Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2213269	**(X3) Date Survey Completed** 12/13/2022
Name of Provider or Supplier Jerry Lewis Md Pa Toxicology Laboratory	**Street Address, City, State** 6161 N State Hwy 161 #305, Irving, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	**Summary Statement of Deficiencies**
D0000	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratory Director; High complexity Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) records, the CMS (Centers for Medicare & Medicaid Services)- 209 form, laboratory survey documents, and confirmed in interview, the laboratory failed to ensure proficiency samples were analyzed by personnel who routinely perform testing in the laboratory for 2 of 2 PT events in 2022 (Events A and B). The findings include: 1. Review of the laboratory policy titled "SOP-Proficiency Testing" revealed: "PROCEDURE ... 1) ... A ... c) Specimens will be tested within the routine workload for the workstation by the prescribed protocol for the assay 2) Additionally, the following system is in place: A) The assigned technologist will: a) Maintain a schedule and assign CAP Surveys to ensure they are rotated between all testing personnel..." 2. Review of the CAP proficiency testing records revealed Testing Person 1 tested the following events: Drug Monitoring for Pain Management Survey-A 2022 Drug Monitoring for Pain Management Survey-B 2022 3. Review of CMS-209 revealed 2 testing persons (TP1 and TP2) were listed to perform high

	complexity testing. 4. Review of laboratory survey documents submitted at the time of survey revealed the following: Testing Person 1 (TP1) Hire Date: 03/01/2021 Testing Person 2 (TP2) Hire Date: 11/01/2021 TP2 performed testing of patient specimens and did NOT participate in PT events for 2022. The laboratory failed to ensure that PT samples were analyzed by personnel who routinely perform testing. 5. During an interview on 12/12/2022 at 11:42 a.m., the Laboratory Director and TP1 confirmed that TP2 had not participated in PT. II. Based on review of laboratory policy, laboratory records, College of American Pathologists (CAP) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to ensure proficiency samples were analyzed with the laboratory's regular patient workload for 1 of 2 PT events in 2022 (Event A). The findings include: 1. Review of the laboratory policy titled "SOP-Proficiency Testing" revealed: "PROCEDURE ... 1 ... A) ... c) Specimens will be tested within the routine workload for the workstation by the prescribed protocol for the assay ... 2) ... B) The testing technologist will ... b) Perform testing in the same manner patient specimens are performed. (Note: Notify assigned tech /Supervisor of any instrument issues that will delay testing.) Do not repeat testing unless you must because of instrument flags or bubbles etc. Handle the testing the same as you will with patient testing." 2. Review of the laboratory's "Toxicology Laboratory Schedule" revealed patient testing for this laboratory took place on Monday, Tuesday, Thursday, and Friday. 3. Review of the CAP proficiency testing records revealed the analysis of PT samples from Drug Monitoring for Pain Management Survey-A 2022 took place on Wednesday 02/09/2022. The laboratory failed to ensure that PT samples were analyzed with the laboratory's regular patient workload. 4. During an interview on 12/12/2022 at 11:42 a.m., the Laboratory Director and Testing Person 1 confirmed the above findings.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to attest to the routine integration of proficiency samples into the patient workload for 1 of 2 PT events in 2022 (Event A). The findings include: 1. Review of the laboratory policy titled "SOP-Proficiency Testing" revealed: "PROCEDURE ... 1) ... 2) ... B) The testing technologist will: a) Follow CAP test kit instructions and prepare the specimen (s) for testing. Do not let specimen sit. Run as soon as possible ... d) Sign the attestation page ... C) The assigned technologist will ... b) Submit the entire raw data package to the medical director. The medical director will review and sign the attestation page ..." 2. Review of the CAP proficiency testing records revealed: "ATTESTATION As stated in the February 28,1992 United States Federal Register under subpart H 493-801 (b) (1), "the individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods." The laboratory director or designee and the testing personnel must sign this form." 3. Further review of CAP proficiency testing records revealed the Laboratory Director failed to sign the

	attestation statement for the Drug Monitoring for Pain Management Survey-A 2022. 4. During an interview on 12/12/2022 at 11:42 a.m., the Laboratory Director and Testing Person 1 confirmed the above findings.
D3007	FACILITIES CFR(s): 493.1101(b) The laboratory must have appropriate and sufficient equipment, instruments, reagents, materials, and supplies for the type and volume of testing it performs. This STANDARD is not met as evidenced by: Based on surveyor observation, review of the laboratory's preparation logs, and staff interview, it was revealed the laboratory failed to maintain its own supplies for reference materials used to make the laboratory's quality control materials and standards. The findings included: 1. Surveyor observation on 12/12/2022 at 3:36 pm identified a freezer labeled in which was stored reference materials used to make the laboratory's quality control material and standards. Examples of the reference materials stored in the freezer were: a) 6-MAM b) 7-Aminoclonazepam c) Alprazolam d) Fentanyl e) Gabapentin f) MDMA g) Lorazepam h) Methadone i) Morphine j) Naloxone 2. A review of the laboratory's preparation logs revealed the laboratory made its own controls and standards for urine toxicology confirmatory testing performed on its LC/MS instrumentation. Further review identified the following lots prepared and used by the laboratory: a) Calibration Curve Stock in MeOH Lot: CCS-10X Lot: CCS-7X Lot: CCS-3X Lot: CCS-3X Lot: CCS-1X (cutoff) Lot: CCS-40% b) QC Stock in MeOH Lot: QCS-High Lot: QCS-Low Lot: QCS-Negative c) Calibration Curve in Synthetic Urine Lot: 40% Cutoff Lot: Cutoff Lot: 3X Cutoff Lot: 7X Cutoff Lot: 10X Cutoff Lot: 20X Cutoff d) QC in Synthetic Urine Lot: High QC 5X Lot: Low QC 2X Lot: Negative QC sol 3. An interview on 12/12 /2022 at 3:36 pm, Testing Person-1 revealed controls and standards were prepared from the reference materials in the freezer. She stated the same reference material was used to make a single preparation of controls and standards for two laboratories (45D2213269 and 45D2218755). She added the reference materials were shared by both laboratories. This confirmed the findings.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's establishment studies for the modified FDA-approved DRI Ethyl Gluconeride assay and staff interview, it was revealed the laboratory failed to retain 25 of 30 instrument records for sensitivity studies. The findings include: 1. A review of the laboratory's establishment studies for its modified FDA-approved DRI Ethyl Gluconeride assay revealed the values evaluated for sensitivity were identified as being obtained on 10/14/2021. 2. Further review of the laboratory's establishment studies revealed the instrument records provided to correspond with the values evaluated were from testing performed on 10/13/2021. 3. Comparison of the evaluation values and instrument records revealed 25 of 30 values

	did not have corresponding instrument records. They were: Negative sample: 10 of 10 Cut-off point + 25%: 5 of 10 Positive sample: 10 of 10 4. The laboratory was asked to provide documentation of instrument records to support the values evaluated. No documentation was provided. 5. An interview with testing personnel number 2 (as listed on Form CMS 209) on 12/13/2022 at 915 hours in the break room revealed he was unable to locate the instrument records for the testing performed on 10/14/2021. This confirmed the findings.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of laboratory policy, CAP code instructions, College of American Pathologists (CAP) Proficiency Testing (PT) records, and confirmed in interview, the laboratory failed verify and document the accuracy of toxicology scores that were not graded by the PT company for 1 of 2 PT events in 2022 (Event B). The findings include: 1. Review of the laboratory policy titled "SOP-Proficiency Testing" revealed: "PROCEDURE ... 3) CAP Original Evaluation Result Package: a) The Supervisor /Medical Director will review the results in a timely manner. b) When there are ungraded results, e.g., Educational Challenge, Outside of Reportable Range, Other CAP exception Codes etc., a self-evaluation will be performed. c) The Medical director will review and sign. F) [sic] The signed survey will then be filed in the appropriate CAP binder ..." 2. Review of the CAP exception code instruction's revealed: Code: "27, 31" Exception Reason Code Description: "Lack of participant or referee consensus" Action Required: "Document that the laboratory performed a self-evaluation and compared its results to the intended response when provided in the participant summary. If comparison is not available, perform and document alternative assessment (i.e., split samples) for the period that commercial PT reached non-consensus to the same level and extent that would have been tested." 3. Review of the CAP PT records for Drug Monitoring for Pain Management Survey-B 2022 revealed the following results with code 27 that did NOT have a documented evaluation by the laboratory: Drug Monitoring for Pain Management Survey-B 2022 Specimen: DMPM-08 4. During an interview on 12/12/2022 at 11:42 a.m., the Laboratory Director and Testing Person 1 confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed.

	This CONDITION is not met as evidenced by: Based on review of the laboratory's records, review of the laboratory's establishment studies, surveyor observation of samples, and staff interview, it was revealed the facility failed to provide overall quality in preanalytic systems. The findings include: 1. The laboratory failed to ensure studies were performed for its laboratory developed and FDA-modified assays to support its claims of sample stability, transport requirements, and storage (refer to D5311 I). 2. The laboratory failed to have a mechanism in place to ensure samples received were maintained at the laboratory's defined transport/sample stability temperatures and failed to document the specimen disposition (refer to D5311 II). 3. The laboratory failed to ensure written instructions for sample storage and transport were provided to clients (refer to D5317).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's test menu, review of the laboratory's procedures and policies, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing studies to support its claims of sample stability, transport and storage requirements. The findings include: 1. A review of the laboratory's test menu revealed the laboratory performed the following 43 laboratory-developed tests on the AB Sciex 4500 LC/MSMS (liquid chromatography/mass spectrophotometer mass spectrophotometer): Amphetamine Methamphetamine Butalbital Phenobarbital 7-aminoclonazepam alpha-hydroxyalprazolam Alprazolam Clonazepam Diazepam Lorazepam Noridiazepam Temazepam Buprenorphine Norbuprenorphine Benzoylecgonine Fentanyl Norfentanyl Gabapentin 6-monoacetylmorphine 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine Methadone Codeine Hydrocodone Hydromorphone Morphine Norhydrocodone Meperidine Naloxone Noroxycodone Oxycodone Oxymorphone Phencyclidine Zolpidem Pregabalin Carisoprodol Cyclobenzaprine Meprobamate 3, 4-Methylenedioxymethamphetamine Tapentadol 11-Nor-9-carboxy-THC Amitriptyline Nortriptyline Tramadol 2. A review of the laboratory's test menu revealed the laboratory performed the following two modified FDA-approved assays: Microgenics DRI - Creatinine Detect Microgenics DRI - Ethanol Glucuronide 3. A review of the laboratory's procedure titled "Analytical Test Method Procedure and Validation Plan Quantitative Analysis of Drugs of Abuse and Pain Management" for the testing performed on the LC/MSMS under the section titled "Specimen Requirements" revealed: "Stability: - Ambient: for 5 days - Refrigerated: 2 - 8 C for 30 days - Frozen: -20C for 60 days - No more than 3 freeze/thaw cycles" 4. Further review of the procedure in Appendix I revealed: "iv. Suggested Specimen Storage Stability: 1. Ambient Storage Stability: a. 5 Days 2. Refrigerated Storage Stability: a. 2 C to 8 C b. 30 days 3. Frozen Storage Stability: a. -15 C to -25 C b. 60 days 4. Deep Frozen Storage Stability: a. -65 C to -85 C b. 90 days 5. Stability Studies a. These stability guidelines are suggestions, industry guidelines include ambient stability for 5 Days and refrigerated stability of 7 Days. b. Ensure that acceptable stability data is obtained

through experiment before using the suggested guidelines." 5. The laboratory was asked to provide documentation of performing studies to support the storage stability claims in Appendix I. No documentation was provided. 6. The laboratory reported performing 126720 tests annually. 7. An interview with the laboratory director on 12 /12/2022 at 1050 hours at the front desk revealed the required studies had not been performed. This confirmed the findings. 46891 II. Based on direct observation, review of laboratory records, patient test reports, and confirmed in interview, the laboratory failed to have a mechanism in place to ensure samples received from outside clinics were maintained at the laboratory's defined transport/sample stability temperatures and failed to document the specimen disposition for 25 of 25 patients on 12/12/2022 and 12/13/2022. The findings include: 1. During a tour of the laboratory on 12/12 /2022 at 12:20 p.m., patient samples delivered from outside clinics by the laboratory's courier were observed to be set on the ground in front of the refrigerator awaiting receipt and distribution for testing. The urine samples delivered by courier were observed to be in a softshell cooler with no icepacks or thermometer. The laboratory received the following specimens: 17 urine cups that were cool to the touch and 4 urine cups that were warm to the touch. During an interview on 12/12/2022 at 12:20 p. m., the courier, Testing Person 1 and Testing Person 2 were asked if the temperature of the specimens was documented when they arrived at the facility. They all stated "no". The courier was asked where the specimens were kept while awaiting transport. He stated the specimens were kept in the refrigerator at the clinic. The courier was also asked if he regularly used icepacks in the cooler for specimen transport. He stated that he "usually does, but there were no ice packs available today and it was only a 20-minute drive". During an interview on 12/12/2022 at 12:24 p.m., Testing Person 1 was asked if the facility had performed shipping studies to validate the temperature of the coolers. She stated "no". During a tour of the laboratory on 12/13/2022 at 12:06 p.m., patient samples delivered from outside clinics by the laboratory's courier were observed to be set on the ground in front of the refrigerator awaiting receipt and distribution for testing. The urine samples delivered by courier were observed to be in a softshell cooler with 3 large frozen icepacks and no thermometer. The laboratory received the following specimens without documenting temperature upon arrival: 4 urine cups that were cool to the touch. The temperature of the specimens received from outside clinics on 12/12/2022 and 12/13/2022 was not monitored or documented. The laboratory failed to ensure samples received from outside clinics were maintained at the laboratory's defined transport/sample stability temperatures and failed to document the specimen disposition. 2. Review of the laboratory's policy titled "SOP-Analytical Test Method Procedure for Quantitative Analysis of Drugs of Abuse and Pain Management by AB Sciex 4500 LC-MS/MS" revealed: "SPECIMEN REQUIREMENTS ... Stability: Ambient: for 5 days. Refrigerated: 2-8C for 30 days. Frozen: -20C for 60 days. No more than 3 freeze/thaw cycles." Note: "Ambient" was not defined 3. Review of the laboratory's establishment studies revealed no documentation of stability studies to support the laboratory's specimen requirements or shipping studies to validate the temperature of the coolers. The surveyor requested documentation of stability studies and shipping studies. None was provided. Refer to D5311 I. 4. Review of patient test reports from 12/12/2022 and 12/13/2022 revealed the following 25 specimens that were received from outside clinics when laboratory did not have a mechanism in place to ensure specimens were maintained at the laboratory's defined transport/sample stability temperatures for testing: 12/12/2022 Patient IDs: 11371, 1445, 700, 10128, 911733162001205, 911733162001794, 910962727641200, 1541, 911733162202371, 911733162202738, 734, 1527, 911733162201640, 911733162202716, 11266, 911733162202455, 91173316220126, 11380, 911733162202573, 7852, 9117331622014444 12/13/2022 Patient IDs: 911733162201547, 1403, 1607, 911733162202067 5. During an exit interview on 12

	/13/2022 at 1:15 p.m., the Laboratory Director, Testing Person 1, Testing Person 2, and the Practice Manager confirmed the above findings.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the laboratory's policies, and staff interview, it was revealed the laboratory failed to have documentation of providing clients with written instructions for sample storage. The findings include: 1. A review of the laboratory's procedure titled "Analytical Test Method Procedure and Validation Plan Quantitative Analysis of Drugs of Abuse and Pain Management" for the testing performed on the LC/MSMS under the section titled "Specimen Requirements" revealed: "Stability: - Ambient: for 5 days - Refrigerated: 2 - 8C for 30 days - Frozen: -20C for 60 days - No more than 3 freeze/thaw cycles" 2. A review of the laboratory's policy titled "Specimen Collection" (approved by the laboratory director on 04/01/2021) provided to clients as the instructions revealed the laboratory failed to include written instructions how urine samples were to be stored at the facility after collection until courier pick-up. 3. The laboratory was asked to provide documentation of providing written instructions on how samples were to be stored after collection. No documentation was provided. 4. An interview with the laboratory director on 12/12/2022 at 1050 hours at the front desk confirmed that clients were not provided written instructions for temperature requirements for sample storage after collection. This confirmed the findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Management Plan, review of the laboratory's records, and surveyor observation of samples received by the laboratory, and staff interview it was revealed the laboratory's Quality Management Plan was not followed. The findings include: 1. A review of the laboratory's Quality Management Plan (approved by the laboratory director on 04/01/2021) under the section titled "A. Pre-Analytical" revealed: "2. Specimen Acceptability a. Prior to testing, all specimens must be evaluated to asses sample integrity. The accuracy and quality of a laboratory testing is dependent on the quality of the specimen received. When the identity or integrity of the specimen is in question, a decision must be made about acceptance or rejection." 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing specimen stability, transport, and storage studies to ensure sample integrity (refer to D5311 I.) 3. A review of the laboratory's records and surveyor observation revealed the laboratory failed to ensure samples were transported at its defined acceptable temperature (refer to D5311 II). 4. A review of

	the laboratory's records revealed the laboratory failed to provide written instructions for the storage of samples after collection (refer to D5317). 46891 II. Based on review of the laboratory policy, patient test requisitions, and confirmed in interview, the laboratory's quality assurance plan failed to effectively monitor, assess, and correct problems in pre-analytic systems. The findings include: 1. Review of the laboratory policy titled "Quality Management Plan" revealed: "A. QUALITY IMPROVEMENT 1. Quality indicators are selected to evaluate system or analytical issues 2. System issues may be monitored as part of toxicology Laboratory Services monitoring initiative. 3. Monitors must include pre-analytical, analytical, and post-analytical measures. 4. Issues are chosen and monitored for improvement in response to user and customer concerns." Note: The Quality Improvement plan did NOT define what quality indicators were being monitored. 2. Review of patient test requisitions revealed the following 6 out of 25 requisitions (random sampling) where the patient signature and ordering provider signature date was inconsistent with the collection date of the sample: Patient ID: 911733162202573 Date of Collection: 12/08/2022 Patient Signature Date: 11/10/2022 Ordering Provider Signature Date: 11/10/2022 Patient ID: 7852 Date of Collection: 12/08/2022 Patient Signature Date: 10/10/2022 Ordering Provider Signature Date: 10/10/2022 Patient ID: 11266 Date of Collection: 12/12/2022 Patient Signature Date: 11/14/2022 Ordering Provider Signature Date: 11 /14/2022 Patient ID: 911733162202455 Date of Collection: 12/12/2022 Patient Signature Date: 09/06/2022 Ordering Provider Signature Date: 09/06/2022 Patient ID: 911733162201126 Date of Collection: 12/12/2022 Patient Signature Date: 11/14/2022 Ordering Provider Signature Date: 11/14/2022 Patient ID: 11380 Date of Collection: 12/12/2022 Patient Signature Date: 11/14/2022 Ordering Provider Signature Date: 11 /14/2022 3. During an interview on 12/12/2022 at 3:01 p.m., Testing Person 1 confirmed the above findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, direct observation, patient test requisitions, and confirmed in interview, the laboratory failed to follow their own written policy for documenting urine temperature on their drug screen test requisitions in December 2022. The findings include: 1. Review of the laboratory policy titled "SOP-SPECIMEN COLLECTION" revealed: "URINE COLLECTION PROCEDURE ... 5) upon receipt of the specimen from the donor, immediately apply the temperature strip (if applicable) to the outside of the bottle. If using a drug screen test request form, record the urine temperature on the form. NOTE: Urine temperature should be measured within (4) four minutes of collection and should read between 90-100F." 2. During a tour of the lab on 12/12/2022 at 2:44 p.m., the surveyor asked Testing Person 2 to retrieve a patient urine cup for inspection. Testing Person 2 retrieved a discarded patient urine cup, and the cup did not have a temperature strip, or a temperature documented on the container. 3. Review of patient test requisitions revealed the following 21 patients from 12/12/2022 who had orders exed on their requisitions for a presumptive drug test and a definitive drug test with no documentation of urine temperature on the requisition. 12/12/2022 Patient IDs: 11371,

	1445, 700, 10128, 911733162001205, 911733162001794, 910962727641200, 1541, 911733162202371, 911733162202738, 734, 1527, 911733162201640, 911733162202716, 11266, 911733162202455, 91173316220126, 11380, 911733162202573, 7852, 9117331622014444 4. During an interview on 12/12/2022 at 2:44 p.m., the surveyor asked a Medical Assistant if urine temperatures were documented at collection. She stated "no". This confirmed the above findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory environmental logs, and confirmed in interview, the laboratory failed to define a humidity range in accordance with Diatron p450 manufacturer's instructions in 2021 (November and December) and 2022 (September to November). The findings include: 1. Review of the Diatron p450 technical specifications revealed: "Operating conditions Temperature: 18-30C Relative humidity: 35-80% non-condensing ..." 2. Review of the laboratory's humidity logs from 2021 (November and December) and 2022 (September to November) revealed a defined humidity range of 30-80%. The laboratory's defined humidity range was not within the manufacturer's defined range for operating conditions. 3. During an interview on 12/13/2022 at 10:28 a.m., Testing Person 1 confirmed the above findings.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's establishment studies, and staff interview, it was revealed the laboratory failed to have documentation of complete studies. The findings include: A. DRI - Creatinine Detect 1. A review of the laboratory's test menu revealed the laboratory performed the following two modified FDA-approved assays: Microgenics DRI - Creatinine Detect

	Microgenics DRI - Ethanol Glucuronide 2. A review of the laboratory's establishment studies for the Microgenics DRI-Creatinine Detect revealed the laboratory failed to have documentation of performing sensitivity and specificity studies. 3. The laboratory was asked to provide documentation of the missing studies. No documentation was provided. 4. The laboratory reported performing 2816 creatinine detect tests annually. 5. An interview with testing personnel number 2 (as listed on Form CMS 209) on 12/13/2022 at 910 hours in the break room revealed the studies had not been performed. This confirmed the findings. B. AB Sciex 4500 LC/MSMS 1. A review of the laboratory's test menu revealed the laboratory performed the following 43 laboratory-developed tests on the AB Sciex 4500 LC/MSMS (liquid chromatography/mass spectrophotometer mass spectrophotometer) analyzer: Amphetamine Methamphetamine Butalbital Phenobarbital 7-aminoclonazepam alpha-hydroxyalprazolam Alprazolam Clonazepam Diazepam Lorazepam Noridiazepam Temazepam Buprenorphine Norbuprenorphine Benzoylecgonine Fentanyl Norfentanyl Gabapentin 6-monoacetylmorphine 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine Methadone Codeine Hydrocodone Hydromorphone Morphine Norhydrocodone Meperidine Naloxone Noroxycodone Oxycodone Oxymorphone Phencyclidine Zolpidem Pregabalin Carisoprodol Cyclobenzaprine Meprobamate 3, 4-Methylenedioxymethamphetamine Tapentadol 11-Nor-9-carboxy-THC Amitriptyline Nortriptyline Tramadol 2. A review of the laboratory's establishement studies approved by the laboratory director on 03/09/2021 revealed the laboratory failed to have documentation of accuracy, precision, linearity, sensitivity, and specificity for 3 of the 43 tests performed. They were: Gabapentin Norhydrocodone Noroxycodone 3. Further review of the studies revealed samples had been tested as part of the studies for the identified tests, however, the data had not been compiled and evaluated for acceptability. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 12/12/2023 at 1240 hours in the laboratory- after her review of the records- confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's quality control statistics for DRI Creatinine Detect and DRI Ethyl Glucuronide from July 2022 to November 2022, and staff interview, it was revealed the laboratory failed to have documentation of evaluating quality control results over time for 5 of 5 months. The findings include: 1. A review of the laboratory's policy titled "Quality Controls" (approved by the laboratory director on 04/01/2021) revealed: "At least monthly, Quality Control data are reviewed and assessed by the laboratory director or designee using either LJ charts and/or statistics." 2. The laboratory was asked to provide

	documentation of the review of quality control results for DRI Creatinine Detect and DRI Ethyl Glucuronide from July 2022 to November 2022. The laboratory provided Levy Jennings (LJ) charts for each month requested. However, the charts were printed the day of the request and did not have documentation of the review and assessment. 3. An interview with testing personnel number 2 (as listed on Form CMS 209) on 12 /13/2022 at 1135 hours revealed he had just printed up the charts when asked for them. This confirmed the findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of quality control records from 2021 and 2022, review of patient test records, and staff interview, it was revealed the laboratory failed to ensure quality control values were acceptable prior to reporting patient test results. The findings include: 1. A review of the laboratory's procedure titled "Quality Controls" (approved by the laboratory director on 04/01/2021) revealed: "Quality control results are evaluated and determined to be acceptable by the testing personnel prior to reporting patient results." 2. A review of the laboratory's quality control records from May 2021 to November 2022 identified the following day when two of three levels of quality control testing were identified as unacceptable, however patient results were still reported. It was: a) test: EDDP date: 07/14/2022 Failed QC: 50% QC 5X QC 3. A review of patient test records from the identified days revealed the following 9 patient results were reports when quality control results were unacceptable: Patient IDs: 1283 1573 1584 1656 62854-2871001 1197 911733162201930 911733162202308 911733162201508 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 12/13/2022 at 1100 hours in the laboratory revealed the facility would report patient results unless the drug with the failed quality control was detected in the original run. This confirmed the findings. Key EDDP - 2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine QC - quality control
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Management Plan, review of the laboratory's establishment studies for testing performed on the AB Sciex 4500 LC /MSMS (liquid chromatography/mass spectrophotometer mass spectrophotometer), and staff interview, it was revealed the laboratory's quality management plan failed to identified that calculations for determining the acceptability for accuracy and precision were performed incorrectly. The findings include: 1. A review of the laboratory's Quality Management Plan (approved by the laboratory director on 04/01

	/2021) under the section titled "2. Method Validation" revealed: "Each study will be analyzed with acceptability criteria defined by the section medical director." 2. A review of the laboratory's establishment studies (approved by the laboratory director on 03/09/2021) revealed the laboratory's calculation for percent recovery for accuracy and precision were not correct. Examples are: a) Low Control Day 1 Accuracy Drug: 6 MAM Target: 15.00 Mean: 63.53 Calculated recovery: 105.88% Actual recovery: 423.53% Drug: Amitriptyline Target: 30.00 Mean: 6.31 Calculated recovery: 105.14% Actual recovery: 21.03% Drug: Fentanyl Target: 1.20 Mean: 32.18 Calculated recovery: 107.27% Actual recovery: 2681.67% Drug: Methadone Target: 60.0 Mean: 31.11 Calculated recovery: 103.71% Actual recovery: 51.85% Drug: Phencyclidine Target: 6.00 Mean: 31.78 Calculated recovery: 105.92% Actual recovery: 529.67% b) High control Day 2 Accuracy Drug: Fentanyl Target: 6.00 Mean: 165.98 Calculated recovery: 110.66 Actual recovery: 2750.00% Drug: Lorazepam Target: 120.00 Mean: 26.47 Calculated recovery: 110.28% Actual recovery: 22.05% Drug: Tramadol Target: 300.00 Mean: 125.60 Calculated recovery: 83.73% Actual recovery: 41.87% 3. An interview with the laboratory director on 12/12 /2022 at 1230 hours at the front desk - after her review of the records confirmed the findings. When asked about her review of the establishment studies for acceptability, she stated that she was told the studies were acceptable so she signed them.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, and staff interview, it was revealed the Laboratory Director failed to provide oversight of the laboratory. The findings include: 1. The Laboratory Director failed to ensure requirements were met for pre-analytical systems (refer to D6082). 2. The Laboratory Director failed to ensure establishment studies were complete (refer to D6085). 3. The Laboratory Director failed to ensure accuracy and precision acceptability calculation were performed correctly (refer to D6086). 4. The Laboratory Director failed to ensure a quality control program was followed (refer D6093). 5. The Laboratory Director failed to ensure a quality assessment plan was followed and could detect errors (refer to D6094).
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of laboratory records, patient records, direct observation, and confirmed in interview, the Laboratory Director failed to ensure requirements were met for pre-analytical systems as evidenced by: 1. The laboratory failed to ensure

	studies were performed for its laboratory developed and FDA-modified assays to support its claims of sample stability, transport requirements, and storage. Refer to D5311 I. 2. The laboratory failed to have a mechanism in place to ensure samples received from outside clinics were maintained at the laboratory's defined transport /sample stability temperatures and failed to document specimen disposition. Refer to D5311 II. 3. The laboratory failed to have documentation of providing clients with written instructions for sample storage. Refer to D5317.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure establishment studies were complete (refer to D5423).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure accuracy and precision acceptability calculation were performed correctly (refer to D5791).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure a quality control program was followed (refer to D5441 and D5481).
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview it was revealed the laboratory director failed to ensure a quality assessment plan was followed and could detect errors (refer to D5391-I, D5391-II and D5791).