, in the experiments run by the technical director after observing discrepancies in results from the DFW and El Paso instruments, significant artifactual formation occurred with much lower CBD concentrations. For example, in one instance a 10% CBD standard formed 0.6% $\Delta 9$ -THC. Though this amount would not be sufficient to push a sample that arrived at the laboratory with $\Delta 9$ -THC below the legal limit (0.3%) to a point where it would exceed the administrative cutoff (1%), it was still greatly concerning. Moreover, $\Delta 9$ -THC could be qualitatively identified and reported as $\Delta 9$ -THC “confirmed” in standards that originally contained no $\Delta 9$ -THC and a relatively low concentration (1%-2%) of CBD. In other words, a sample analyzed under the testing conditions that were originally validated by NMS could arrive at the laboratory with no $\Delta 9$ -THC and low concentrations of CBD, yet $\Delta 9$ -THC could be observed through the testing process (attributable to artifactual formation).

IV. CASE REVIEW AND LEGAL DISCLOSURES BY NMS

The seized drugs technical director assessed the impact of the observations described above on previously reported casework. She determined the conversion of CBD to $\Delta 9$ -THC may have

resulted in erroneous identifications of Δ 9-THC or an inaccurate hemp-marijuana differentiation result in the following situations:

1. Exhibits with 1-20% CBD, where subtracting 10% of the CBD concentration from the Δ 9-THC concentration changed the hemp marijuana differentiation result from $> 1\%$ to $< 1\%$. The technical director identified sixty-one such cases (with a total of 80 exhibits). NMS notified all affected agencies for these cases on June 16, 2021. (*See, Exhibit B*). The notification included a general disclosure describing the technical issue as well as a recommendation the client return the evidence for re-analysis.
2. Exhibits where Δ 9-THC was not initially present in non-plant exhibits meeting all three of the following criteria: CBD $> 1\%$, Δ 9-THC $< 1\%$, and CBD $> \Delta$ 9-THC. The technical director identified eleven cases (with a total of 11 exhibits) that met these criteria. Results would have been reported as Δ 9-THC “confirmed” and hemp marijuana $< 1\%$ where the technical leader believed it was unclear whether Δ 9-THC was actually present prior to GC/MS analysis.

The laboratory realized that quantitative results may be unobtainable for a number of resubmissions under the new reporting guidelines related to CBD and Δ 9-THC concentrations. Therefore, all resubmitted exhibits were analyzed by the laboratory’s Δ 9-THC quantitation by HPLC-DAD (high performance liquid chromatography-diode array detection) method, as CBD to Δ 9-THC conversion does not occur with this instrumentation. Plant-material cases reported with a hemp marijuana differentiation value of $< 1\%$ and a marijuana identification of “inconclusive” did not need to be remediated as Δ 9-THC was not reported as confirmed for these cases.

3. Exhibits where the laboratory confirmed Δ 9-THC identification via a positive Duquenois-Levine color test and GC/MS and the submitting agency did not request quantitation of Δ 9-THC or hemp marijuana differentiation. However, the laboratory determined it was not feasible to re-evaluate *all* cases where this testing has been performed and noted that this type of testing has been universally performed in the forensic chemistry field for decades.

The laboratory issued notification in all the cases identified as having been affected. (**Exhibit C**). Clients were encouraged to submit their cases for re-testing. The laboratory reworked 33 cases out of 71 identified. Six cases resulted in a change in conclusions (**Exhibit D-**

Spreadsheet Column P). The laboratory issued corrected reports for these cases.¹⁸

V. ROOT CAUSE ANALYSIS

The laboratory's initial root cause focused on two areas: (1) the significant increase in sample volume analyzed by NMS from 2019 to 2020 (350 to 6,000 exhibits); and (2) the increase in CBD content in products introduced to the market after the legalization of hemp. The Commission advised the laboratory to revise its root cause analysis to emphasize the following additional significant factors observed during the course of the laboratory's internal investigation: (1) the impact of injection port maintenance (or lack thereof) on CBD to $\Delta 9$ -THC conversion; and (2) the critical importance of conducting an independent and rigorous validation each time the method is deployed. NMS provided an updated root cause analysis to the Commission in December 2021. (*See Exhibit E.*)

VI. CORRECTIVE AND PREVENTIVE ACTIONS

NMS resumed testing using the HMD method for plants and liquids in May 2021. The laboratory incorporated the following initiatives to improve its HMD method and related reporting:

- (1) Injecting a 5% CBD conversion control near the beginning of the run, after every 10 samples/reagent blanks, and at the end of the run. If the amount of $\Delta 9$ -THC is equal to or exceeds 0.100%, the control is considered unacceptable. Samples must be bracketed by two acceptable controls in order for the data to be used for reporting.¹⁹
- (2) Added a reporting limit at 0.150%. When $\Delta 9$ -THC concentration is less than 0.150% in non-plant matrices (liquids and waxes), the result is reported as "not present above the reporting limit," as opposed to "confirmed." In plant matrices, marijuana is reported as "inconclusive." Additionally, HMD and identification results from this method are not reported if CBD is greater than or equal to 5% and $\Delta 9$ -THC is less than 6%. In plant matrices, marijuana is reported as "inconclusive."

¹⁸ Initially the laboratory intended to use its updated HMD method to retest exhibits. However, the technical director realized quantitative results may be unobtainable for a number of the resubmissions under the new reporting guidelines related to CBD and $\Delta 9$ -THC concentrations. Instead, to enact a streamlined and efficient process, all resubmitted exhibits are analyzed by the lab's $\Delta 9$ -THC quantitation by HPLC-DAD method. CBD to $\Delta 9$ -THC conversion does not occur using this instrument.

¹⁹ There are two situations where cases may be reported when a conversion control fails: when the sample contains no CBD or CBD is less than 1% and total $\Delta 9$ -THC is greater than 1%. This is because CBD values less than 1% do not significantly affect the $\Delta 9$ -THC result.

- (3) Instrument maintenance has been increased to at least weekly and more frequently if run controls were failing. The laboratory is also tracking trends, and if a run fails due to high rate of CBD conversion, maintenance must be performed before analyzing samples using the method.
- (4) For both HMD and $\Delta 9$ -THC identification-only casework, the laboratory validated an improved TLC method utilizing a different mobile phase (*i.e.*, solvent that moves through the paper, carrying difference substances with it). (**Exhibit E.**) The mobile phase effectively separates $\Delta 9$ -THC and CBD, thereby ensuring the identification of $\Delta 9$ -THC when it is present by both GC/MS and TLC.
- (5) Validating a 4-AP color test. With this test, the color change is dependent on the ratio of CBD to $\Delta 9$ -THC in the sample. This allows the quick identification of samples where $\Delta 9$ -THC is greater than CBD, with a positive 4-AP color test confirming that the $\Delta 9$ -THC identified in the hemp marijuana differentiation analysis was present in the sample and not there as a result of conversion. Incorporating 4-AP in the testing scheme also decreases the number of cases that require TLC (a more involved process than the simple color test) and is beneficial in cases where there is no CBD, but $\Delta 9$ -THC isn't readily present on the TLC plate.
- (6) As a more permanent solution, the laboratory plans to transition to a derivatized GC/MS method for HMD analysis. This will require the acquisition of additional instrumentation. The laboratory expects acquisition and training to take 6-7 months.
- (7) For future improvements of $\Delta 9$ -THC testing methods, additional validation experiments will be performed on all instruments on which the method will be run with the goal of identifying any possible stability and/or breakdown/conversion issues with other cannabinoids. While comprehensive validation of the method will be run on one instrument at NMS' Willow Grove Laboratory, instead of verification consisting only of comparison samples on other instruments, an expanded verification of test performance on any instrument at any site on which the test is to be performed will occur. Validation experiments will be expanded to include imprecision, accuracy, robustness, and carryover studies in addition to comparison data. Changes to the validation SOP reflecting these changes are in process.
- (8) Finally, the laboratory plans to discontinue THC identification-only and transition all clients to HMD analysis.

VII. COMMISSION INVESTIGATION

A. Investigative Panel and Document Review

At its July 16, 2021, quarterly meeting, the Commission voted to form an investigative panel (“Panel”) to review NMS’ disclosure and issue recommendations. The Panel consists of commissioners Jasmine Drake, Ph.D., Patrick Buzzini, Ph.D., Sarah Kerrigan, Ph.D., and Jarvis Parsons, Esq.

The Panel and Commission staff reviewed all documents provided by NMS, including the initial self-disclosure, the laboratory’s corrective action and corresponding exhibits, responses to the Panel’s questions, and the laboratory’s revised corrective action and corresponding exhibits.

B. Interviews/Discussions with NMS and Panel

The Commission notified NMS it accepted the self-disclosure for investigation on July 22, 2021. (**Exhibit F**) The Panel met virtually on September 2, 2021 and directed staff to pose certain follow-up questions to NMS regarding the laboratory’s self-disclosure and supporting documents. The Panel requested additional information as described in the attached **Exhibit G**.

C. NMS’ Responses to Questions by the Panel

On September 14, 2021, staff sent specific questions to NMS via e-mail and on October 1, 2021, NMS (Barry Logan) responded via e-mail with answers as noted in **Exhibit G**.

VIII. FINDINGS RE: PROFESSIONAL NEGLIGENCE/MISCONDUCT

The Commission finds no evidence to support a finding of “professional negligence” or “professional misconduct” as those terms are defined in the Texas Administrative Code.²⁰ The

²⁰ 37 TEX. ADMIN. CODE § 651.302(7) and (8) (2020).

Commission commends NMS for bringing concerns regarding its HMD method to the Commission's attention. The observations highlight issues related to instrument maintenance and method validation that apply to all laboratories performing seized drug analysis

IX. RECOMMENDATIONS/OBSERVATIONS

All forensic laboratories in Texas that perform any type of HMD method should read this report and the accompanying exhibits, as well as review the information contained in the document entitled "Analytical Protocol for the Qualitative Identification of Marijuana using GC/MS" (**Exhibit A**) distributed by the Commission to the Texas Association of Crime Laboratory Directors in September 2020.²¹ By proactively alerting the Commission to the issues described in this report, NMS highlighted important considerations for all laboratories. The following are valuable reminders:

- (1) Full independent and rigorous validation is needed to address limit of detection, selectivity, precision, accuracy, dilution integrity, carryover, extract stability, decarboxylation efficiency, measurement uncertainty, and potential interference from CBD.
- (2) It is critical for robust quality assurance practices to be incorporated as a component of any HMD method, especially with respect to factors such as injection port maintenance and selection of inlet liner.
- (3) The inclusion of a CBD control for risk mitigation is highly recommended and should be adjusted as dictated by the laboratory's ongoing monitoring of the method.
- (4) Analysts may need additional training to properly apply the method as well as to flag any issues of concern when they arise, as NMS did in this disclosure.
- (5) Laboratory standard operating procedure must be developed based on method performance in the laboratory where the method is being run.
- (6) It may be useful for laboratories to incorporate personnel from other forensic disciplines such as toxicology during method validation.

²¹ It is important to note that while the Commission helped to facilitate the inter-laboratory validation study referenced throughout this report, the accredited laboratories employing the method are ultimately responsible for ensuring validity and reliability during routine use.

NMS has proposed significant enhancements to its validation process that, in combination with more frequent instrument maintenance, should have flagged the issues that prompted this disclosure had they been in place at the time. NMS plans to expand validation experiments to include imprecision, accuracy, robustness, and carryover studies in addition to comparison data. These are all critically important and helpful expansions, and what NMS proposes is compliant with existing published seized drugs standards.²² However, the Commission notes that the details of these plans, such as the number of samples to be run, require some degree of risk assessment. Judgments made with respect to the details in any validation plan can be critical in determining whether the plan is fit for its intended purpose. All laboratories should take the information contained in this report into account as they engage in ongoing investigation and monitoring of their own HMD methods.

²² See e.g., ASTM E2549-14, titled “Standard Practice for Validation of Seized-Drug Analytical Methods.”

EXHIBIT A

For a copy of the method, please contact the laboratory.

EXHIBIT B



June 16, 2021

Corrective Action 25349: DISCLOSURE REGARDING CONVERSION OF CBD TO THC

Greetings,

In the presence of heat, CBD, a non-scheduled component of some hemp and marijuana derived products, can convert to delta-9-THC (THC), a Schedule I controlled substance. With higher volume testing and more products containing elevated levels of CBD, we have recently observed a higher rate of CBD to THC conversion than previously noted in the original validation of our hemp-marijuana differentiation (HMD) test. The conversion of CBD to THC takes place in the injection port of the instrumentation commonly used for this test, and, as noted in a Sam Houston (Texas) State University multi-lab validation study, can occur in any laboratory performing testing on this platform.

Following discovery of this increased risk of conversion, NMS Labs temporarily suspended HMD testing pending an evaluation of the issue. Testing has resumed with the use of additional CBD controls and increased frequency of injection port maintenance in order to better detect CBD to THC conversion. The threshold for test cancellation has been lowered from 20% CBD to 5% CBD to address the risk of conversion.

We have retrospectively reviewed over 10,000 HMD exhibits and have identified less than 75 cases where reporting may have been affected by the conversion of CBD to THC.

An additional letter will contain the request for retesting and a complete listing of your agency's impacted cases. We recommend that these cases be returned to NMS Labs for retesting under our new HMD protocol. This testing will be performed at no charge.

Regards,

A handwritten signature in black ink, appearing to read "Erin A. Spargo".

Erin A. Spargo, PhD, F-ABFT
Assistant Laboratory Director
NMS Labs
erin.spargo@nmslabs.com
215-366-1227

EXHIBIT C

June 16, 2021

XXXX Police Department
Attn: XXXX
XXXXXXXXXXXX
XXXXXX, XX XXXXX

Corrective Action 25349: Conversion of CBD to THC

Dear XXXX:

NMS Labs has identified an issue with cases that contain high concentrations of CBD, which were analyzed by our hemp-marijuana differentiation (HMD) test. It has been observed that CBD can be converted into a small percentage of THC more frequently than originally noted during method validation (refer to "Disclosure Regarding Conversion of CBD to THC").

We have identified 1 case submitted by XXXXX Police Department where reporting may have been affected by this issue. We recommend that this case be retested under our new HMD protocol. This testing will be performed at no charge. The list of case(s) is reflected below:

Cust. ID	Name	Case ID	NMS Workorder
XXXXXX	XXXXX Police Department	21-XXXXX	21-DFW-XXXXX

Please contact Forensic Client Support at 866-522-2216 for submission/technical questions and/or your local territory manager Kacie Tross (email: Kacie.Tross@nmslabs.com) at NMS Labs.

Regards,

A handwritten signature in black ink, appearing to read "Erin A. Spargo".

Erin A. Spargo, PhD, F-ABFT
Assistant Laboratory Director
NMS Labs
erin.spargo@nmslabs.com
215-366-1227

EXHIBIT D

Act. Number	Client Name	Agency Case ID	NMS Case ID	Item Number	Testing in Question	Case Resubmitted Date	Date Arrived at WLG	Due Date	Analyst Initials	Date Reported	Comments	Original Results (HMD)	Retest Results (Full Quantitation)	Results Agree?	Conclusions Agree?
20151	United States Postal Inspection Service	1	20-WLG-012136	1	HMD			2/30/1900						Y	Y
20151	United States Postal Inspection Service	1	20-WLG-020442	4,8	N/A	N/A - Full Quant Already Performed	N/A	N/A	N/A	N/A	N/A	N/A	N/A	Y	Y
40043	Upper Dublin Twp. Police, Ft. Washington	2020-10969	20-WLG-018337	10,16	HMD	6/22/21	6/22/21	7/22/2021	SLN	8/3/2021		(10) $\pm 1.00\%$ (41) $\pm 1.00\%$	(10) 0.45% (+/- 0.06%) (51) 0.37 (+/- 0.025%)	N	Y
40928	Burlison Police Department, Burlison	20-001845	20-DFW-010644	2	HMD	8/30/21	9/3/2021	9/29/2021	SLN	9/29/2021	plant	$\pm 1.00\%$	Delta-9-THC: 0.25% (+/- 0.021%) THCA - Not present above reporting limit (0.15% by weight)	N	Y
40928	Burlison Police Department, Burlison	21-000222	21-DFW-002121	1	ID	8/30/21	9/3/2021	9/29/2021	SLN	9/29/2021	liquid	Delta-9-THC Confirmed Total Delta-9-THC $\leq 1.00\%$	Delta-9-THC: Unable to be determined due to interfering substances Delta-9-THC (Full quant) - Unable to be determined due to interfering substances THCA - None Detected	N	N
40928	Burlison Police Department, Burlison	21-000379	21-DFW-002475	2	HMD	8/30/21	9/3/2021	9/29/2021	SLN	9/29/2021	plant	$\pm 1.00\%$	0.38% (+/- 0.072%)	Y	Y
40942	S.T.O.P., Cleburne	20-0104	21-DFW-002488	1.1	HMD	8/31/21 Client declined to resubmit			#VALUE!					Y	Y
40949	North Richland Hills Police Dept., North Richland Hills	2020-03215	20-DFW-012673	1	HMD	6/30/21	7/1/2021	7/30/2021	SLN	8/4/2021		$\pm 1.00\%$ $\pm 1.00\%$	9.1% (+/- 1.5%) (10) (+/- 1.7%)	Y	Y
41468	Lewisville Police Department, Lewisville	20-09557	21-DFW-003759	1	HMD	6/21/21	7/8/2021	7/21/2021	SLN	8/4/2021		$\pm 1.00\%$		Y	Y
41560	Mesquite Police Department, Mesquite	19113999	20-DFW-007725	1	ID	6/24/21	7/1/2021	7/24/2021	SLN	7/22/2021		Delta-9-THC Confirmed: Total Delta-9-THC $\leq 1.00\%$	Delta-9-THC: None Detected	N	N
41568	Itasca County Sheriff's Office, Stateville	2000169	21-WIN-006991	1	ID			1/30/1900							
41588	Plano Police Department, Plano	20-66084	20-DFW-008615	2	ID	7/22/21	7/26/2021	8/21/2021	AAH	9/8/2021	Insufficient Material for Quant	Delta-9-THC Confirmed: Total Delta-9-THC $\leq 1.00\%$	Delta-9-THC: Unable to be determined due to interfering substances Total Delta-9-THC: Unable to be determined due to interfering substances	N	N
41612	Watauga Police Department, Watauga	200723044	21-DFW-004156	1	ID			1/30/1900							
41622	Moore County Sheriff's Office, Carthage	2020-03215	20-WIN-017087	1.1	HMD	9/1/21	9/7/2021	10/1/2021	SLN	9/30/2021	plant	$\pm 1.00\%$	Delta-9-THC: 0.30% (+/- 0.071%) THCA - Not present above reporting limit (0.15% by weight)	N	Y
41625	DFW Airport Police Department, DFW Airport	19-00865	20-DFW-007753	3	ID	7/9/21	7/16/2021	8/9/2021	SLN	8/5/2021		Delta-9-THC Confirmed, Total Delta-9-THC Below the reporting limit (0.15% by weight)	Delta-9-THC Confirmed: Total Delta-9-THC: Unable to be determined due to interfering substances	Y	Y
41625	DFW Airport Police Department, DFW Airport	20-02065	20-DFW-012895	1	HMD	7/9/21	7/16/2021	8/9/2021	SLN	8/4/2021		$\pm 1.00\%$	0.42% (+/- 0.061%)	N	Y
41625	DFW Airport Police Department, DFW Airport	19-01205	20-DFW-012902	1.2	HMD	7/9/21	7/16/2021	8/9/2021	SLN	8/12/2021		Delta-9-THC Confirmed Total Delta-9-THC $\leq 1.00\%$	Delta-9-THC - Quant not possible due to an interfering substance; THCA - None detected	N	N
41625	DFW Airport Police Department, DFW Airport	20-01988	20-DFW-012911	1	HMD	7/9/21	7/16/2021	8/9/2021	SLN	8/4/2021		$\pm 1.00\%$	1.4% (+/- 0.29%)	Y	Y
41625	DFW Airport Police Department, DFW Airport	20-02147	20-DFW-012915	1.2	HMD	7/9/21	7/16/2021	8/9/2021	SLN	8/4/2021		$\pm 1.00\%$	1.4% (+/- 0.29%)	Y	Y
41641	Hurst Police Department, Hurst	2020002931	20-DFW-012733	1.1	HMD	8/31/21 Client declined to resubmit			#VALUE!					Y	Y
145779	Ellis County Sheriff's Office, Waxahachie	20-11515	20-DFW-014620	1	HMD	7/13/21	7/16/2021	8/12/2021	SLN	8/4/2021		$\pm 1.00\%$	1.8% (+/- 0.29%)	Y	Y
145779	Ellis County Sheriff's Office, Waxahachie	20-11514	20-DFW-014629	4.5	HMD	7/13/21	7/16/2021	8/12/2021	SLN	8/4/2021		(4) $\pm 1.00\%$ (1) $\pm 1.00\%$	(4) 0.38% (+/- 0.056%) (1) 0.50% (+/- 0.086%)	N	Y
147595	Garza County Sheriff's Office, Post	2020-04-1019	20-DFW-008805	18	ID	8/26/21 - client needs to resubmit; waiting on client			#VALUE!						
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377	20-DFW-012728	2	HMD			10/16/2021							
148440	Garza County Sheriff's Office, Post	2020-03-1377													

EXHIBIT E

Corrective Action 25349 CBD to THC Conversion - ADDENDUM

Texas Forensic Science Commission 21.41

DESCRIPTION OF INCIDENT

GC/MS is the most common instrumentation used for the analysis of delta-9-THC (THC) in controlled substances laboratories and is used for Hemp/Marijuana Differentiation (HMD) and THC identification at NMS Labs. The HMD assay is performed in scan mode, with quantitation performed on a target ion. Identification is based on the full scan spectrum.

It is a known phenomenon that CBD can be converted to THC when an underivatized sample is run at the high temperatures necessary for GC/MS analysis. During the initial validation of the HMD GC/MS method in 2019, CBD concentrations of $\geq 20\%$ were associated with significant artifactual THC formation and samples required additional evaluation before reporting.

More recently, in reviewing comparison data to qualify GCMS07-DFW and GCMS04-ELP to analyze HMD casework, it was discovered that a number of samples resulted in a total THC concentration less than 1% on one instrument and greater than 1% when analyzed on another instrument. These samples contained large amounts of CBD ($>14\%$). It was hypothesized that the CBD was converting to THC during analysis and the difference in the amount of conversion was due to differences in the length of time/number of samples analyzed since the last injection port maintenance. Standards containing various amounts of CBD were prepared and analyzed over multiple days. In general, injection port maintenance decreased the amount of THC artifactually formed from CBD and the amount of THC started to increase as more samples were analyzed. However, additional investigation would be necessary to determine if specific guidelines regarding frequency and type of maintenance can be put into place.

In some experiments, the amount of THC formed was higher than what was originally observed during method validation. This could affect the decision point result in that samples that contained less than 1% total THC could be reported as greater than 1% total THC. In one instance, a 10% CBD standard formed 0.6% THC. Though this would not be enough to make a sample with THC present below the legal limit (0.3%) report as $\geq 1\%$, it is approaching the cut-off. In addition, THC could be qualitatively identified and therefore reported as THC "confirmed" in standards that originally contained no THC and contained a relatively low concentration (1%-2%) of CBD (i.e. the THC observed was all artifactual formation from the CBD). This would impact all THC qualitative analyses performed by GC/MS.

As a precaution, at an analyst's discretion, samples with large amounts of CBD and small amounts of THC could be run on a low temperature method to confirm the presence of THC. However, in these more recent experiments, confirmable artifactual formation of THC was observed on the low temperature method when the amount of CBD present was around 10% and the injection port needed maintenance. Again, additional investigation is required to determine when this method is a suitable alternative.

When this was discovered, all THC analyses and reporting were paused, except for in those situations denoted in the attached memo (Reporting HMD and Drug ID Cases Containing CBD and THC).

IMMEDIATE INVESTIGATION AND ACTION

As previously described, most THC analyses and reporting were paused at the time this issue was identified. S. Shuda, Technical Director, conducted experiments in order to provide a recommendation for a suitable approach to analysis moving forward; additionally, she assessed the impact on previously reported casework. Frequent discussions were held with laboratory management regarding an optimal testing scheme. The approach moving forward is discussed in the Preventive Action section. The impact on previously reported casework is described below.

S. Shuda reviewed HMD casework from the inception of the assay (> 10,000 exhibits since 2019). Based on her experiments, the conversion of CBD to THC may have resulted in an erroneous identification of THC or an inaccurate HMD result in the following situations:

1. The HMD result may have been incorrect in exhibits with 1-20% CBD, where subtracting 10% of the CBD concentration from the THC concentration changed the HMD result from > 1% to < 1%. Sixty-one cases (80 exhibits) met these criteria. Affected agencies were notified on 6/16/21. The notification included a general disclosure regarding the technical issue, as well as a recommendation to return the evidence for re-analysis (general disclosure letter and one de-identified client letter attached).

2. THC may have been identified when not initially present in non-plant exhibits meeting all three of the following criteria: CBD > 1%, THC < 1%, and CBD > THC. Eleven cases (11 exhibits) met these criteria. Results would have been reported as delta-9-THC "Confirmed" and HMD <1%; however, based on recent experiments, it is unclear whether delta-9-THC was present prior to GC/MS analysis. Affected agencies were notified on 6/16/21. The notification included a general disclosure regarding the technical issue, as well as a recommendation to return the evidence for re-analysis (memos referenced in #1).

Although, initially, we had planned to use the updated HMD testing methodology to retest exhibits, we realized that quantitative results may be unobtainable for a number of the resubmissions under the new reporting guidelines related to CBD and THC concentrations. Instead, to enact a streamlined and efficient process, all resubmitted exhibits will be analyzed by our THC Quantitation by HPLC-DAD method, as CBD to THC conversion does not occur with this instrumentation.

Plant-material cases reported with an HMD value of <1% and a marijuana identification of "Inconclusive" do not need to be remediated as delta-9-THC was not reported as confirmed.

The other category of casework that may have been affected by this conversion are exhibits where THC identification was confirmed via a positive Duquenois-Levine color test and GC/MS and no quantitation of THC or HMD was requested. It is not feasible to re-evaluate all cases where this testing has been performed. This is testing that has been universally performed in the forensic chemistry field for decades. As this is not an issue limited to NMS Labs, a communication has been drafted to the Texas Forensic Science Commission. In it, we request their input on whether we need to notify client agencies who have historically received reports of marijuana identification based on GC/MS and color testing, that the THC identification could be a false positive depending on the presence of CBD in those exhibits.

As noted in the root cause analysis, cases with higher concentrations of THC have been observed more frequently recently, so it is not likely that an abundance of cases were historically affected.

ROOT CAUSE ANALYSIS COMMENTS

Although the conversion of CBD to THC was not unexpected, this phenomenon was not observed to occur to a significant degree during method validation when CBD concentrations were <20%. At the time of validation however, the number of samples containing higher amounts of CBD was low and as samples had not yet been submitted for testing, the throughput on the instrument was also low. The number of exhibits tested for HMD rose from approximately 350 exhibits in 2019 to nearly 6000 exhibits in 2020. Most exhibits contained 0-1% CBD over the time frame evaluated (greater than 80% of all exhibits in each quarter); however, the number of exhibits that contained > 5% CBD rose from 5.4% in 2019 Q1-Q3 (2 exhibits) to 12% in 2019 Q4 -2021 Q1 (904 exhibits). We believe the high throughput analysis, with concentrations of CBD having increased in recent years, are the root cause of the issue. As higher CBD concentration products are newer to the market, extensive research has not yet been performed and we were unaware of the increased risk of conversion.

Maintenance of GCMS instruments previously was performed weekly or could be waived if the runs were performing appropriately for identification based on the Drug ID Test Mix. CBD to THC conversion rates were not tracked because it was demonstrated during validation that conversion was not significant at CBD concentrations less than 20%; per NMS Labs protocols, a THC concentration was not reported if CBD was $\geq 20\%$.

PREVENTIVE ACTION

Laboratory management conducted routine meetings to determine the best approach to THC testing moving forward, guided by technical input from S. Shuda.

Additional experiments resulted in the inclusion of additional controls in the HMD assay, as well as updated reporting guidelines related to the amount of CBD and THC in the exhibit:

Specifically, a 5% CBD conversion control is injected near the beginning of the run, after every 10 samples/reagent blanks, and at the end of the run. The amount of delta-9-THC present in the conversion control must be less than 0.100%. If the amount of delta-9-THC is equal to or exceeds 0.100%, the control is considered unacceptable. Samples must be bracketed by two acceptable controls in order for the data to be used for reporting. There are only two situations where cases may be reported when a conversion control fails: when the sample does not contain CBD or if the CBD is less than 1% and the total delta-9-THC is greater than 1%. (It has been shown that CBD values less than 1% do not significantly affect the delta-9-THC result. There were no instances of a 1% CBD standard producing delta-9-THC above the reporting limit in in-house laboratory experiments.)

A reporting limit of 0.150% has been established for Delta-9-THC. When the Delta-9-THC concentration is less than 0.150% in non-plant matrices, the result is reported as "Not present above the reporting limit (0.15% by weight)"; it will no longer be reported as "Confirmed". In plant matrices, marijuana is reported as "Inconclusive". Additionally, HMD and identification results (from this method) are not reported if CBD is $\geq 5\%$ and delta-9-THC is <6%. In plant matrices, marijuana is reported as "Inconclusive". The Delta-9-THC and Total Delta-9-THC concentrations, as applicable, in all matrices are

reported as “Unable to be determined by this method due to an interfering substance(s). An alternate method may be available.”

A memo was issued for each site to update the HMD protocol (BUX memo attached), and testing resumed on 5/18/21 and 5/25/21 (site dependent).

Furthermore, the instrument maintenance practice has been changed to at least weekly and more frequently if the run controls were failing. Conversion control charts have been initiated in order to track trends. If a run should fail due to a high rate of CBD conversion as described above, maintenance must be performed prior to analyzing additional HMD samples.

For both HMD and THC identification-only casework, an improved TLC method utilizing a different mobile phase has been validated (see attached validation summary). This mobile phase effectively separates THC and CBD, thereby ensuring the identification of THC when it is present by both GC/MS and TLC.

As a further improvement to the HMD testing scheme, the 4-AP color test has been validated and is being considered for use. With this test, the color change is dependent on the ratio of CBD to THC in the sample. This will allow the quick identification of samples where THC is greater than CBD, with a positive 4-AP color test confirming that the THC identified in the HMD analysis was present in the sample and not a result of conversion. Incorporating 4-AP in the testing scheme will decrease the number of cases that require TLC (a more involved process than the simple color test) and will be beneficial in cases where there is no CBD, but THC isn't readily present on the TLC plate.

As a more permanent solution, the laboratory plans to transition to a derivatized GC/MS method for HMD analysis. Although this will be the same method currently used for THC quantitation, thereby allowing for a more consistent approach to analysis, it will require the purchase of additional instrumentation and laboratory equipment. Also, the method must be validated for use with HMD, StarLims updated appropriately, and staff trained. This process is estimated to take approximately 6-7 months once formal approval for the purchases is obtained.

For future improvements of THC testing methods, additional validation experiments will be performed on all instruments on which the assay will be run with the goal of identifying any possible stability and/or breakdown/conversion issues with other cannabinoids. While comprehensive validation of the method will be run on one instrument at the Willow Grove Laboratory, instead of verification consisting only of comparison samples on other instruments, an expanded verification of assay performance on any instrument at any site on which the test is to be performed will occur. Validation experiments will be expanded to include imprecision, accuracy, robustness, and carryover studies in addition to comparison data. Changes to the validation SOP reflecting these changes are in process.

Although THC identification without HMD or quantitation continues to be offered with the updated TLC method as described above, the laboratory plans to ultimately discontinue THC identification-only and transition clients to HMD analysis.

EXHIBIT F



TEXAS FORENSIC
SCIENCE COMMISSION

Justice Through Science

1700 North Congress Ave., Suite 445
Austin, Texas 78701

July 22, 2021

Via e-mail to aliece.watts@nmslabs.com

Aliece Watts
NMS Labs
2300 Stratford Avenue
Willow Grove, PA 19090

Re: Forensic Science Commission Laboratory Self-Disclosure No. 21.41; NMS (Seized Drugs)

Dear Ms. Watts:

At its July 16, 2021 meeting, the Commission reviewed the referenced self-disclosure and voted to create an investigative panel to assist with evaluating the laboratory's root cause analysis and corrective actions and offering related recommendations. The panel consists of commissioners Jasmine Drake, Ph.D., Patrick Buzzini, Ph.D., Jarvis Parsons, Esq., and Sarah Kerrigan, Ph.D.

Commission staff will be in touch with you regarding the scope and timing of the investigation over the coming weeks. If you have any questions, please feel free to contact our office at (512) 936-0770 or info@fsc.texas.gov.

Sincerely,

Leigh Tomlin

Leigh M. Tomlin
Associate General Counsel

EXHIBIT G

Subject: Re: NMS 21.41

Date: Friday, October 1, 2021 at 9:14:24 AM Central Daylight Time

From: Lynn Garcia

To: Logan, Barry

CC: Leigh Tomlin, Kathryn Adams, Watts, Aliece, Spargo, Erin, Shuda, Sarah, Menendez, MJ

Received; thank you Barry.

Lynn

> On Oct 1, 2021, at 8:58 AM, Logan, Barry <Barry.Logan@nmslabs.com> wrote:

>

> Hello Lynn; Please see below for our responses to the questions you sent me a couple of weeks ago (Sorry I have been out of the office).

>

> Regards

>

> BKL

>

> From: Lynn Garcia <Lynn.Garcia@fsc.texas.gov<mailto:Lynn.Garcia@fsc.texas.gov>>

> Sent: Tuesday, September 14, 2021 9:31 PM

> To: Logan, Barry <Barry.Logan@NMSLABS.COM<mailto:Barry.Logan@NMSLABS.COM>>; Spargo, Erin <Erin.Spargo@NMSLABS.COM<mailto:Erin.Spargo@NMSLABS.COM>>; Shuda, Sarah <Sarah.Shuda@NMSLABS.COM<mailto:Sarah.Shuda@NMSLABS.COM>>; Menendez, MJ <MJ.Menendez@NMSLABS.COM<mailto:MJ.Menendez@NMSLABS.COM>>

> Cc: Watts, Aliece <Aliece.Watts@nmslabs.com<mailto:Aliece.Watts@nmslabs.com>>; Kathryn Adams <Kathryn.Adams@fsc.texas.gov<mailto:Kathryn.Adams@fsc.texas.gov>>; Leigh Tomlin <Leigh.Tomlin@fsc.texas.gov<mailto:Leigh.Tomlin@fsc.texas.gov>>

> Subject: FW: [EXT]: FW: NMS 21.41

>

> CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

> All:

> Here are a few questions the panel has. I apologize if any of this information was provided previously. It could be that we are misunderstanding (or missing) a couple of items, so please feel free to clarify anything we may have missed.

>

>

> 1. The memorandum summarizing the validation work is dated August 2019, and a subsequent memo dated March 2020 described a decision to change the internal standard used from delta-9-THC d3 to delta-9-THC d9. Does that mean the data contained in the spreadsheet entitled "HMD Method Validation Data" reflect use of the original internal standard or does it include the new internal standard? In other words, is the spreadsheet entitled "ISTD Update d3 to d9" reflective of the switch but not the spreadsheet entitled "HMD Method Validation Data"?

>

> a. The original validation was done with the d3 internal standard so all of the data in the HMD Method Validation Data spreadsheet represents work with the d3 internal standard. The spreadsheet titled ISTD Update – d3 to d9 was the comparison data run to ensure the results remained consistent with the d9 internal standard in order to make the change. So your final statement is correct. The spreadsheet entitled

“ISTD Update d3 to d9” is reflective of the switch but not the spreadsheet entitled “HMD Method Validation Data”.

>

>

> 1. It is a bit difficult to tell from the validation summary whether the full validation was run on a single instrument or multiple instruments. Would you clarify please? Would you kindly describe the sites for the data collected in the document entitled “HMD Method Validation Data?” If full validations were not run on each instrument on which the method is performed in each site, can you please describe what was done in the form of confirmation validation for other instruments?

>

> a. The full validation was run on a single instrument at the WLG site. After the method was validated, we ran comparison data on the other instruments that would be used for this analysis in order to verify they were capable of generating appropriate results. For the WLG site that was done at the time of initial validation so it is captured in the tab labeled “Comparison between GCs – WLG” in the HMD Method Validation Data spreadsheet.

>

>

> 1. How many instruments per site were affected by the issues described in the quality incident and were they the instruments on which full validation was performed or a confirmation validation (or both)? The disclosure indicates more than one instrument but we want to be sure we are understanding correctly.

>

> a. This could affect all instruments performing the analysis. During the investigation, experiments were run on the 3 instruments at WLG that were used to analyze HMD samples and similar results were observed.

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> 1. The memorandum dated May 24, 2021 describes certain “safeguards” taken to modify the method, including changing the reporting limit to 0.150% for delta-9-THC, lowering the point at which CBD is considered an interferent from 20% to 5%, and increasing the percentage for reporting delta-9-THC from 4% to 6%. Have there been any modifications to this approach since the memo was provided to us? Any additionally impacted cases or has the whole universe of cases been identified?

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> * There have not been any additional modifications to the HMD method. Also included in the original safeguards is running a conversion control at 5% CBD at the beginning and end of the run and after every 10 samples to monitor potential conversion throughout. We have not identified additional impacted cases.

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> 1. Some of the figures in the “Uncorrected % THC GCMS06-DFW” column in the “Combined HMD Instrument Qualification Data” spreadsheet have percentages above 100. We are having a bit of a hard time understanding why that would be. Could you clarify please?

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> * Since the only calibrator is at 1%, when samples have very large peaks they sometimes calculate over 100%. It is because we are extrapolating from one point so much lower than the amount of THC in the sample.

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> 1. Does NMS have quantitative data for affected cases where you saw the discrepant results?

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> Yes, this is in the attached spreadsheet. It indicates what the discrepancy was, whether it changed the result, and whether it changed the conclusion.

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> 1. I am a bit confused about your earlier question regarding notification. Didn't you already issue amended reports in all of the affected cases for the hemp/MJ differentiation method? I thought so but maybe I misunderstood.

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> * Yes, we did issue notification to all the cases we identified as having been affected, along with a copy of the corrective action (example attached). Clients were encouraged to submit their cases for re-testing. To date out of 71 cases that clients were contacted 33 cases have been returned for re-testing so far. Six cases resulted in a change in conclusions (column P), and a corrected report was issued.

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> 1. If you are referring to the letter you sent asking about notification in MJ case reports that pre-date the farm bill, I thought I had answered that in emails we had from June 2021 but upon reflection I did not address the issues clearly/directly enough. Before the bill legalizing hemp was passed in TX, laboratories were not required to identify specific cannabinoids to positively ID a sample as marijuana; any cannabinoid present was sufficient. There was no requirement that THC be detected specifically to make a positive marijuana ID. This is the prevailing view among the laboratories and TX prosecutors. So unless a court determines this view is incorrect, I don't believe notification would be required, because a report containing a positive ID for MJ did not require detection of THC. Having said that, we are not a court and it is possible a court could view it differently. The courts are the authority on statutory and caselaw interpretation, including the laws related to MJ/Hemp, the Michael Morton Act, Brady, Giglio, etc.

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> * Thank you for this clarification. We have started the process of reviewing qualitative identifications performed after the passage of the 2018 Farm Bill, and are currently seeing very little impact from CBD to THC conversion.

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> Note that we continue to look for ways to improve our testing options, and we anticipate that going forward, the HMD method will be re-developed to include a derivatization step that will prevent any possible conversion of CBD to THC. This is currently in development and expected to be live at the beginning of 2022.

>
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