Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2218755	12/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Southlake Pain Center Toxicology Laboratory	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) ... 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 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) ... 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 Wednesday. 3. Review of the CAP proficiency testing records revealed the analysis of PT samples from Drug Monitoring for Pain Management Survey-B 2022 took place on Tuesday 10/18/2022. 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 ... B) The testing technologist will: a) Follow CAP test kit instructions ... 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.
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.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the CMS (Centers for Medicare & Medicaid Services)- 116 form, laboratory policy, College of American Pathologists (CAP) proficiency testing (PT) records, and confirmed in interview, the laboratory failed to perform twice annual accuracy assessments for 43 of 43 toxicology analytes for 1 of 1 event in 2021. The findings include: 1. Review of the laboratory's submitted 116 form revealed the laboratory tested the following unregulated toxicology analytes 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. Review of the laboratory's policy "SOP-PROFICIENCY TESTING" revealed: "POLICY The purpose of this procedure is to define the proficiency testing (PT) program that is required by a laboratory enrolled in a PT program for every analyte offered on the laboratory scope of service. The toxicology Laboratory is enrolled in the College of American Pathologist (CAP) Proficiency Testing program to challenge each test performed." 3. Review of the laboratory's CAP PT records revealed no twice annual accuracy assessment for 1 of 1 event in 2021 for the above-mentioned toxicology analytes. 4. During an interview on 12/12/2022 at 10: 45 a.m., the Laboratory Director and Testing Person-1 confirmed the laboratory failed to perform a twice annual accuracy assessment in 2021.
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 written instructions for sample storage and transport were provided to clients. Refer to D5317. 2. The laboratory failed to have documentation of performing establishment studies for 43 of 43 analytes. Refer to D5423.
D5301	TEST REQUEST CFR(s): 493.1241(a) The laboratory must have a written or electronic request for patient testing from an authorized person. This STANDARD is not met as evidenced by: Based on review patient final results and confirmed in interview of laboratory personnel, the laboratory failed to provide documentation having a written or electronic request for patient testing for 19 of 19 random patient records reviewed in 2022 (December). The findings were: 1. Review of test records revealed the following 19 of 19 patient records reviewed did not have documentation of a written or electronic request for urine toxicology tests performed by the laboatory: Patient ID: 6384 Collection Date/Time: 12/08/2022 10:15 am Final Report Date/Time: 12/10 /2022 10:10 am Patient ID: 7230 Collection Date/Time: 12/06/2022 10:15 am Final Report Date/Time: 12/10/2022 10:10 am Patient ID: 4645 Collection Date/Time: 12 /07/2022 9:00 am Final Report Date/Time: 12/10/2022 10:10 am Patient ID: 1992 Collection Date/Time: 12/07/2022 9:30 am Final Report Date/Time: 12/10/2022 10: 10 am Patient ID: 6905 Collection Date/Time: 12/07/2022 9:45 am Final Report Date /Time: 12/10/2022 10:10 am Patient ID: 6130 Collection Date/Time: 12/08/2022 10: 30 am Final Report Date/Time: 12/10/2022 10:10 am Patient ID: 7077 Collection Date /Time: 12/07/2022 11:00 am Final Report Date/Time: 12/10/2022 10:10 am Patient ID: 5085 Collection Date/Time: 12/06/2022 10:45 am Final Report Date/Time: 12/10 /2022 10:10 am Patient ID: 7404 Collection Date/Time: 11/29/2022 Final Report Date /Time: 12/03/2022 8:25 am Patient ID: 5513 Collection Date/Time: 11/30/2022 11:00 am Final Report Date/Time: 12/03/2022 8:25 am Patient ID: 7805 Collection Date /Time: 11/28/2022 2:15 pm Final Report Date/Time: 12/03/2022 8:25 am Patient ID: 7240 Collection Date/Time: 11/29/2022 1:15 pm Final Report Date/Time: 12/03/2022 8:25 am Patient ID: 5126 Collection Date/Time: 11/29/2022: 2:00 pm Final Report Date/Time: 12/03/2022 8:25 am Patient ID: 7462 Collection Date/Time: 11/29/2022 10:30 am Final Report Date/Time: 12/03/2022 8:25 am Patient ID: 4763 Collection Date/Time: 11/30/2022 8:00 am Final Report Date/Time: 12/03/2022 8:25 am Patient ID: 6009 Collection Date/Time: 12/02/2022 10:45 am Final Report Date/Time: 12/03 /2022 8:25 am Patient ID: 7811 Collection Date/Time: 11/30/2022 10:15 am Final Report Date/Time: 12/03/2022 8:25 am Patient ID: 7362 Collection Date/Time: 11/22 /2022 10:15 am Final Report Date/Time: 12/03/2022 8:25 am Patient ID: 5638 Collection Date/Time: 11/23/2022 10:30 am Final Report Date/Time: 12/03/2022 8: 25 am 2. The laboratory was asked to provide requisitions for the above listed patients, and none were provided. 3. During an interview on 12/13/2022 with Testing

	Personnel 1 (as listed on Form CMS-209) revealed that she discarded the requisitions once the patient information was entered into the LIS. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services
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: 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 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" 3. 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." 4. The laboratory was asked to provide documentation of performing studies to support the storage stability claims in Appendix I. No documentation was provided. 5. The laboratory reported performing 43516 tests annually. 6. 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.
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.
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). 3. 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).
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 records, and staff interview, it was revealed the laboratory failed to have documentation of performing establishment studies for 43 of 43 analytes. The findings include: 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. The laboratory was asked to provide documentation of performing establishment studies to include accuracy, precision, reportable range, sensitivity, specificity, etc. No documentation was provided. 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.
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 2022 to November 2022 identified the following 2 days when two of three levels of quality control testing were identified as unacceptable, however patient results were still reported. They were: a) test: MDMA date: 06/25/2022 Failed QC: 50% QC 2X QC date: 07/30/2022 Failed QC: 50% QC 2X QC 3. A review of patient test records from the identified days revealed the following patient results were reports when quality control results were unacceptable: a) 06/25/2022 Patient IDs: 5085 7416 5513 2756 7434 7277 6902 b) 07/30/2022 6059 5265 5107 2349 7359 7166 6165 2247 1549 2794 7519 7267 3271 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 MDMA - 3,4-Methylenedioxymethamphetamine QC - quality control
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 establishment studies were performed (refer to D6085). 2. The laboratory director failed to ensure a quality control program was followed (refer D6093).
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 performed (refer to D5423).
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 D5481).
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy manual, CMS form 209, personnel records, and interview with staff, the Technical Supervisor failed to evaluate competency of 2 of 2 testing persons (TP-1, TP-2) responsible for high complexity testing, at least semiannually during the first year of testing. The findings include: 1. Review of the laboratory's policy manual "SOP-QUALITY MANAGEMENT" page 2 stated: "B. ANALYTICAL ... 4. Competency Assessment a. Annual competency assessment will be assessed according to laboratory policy to include laboratory familiarity with procedure manual, periodic performance assessments by participating in proficiency surveys, monitoring the recording and reporting of patient test and QC results, review of preventative maintenance records, problem resolution, ability and direct observation. b. All Proficiency Testing is performed in accordance with Proficiency Testing Proc [sic]" 2. Review of the CMS 209 form revealed TP-1 and TP-2 performed high complexity testing. 3. Review of testing personnel records TP-1 high complexity testing included documented training from 11/2021 through 12/2021- AB Sciex 4500 LC/MSMS (liquid chromatography/mass spectrophotometer mass spectrophotometer): Records did not include documented evaluated competency for TP-1 at least semiannually. Review of testing personnel records for TP-2 high complexity testing included documented training from 11/2021 through 12/2021- AB Sciex 4500 LC/MSMS (liquid chromatography/mass spectrophotometer mass spectrophotometer): Records did not include documented evaluated competency for TP-2 at least semiannually. The Technical Supervisor did not evaluate and document competency assessments for all testing personnel at least semiannually. 4. During an interview on 12/12/2022 at 9:54 a.m., the Technical Supervisor confirmed the above findings.