**Michigan Supreme Court**
State Court Administrative Office
Michigan Hall of Justice
P.O. Box 30048
Lansing, Michigan 48909
517-373-0128

Thomas P. Boyd
State Court Administrator

# MEMORANDUM

DATE: March 22, 2021

TO: Family Court Judges

FROM: Thomas P. Boyd

SUBJECT: Averhealth Independent Investigation

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Consistent with the State Court Administrative Office's memorandum dated November 6, 2020 (Concerns Raised Regarding Averhealth Drug Test Results), attached is a memorandum from the Michigan Department of Health and Human Services, and the final report of the independent investigators for your review and information.

STATE OF MICHIGAN
DEPARTMENT OF HEALTH AND HUMAN SERVICES
LANSING

GRETCHEN WHITMER
GOVERNOR

ELIZABETH HERTEL
DIRECTOR

# MEMORANDUM

**DATE:** March 15, 2021

**TO:** State Court Administrative Office

**FROM:** Demetrius Starling, State Bureau Administrator, Bureau of In-Home Services

**SUBJECT:** Averhealth Drug Testing Validity

In November 2020, the State Court Administrative Office (SCAO) received a letter that called into question the validity of drug testing services completed by the Michigan Department of Health and Human Services (MDHHS) contractor, Averhealth. Based on the concerns raised and the request of various courts, MDHHS contracted with Wagner Toxicology Associates for Jarrad Wagner, Ph.D., F-ABFT and Larry Broussard, Ph.D., D-ABCC, to complete a thorough assessment of the Averhealth laboratory in St. Louis, Missouri. This assessment included an audit of laboratory procedures, validation of the testing process, and an assessment to determine if Averhealth was meeting the College of Pathologists – Forensic Drug Testing accreditation standards. MDHHS requested the assessors review specific concerns related to testimony provided on February 19, 2021 by former Averhealth Lab Director, Dr. Sarah Riley, regarding employee practices and alleging that the testing practices used could have yielded false-positive drug test results.

Dr. Wagner and Dr. Broussard completed their assessment at the Averhealth laboratory and although there were recommendations made to strengthen testing procedures, the assessors concluded that the results reported by the laboratory are scientifically sound and forensically defensible in a court of law. There were no issues noted with the testing process, the validity of the results, or the qualifications of the lab and personnel. The team reviewed the specific concerns noted by the judiciary and found that none of these concerns were observed during the audit.

The executive summary report [Attachment 1] indicates there was no concern with bypassing the immunoassay screen as the chromatography test is a more sensitive and scientifically reliable test with more accurate results than immunoassay screening. If samples are positive in the immunoassay, the positive result is confirmed using the Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) testing for definitive results.

The assessors noted concerns about the relatively low cut off levels established by MDHHS. As a result, the Department has asked Dr. Wagner and Dr. Broussard to

conduct further assessments related to the established testing levels and offer recommendations regarding adjustments to the current levels. These assessments are currently being conducted and recommendations will be made to MDHHS no later than May 1, 2021. MDHHS is likely to receive these recommendations in March or early April.

The assessors also reviewed the testimony provided by Averhealth Chief Operating Officer, Ms. Dominique Delagnes and observed the analytical data used for reporting results. Specific to the contradicting testimony provided by the former laboratory director, Sarah Riley, and the current Chief Operating Officer, Dominique Delagnes, the assessors found the testimony given by Dominique Delagnes to be accurate based on their review and assessment. Assessors reviewed a report of a false positive with a later retest of the specimen being reported as negative. The team found that the testimony provided by Ms. Delagnes was accurate because the first test was completed using Michigan's cut off levels and the second test was reported based on an incorrect cutoff level; therefore, the data was analytically correct and reflected a positive result in both testing instances. Finally, the prior report of 13 "false positives" was noted as a human error and the assessors determined that Averhealth appropriately took actions to address this to prevent a similar occurrence in the future.

A meeting is scheduled on March 29th at 4:00 p.m. to provide an opportunity for jurists with interest to attend an overview presentation given by Dr. Wagner and Dr. Broussard. At this meeting, the doctors will explain the findings of their audit and take questions.

MDHHS remains committed to assuring accurate and reliable testing results are provided to clients, staff, and courts. We would like to be made aware of and have an opportunity to respond promptly to any concerns that arise. Please contact Demetrius Starling at StarlingD@michigan.gov with any questions or concerns.

2/28/2021

[redacted]

# AVERHEALTH LAB- SITE VISIT REPORT

## Prepared for the State of Michigan DHHS

Prepared by:
Jarrad R. Wagner, Ph.D., F-ABFT & Larry Broussard, Ph.D., D-ABCC

On Behalf of
Wagner Toxicology Associates

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**Laboratory Audit Report**

## 1. Executive Summary

Dr. Larry Broussard and Dr. Jarrad Wagner conducted a laboratory site visit from January 19-20, 2021 at Averhealth Lab in St. Louis, Missouri. In general, the site visit was performed to confirm that the laboratory personnel were performing their laboratory work in accordance with their laboratory manual or standard operating procedure (SOP), and that the laboratory manual accurately reflects what is being done in the lab. The site visitors in this case also assessed if those practices were consistent with acceptable forensic laboratory practices. The laboratory director is Dr. Michele Glinn and she supervises a staff of appropriately educated and trained laboratory staff. A relatively small number of reports was audited during the visit, and the reporting process was observed. Following the visit, the team was made aware of specific concerns brought to the State of Michigan, Department of Health and Human Services through the judiciary. None of the items of concern were observed during the audit or are valid in the current laboratory practices. The team specifically did not audit the software related to submission of sample data or the software used to report, but they did observe the valid analytical data used for reporting. While some issues were identified and recommendations for improvements were made, the results reported by the laboratory can be scientifically supported and forensically defended in court. The Averhealth Lab team has indicated that they have implemented improvements to provide additional confidence to the State of Michigan, Department of Health and Human Services that the results reported are accurate and defensible. The team would be willing to revisit the laboratory and assess the implementation of their recommendations or review them through a virtual site visit.

## 2. Site Visit

Dr. Larry Broussard and Dr. Jarrad Wagner conducted a laboratory audit January 19th and 20th, 2021 (Tuesday and Wednesday) at the Averhealth Lab located at 4709 LaGuardia, Suite 100, St. Louis, MO 63134. The laboratory director is Michelle Glinn, Ph.D., F-ABFT, and she hosted the audit team with the rest of the Averhealth Lab staff.

The site visit consisted of an inspection and data audit. Dr. Wagner conducts NLCP inspections and had also participated in CLIA and COLA accreditation audits. Dr. Broussard conducts NLCP inspections and also participates in CAP, CLIA and COLA inspections. The biographies of the site visitors are provided in Auditor Biographies.

The lab is accredited by the Centers for Medicare and Medicaid Services under the Clinical Laboratory Improvement Amendments (CLIA), the State of New York, and the College of American Pathologists (CAP). It was inspected by CAP in February of 2020 and was given a glowing review: “The management team has done a great job at implementing and maintaining the CAP standards for accreditation. The SOP’s have been updated since the last onsite inspection and provide sufficient detail in all areas. The lab is well maintained and has

sufficient space for current operations and future growth. Bench staff are well trained and very knowledgeable in their duties."

The site visit was initiated by a tour on January 19th. The team focused on oral fluid specimens that were being processed for Michigan only. The team observed accessioning, screening, and confirmation of oral fluid specimens. The testing process has immunoassay screening, followed by confirmation of positives with liquid chromatography-tandem mass spectrometry (LC-MS/MS). Only analytes that have screened positive are reported, according to the information in Table 1. It is common practice in forensic laboratories to only report confirmation results that are associated with positive presumptive screening tests.

*Table 1. Screening and confirmation for MI DHHS*

| Screen Drug | Screen Cutoff | Drug Class | Confirmation Analytes | Cutoff |
|---|---|---|---|---|
| Amphetamines | 12.5 ng/mL | Amphetamines | Amphetamine | 6.25 ng/mL |
| Methamphetamines | 12.5 ng/mL | Amphetamines | MDA | 6.25 ng/mL |
| | | Amphetamines | MDEA | 6.25 ng/mL |
| | | Amphetamines | MDMA | 6.25 ng/mL |
| | | Amphetamines | Methamphetamine | 6.25 ng/mL |
| | | Amphetamines | Phentermine | 6.25 ng/mL |
| Benzodiazepines | 20 ng/mL | Benzodiazepines | Alprazolam | 10 ng/mL |
| | | Benzodiazepines | Clonazepam | 10 ng/mL |
| | | Benzodiazepines | Diazepam | 10 ng/mL |
| | | Benzodiazepines | Flunitrazepam | 10 ng/mL |
| | | Benzodiazepines | Flurazepam | 10 ng/mL |
| | | Benzodiazepines | Lorazepam | 10 ng/mL |
| | | Benzodiazepines | Midazolam | 10 ng/mL |
| | | Benzodiazepines | Nordiazepam | 10 ng/mL |
| | | Benzodiazepines | Oxazepam | 10 ng/mL |
| | | Benzodiazepines | Temazepam | 10 ng/mL |
| Buprenorphine | 5 ng/mL | Buprenorphine | Buprenorphine | 2.5 ng/mL |
| | | Buprenorphine | Norbuprenorphine | 2.5 ng/mL |
| Cocaine | 3.5 ng/mL | Cocaine | Benzoylecgonine | 2 ng/mL |
| | | Cocaine | Cocaine | 2 ng/mL |
| Fentanyl | 2 ng/mL | Fentanyl | Fentanyl | 1 ng/mL |
| | | Fentanyl | Norfentanyl | 1 ng/mL |
| Opiates | 7.5 ng/mL | Opiates | 6-MAM | 0.5 |
| Oxycodone | 10 ng/mL | Opiates | Codeine | 3.75 ng/mL |
| | | Opiates | Hydrocodone | 3.75 ng/mL |
| | | Opiates | Hydromorphone | 3.75 ng/mL |
| | | Opiates | Morphine | 3.75 ng/mL |
| | | Opiates | Noroxycodone | 3.75 ng/mL |
| | | Opiates | Nohydrocodone | 3.75 ng/mL |
| | | Opiates | Oxycodone | 5 ng/mL |
| | | Opiates | Oxymorphone | 5 ng/mL |

| Screen Drug | Screen Cutoff | Drug Class | Confirmation Analytes | Cutoff |
|---|---|---|---|---|
| THC | 1 ng/mL | THC | THC | .5 ng/mL |
| Tramadol | 10 ng/mL | Tramadol | Tramadol | 5 ng/mL |

The accessioning personnel were competent and capable of assigning specimen testing without sample switches. They also performed the initial aliquot for oral fluid screening via immunoassay. All samples appear to be undergoing testing as indicated in the reporting.

If samples are negative, they are reported as such and they are stored for a short time prior to being discarded. If samples are positive in the immunoassay, the positive result is confirmed using LC-MS/MS according to Table 1, and the samples are stored for a longer duration than negative specimens in case a new analysis is requested.

We observed the preparation of a batch of confirmation samples, including standard oral fluid confirmations and some specialty analyses. We also observed a sample get aliquoted for GC/MS confirmation of ethanol. The team did not verify the GC/MS procedure or assess the method or results. This is not a common practice and it is unknown how ethanol detected in oral fluid results are related to blood alcohol concentration, but this will be followed up on in a separate report.

The personnel doing the LC-MS/MS sample preparation were competent. They used barcodes and identified the samples prior to pipetting. They used calibrated and verified pipettes, and they verified pipet performance on a weekly basis with relevant volumes.

The calibrators and quality control samples were made from separate lots and were made at the levels specified in the Standard Operating Procedure (SOP) “18- Oral Fluid Confirmation for the State of Michigan.” The instruments were loaded and unloaded with care to avoid sample switches and allow for reinjection (if needed). The laboratory employs an onsite maintenance person and the LC-MS/MS units are in excellent condition. Performance is verified on a daily basis and within each batch.

The laboratory is one of approximately 100 participating labs in the College of American Pathologists (CAP) Oral Fluid Proficiency Testing program. The laboratory receives 4 sets (A-D) per year consisting of 5 samples/set. Samples are analyzed by immunoassay screening and LC-MS/MS confirmation testing and results are reported to CAP. Results of each lab are compared to the expected results and the results obtained by all of the labs. If a laboratory reports a result outside of the acceptable limits (based on the mean of the values reported by all labs), it must investigate. The results for the 4 PT sets analyzed in 2020 were reviewed during the visit to the lab, and the laboratory received acceptable scores for each set, with appropriate investigation of results outside of acceptable limits, showing that there was no evidence of any systemic problems. The laboratory performed very well on their CAP Proficiency Specimens, with a 100% accuracy score in the last proficiency test set completed in November/December of 2020.

## 3. Areas of Concern

### Immunoassay

In reviewing the revised immunoassay cutoffs for the State of Michigan, it was discovered that the targeted concentration was calculated as the neat value and not the dilute value as intended. Also, too many opiates were included in the calibrator, as there is cross reactivity with multiple analytes in the assay used. Overall, the cutoffs for the immunoassay were more sensitive than intended since the screens were implemented. As this did not result in any false negatives, the site visit team felt this could be easily corrected. The new, correct calibrator was prepared while the team was onsite and was to be validated for implementation.

The immunoassay quality control (QC) results were reviewed on an ongoing basis to determine if they performed acceptably. While the SOP called for the numerical QC result to be quantitatively evaluated, the QC results were evaluated on a qualitative basis, such that as long as expected negatives were negative and expected positives were positive, the assay was considered to be performing acceptably. The team advised that the laboratory should establish an acceptable range of numerical results and correct the calibration if the QCs fall outside of this range, before performing analysis of MI DHHS oral fluid specimens. In the opinion of the auditors this did not create any false positives or negatives in MI DHHS specimens, as the QC results were qualitatively accurate.

### Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS)

Prior to the site visit, 10 random reports and supporting data were provided to the audit team. The reports showed that some analytes were reported that were being flagged as outside identification criteria by the analytical software in use, MultiQuant. This raised a concern prior to arrival, but in and of itself wasn't necessarily an issue, since it was not known how MultiQuant was setup to flag outliers prior to the site visit.

After observation of the LC-MS/MS data processing, the team recommended that the LC-MS/MS identification criteria be clarified in the SOP. Basically, in order for an analyte to be confirmed as positive, it must fall within a specified time frame as compared to an analytical standard (retention time) and the ratio of the ion transitions that are being monitored must be within a specified tolerance to standards run in the batch. The data reviewers need to strictly follow the acceptance criteria that are included in the SOP, and it would make the review process easier if MultiQuant was setup with identical acceptance criteria to the SOP. Analytes that do not meet these requirements should not be reported. It is the understanding of the site visitors that Averhealth has now clearly defined the acceptance criteria for identification of analytes and is using them while reporting results.

The site visitors observed that the laboratory might change the linearity model or internal standard used for a specific analyte if the quality control (QC) values were outside the normal range. While this was written into the SOP, this practice would need to be supported by method validation data to be acceptable in an analytical laboratory.

## 4. Concerns Raised by the Judiciary

Subsequent to the visit, in the week of February 22, 2021, the team was made aware of allegations made by a former laboratory director through communication with judges and in her testimony at a trial. Specifically, the former laboratory director stated that the number of quality control (QC) specimens being run is insufficient and does not meet the 10% threshold that is required of CAP-accredited laboratories. There were an appropriate number of quality controls in the batches (>10%, 6 controls for every 50 specimens), both observed onsite in January and as described in the current SOP for Michigan Oral Fluid confirmations. In fact, the laboratory is currently using those 6 independent quality control specimens for batch sizes of forty (40). The inspectors observed that if the any of the controls failed in the LC-MS/MS, the specimens that required that QC were re-analyzed. The court was also concerned with a prior incident in which there were 13 "false positives" reported. Basically, in a prior batch the vials were put in the autosampler in the wrong location, causing 13 results to be associated with the wrong donors. Based on their discovery of this human error, Averhealth added independent sequence and vial checks that are currently in place, and in the opinion of the inspectors are sufficient to prevent a similar occurrence in the future. It was fortunate that the error was caught and the reports were corrected, and the multiple checks in place are appropriate to prevent this from reoccurring. The testimony of Dominique Delagnes that was provided to the inspectors was found to be accurate. There was an allegation that a false positive was reported, as a retest of the specimen was reported as negative. However, as explained in the testimony, the data in each analysis supported a positive finding with State of Michigan oral fluid cutoffs; however, the second result was reported based on an incorrect cutoff. Therefore, the data was analytically correct and reflected a positive result in both testing instances. Based on the rationale provided here, the inspectors did not observe any practices that support the allegations, and they were unsubstantiated.

## 5. Conclusions

The team feels that the items of concern expressed in this report do not indicate that the laboratory has reported any false negative or false positive results. The team is confident that the observed data was forensically and scientifically defensible in a court of law. Laboratory personnel were receptive to the team's recommendations to address the concerns discussed and indicated that they would begin this process immediately. The team recommends that the laboratory provide the updated procedures for review in order to ensure that the concerns expressed have been adequately addressed and the recommendations made have been appropriately understood and implemented.

## 6. Auditor Biographies

### Dr. Larry Broussard

Larry A. Broussard, Ph.D., DABCC, is Professor Emeritus and former Department Head, Department of Clinical Laboratory Sciences, LSU Health Sciences Center (LSUHSC) in New Orleans, Louisiana. He earned a B.S. from Louisiana State University in Baton Rouge in 1970 and a Ph.D. in chemistry from the University of Texas at Austin in 1974. In 1977, following a

fellowship in the Department of Pathology at LSU Medical Center in New Orleans, he joined Medical Laboratory Associates (currently LabCorp) in Birmingham, Alabama, where he served in various positions including vice-president of technical services. He has also served as Laboratory Director of several laboratories including a SAMHSA-certified drug testing laboratory, the Toxicology Laboratory of the Orleans Parish Coroner's Office, and a regional clinical laboratory. He is board certified in clinical chemistry by the National Registry of Certified Chemists (NRCC) and the American Board of Clinical Chemistry (ABCC) and in toxicology by ABCC. Dr. Broussard received the Award for Outstanding Contributions in Education in 2004 from the American Association for Clinical Chemistry (AACC) and has received the School of Allied Health Professions Excellence in Teaching and the Allen Copping Excellence in Teaching Awards from LSUHSC in 2002 and 2005. He has more than 250 publications and presentations.

Dr. Broussard has been an active member of AACC for more than 40 years and served as President in 2008. He has served on 5 Annual Meeting Organizing Committees (AMOCs) including serving as the Chair of the 2001 AMOC. In addition to his service in AACC Dr. Broussard has served as a member of the Board of Directors of the National Academy of Clinical Biochemistry (NACB), ABCC, and NRCC and as President of NRCC. He has been selected as a fellow by NACB and the American Academy of Forensic Sciences (AAFS).

Dr. Broussard has been an inspector of SAMHSA-certified drug testing laboratories for more than 20 years and CAP-certified clinical laboratories for more than 30 years and continues to perform these inspections. He also serves as a technical specialist for Nuclear Regulatory Commission-required audits of drug-testing labs. In his capacity as Department Head he oversaw a Medical Technology Program that is certified by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS). He retired from LSUHSC in 2016. His post-retirement activities include continued activity in forensic toxicology and laboratory medicine, 9 years of service as a member of the CAP Clinical Chemistry Committee, and currently serves on the AACC Nominations Committee. He also currently serves as Laboratory Director for 5 laboratories including 2 which perform pain management testing, 2 which perform molecular testing for respiratory pathogens, and one clinical regional reference laboratory.

**Dr. Jarrad Wagner**

Jarrad R. Wagner, Ph.D., F-ABFT is a Professor of Forensic Sciences at the Oklahoma State University Center for Health Sciences where he specializes in research and instruction in Forensic Toxicology and Chemistry. He is board certified as a Fellow of the American Board of Forensic Toxicology and an Associate Editor for the Journal of Analytical Toxicology. He works with tandem mass spectrometry (LC/MS/MS) and gas chromatography/mass spectrometry (GC/MS) instruments and supports forensic and clinical laboratories in method development, validation and training. He serves as a member of the AAFS/SOFT Drugs and Driving Committee, the AAFS/SOFT Oral Fluid committee, is a member of the National Safety Council Alcohol, Drugs and Impairment Division and is the Vice Chair of the Oklahoma State Board of Tests for Alcohol and Drug Influence. He is an inspector for National Laboratory Certification Program laboratories, which are Substance Abuse and Mental Health Services Administration (SAMHSA) certified.

Dr. Wagner is the laboratory director for several clinical laboratories, and supervises chemistry, toxicology and molecular biology activities. He provides expert witness in criminal and civil courts, reviewing analytical laboratory results and providing interpretation. Professor Wagner formerly served as a Chemist in the Hazardous Materials Response Unit of the FBI Laboratory, where he specialized in crime scene investigations involving hazardous materials throughout the world. Prior to the FBI, his law enforcement experience includes his time as a Forensic Scientist in the Toxicology section of the Orange County (CA) Sheriff-Coroner's office and his service as a Reserve Police Officer in the City of Irvine, CA. He is a former Assistant Professor of Chemistry and Director of the Forensic Sciences program at California State University, Fresno. Dr. Wagner earned a Ph.D. in Environmental Toxicology from the University of California at Irvine and undergraduate degrees in Biology and Chemistry.