Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2076634	05/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Jemin N Gajipara Md Pa	8210 Walnut Hill Ln, #905, Dallas, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in COMPLIANCE with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 records, College of American Pathologists (CAP) Proficiency testing (PT) records (2019 and 2020) and staff interview, the laboratory director and testing person failed to attest to the routine integration of proficiency samples into the patient workload for 8 of 8 events in 2019 and 2020. Findings included: 1. Review of laboratory records revealed the laboratory tested chemistry samples for urine toxicology confirmation on the Sciex 4000 Liquid Chromatography Mass Spectrometry analyzer for the following analytes which were included in the

	CAP proficiency testing: 6-Monoacetylmorphine; 7-Aminoclonazepam; Alpha-Hydroxyalprazolam; Alprazolam; Amphetamine; Benzoylecgonine; Buprenorphine; Carisoprodol; Codeine; Diazepam; EDDP; Fentanyl; Gabapentin; Hydrocodone; Hydromorphone; Lorazepam; MDA (3,4 Methylenedioxyamphetime); MDMA (3,4 Methylenedioxymethamphetime); Meperidine; Meprobamate; Methadone; Methamphetamine; Morphine; Norbuprenorphine; Nordiazepam; Norfentanyl; Norhydrocodone; Norhydromorphone; Normeperidine; Noroxycodone; O-Desmethyltramadol; Oxazepam; Oxycodone; Oxymorphone; Pregabalin; Tapentadol; Temazepam; THC-COOH (Tetrahydrocannabinol); Tramadol; Ethyl Glucuronide; Ethyl Sulfate; Butalbital; Phenobarbital 2. Review of CAP proficiency test record titled "Attestation/Use of Other Form" revealed the following statement: "Attestation Statement 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 work load using the laboratory's routine methods.' The laboratory director or designee and the testing personnel must sign on the result form. Retain a signed copy of this page in your laboratory for your records and inspection purposes." 3. Review of CAP PT records from 2019 and 2020 revealed the laboratory director and the testing person failed to sign the attestation forms for the following events: 2019 ETB (Ethanol BioMarkers) - Event A 2019 ETB (Ethanol BioMarkers) - Event B 2019 DMPM (Drug Monitoring for Pain Management)- Event A 2019 DMPM (Drug Monitoring for Pain Management)- Event B 2020 ETB (Ethanol BioMarkers) - Event A 2020 ETB (Ethanol BioMarkers) - Event B 2020 DMPM (Drug Monitoring for Pain Management)- Event A 2020 DMPM (Drug Monitoring for Pain Management)- Event B 4. During an interview on 05/26/2021 at 2:30pm in the hallway outside of the laboratory, Testing Person-1, after review of the data, 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: I. Based on review of submitted Centers for Medicare and Medicaid Services (CMS) -116 form, laboratory policy, laboratory proficiency testing records and confirmed by staff interview, the laboratory failed to verify the accuracy of non-regulated urine toxicology analytes at least twice annually for 2019. Findings included: 1. Review of the CMS-116 form submitted at survey revealed the following non-regulated urine toxicology analytes were tested by the laboratory: Baclofen; Cyclobenzaprine; MDEA (3,4 Methylenedioxy-n-ethylamphetamine);Mitragynine; Naloxone; PCP (Phencyclidine); Phentermine; Ritalinic Acid; Zaleplon; Zolpidem; Pentobarbital; Secobarbital 2. Review of the laboratory policy titled, "Proficiency Testing" (signed by the laboratory director 05/26/2021), stated, "Drugs of abuse are not analytes within the specialties/subspecialties that are regulated by CLIA. Whenever analytes that do not require proficiency testing or analytes that are not regulated, the laboratory will verify the accuracy of the test procedure twice annually through external assessment programs or sample comparisons with another laboratory's instrument/method." 3. Review of laboratory proficiency testing records (2019 and 2020) revealed the laboratory performed one accuracy assessment for the non-regulated analytes listed in #1 above in 2019. The laboratory was asked to provide documentation of a second accuracy assessment for 2019. No documentation was provided. The laboratory failed

	to verify the accuracy of non-regulated urine toxicology analytes at least twice annually for 2019. 4. In an interview on 05/26/2021 at 2:35pm in the hallway outside the laboratory, Testing Person-1, after review of the data, confirmed the above findings. II. Based on review of submitted Centers for Medicare and Medicaid Services (CMS)-116 form, laboratory policy, laboratory proficiency testing records and confirmed by staff interview, the laboratory failed to verify the accuracy of the non-regulated urine toxicology analyte, methylphenidate, at least twice annually for 2019 and 2020. Findings included: 1. Review of the CMS-116 form submitted at survey revealed the following non-regulated urine toxicology analyte was tested by the laboratory: Methylphenidate 2. Review of the laboratory policy titled, "Proficiency Testing" (signed by the laboratory director 05/26/2021), stated, "Drugs of abuse are not analytes within the specialties/subspecialties that are regulated by CLIA. Whenever analytes that do not require proficiency testing or analytes that are not regulated, the laboratory will verify the accuracy of the test procedure twice annually through external assessment programs or sample comparisons with another laboratory's instrument/method." 3. Review of laboratory proficiency testing records (2019 and 2020) revealed the laboratory failed to perform twice annual accuracy assessment for the non-regulated urine toxicology analyte, methylphenidate, in 2019 and 2020. The laboratory was asked to provide documentation of twice annual accuracy assessment for methylphenidate. No documentation was provided. The laboratory failed to verify the accuracy of non-regulated urine toxicology analytes at least twice annually for 2019 and 2020. 4. In an interview on 05/26/2021 at 2:35pm in the hallway outside the laboratory, Testing Person-1, after review of the data, confirmed the above findings.
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 manufacturer's instructions, laboratory's policies, review of the laboratory's establishment studies for its modified FDA-approved tests, patient collection and transport instructions, and staff interview, it was revealed the laboratory failed to have documentation of performing stability studies to support its policy of accepting urine specimens for testing on the Synermed IR 500 analyzer for up to 7 days after collection, transported to the facility at ambient temperature. Findings Included: 1. Review of manufacturer's instructions for all listed modified FDA-approved tests, revealed the following specimen storage requirements for toxicology screening: "Specimen Collection and Handling ...If the sample can not be analyzed immediately, it may be stored refrigerated for up to 3 days." 2. Review of the laboratory's policy titled "Validation Protocol & Results for Polypropylene Storage Containers and Frozen Temperature Storage" (Approved by the laboratory director on 6/7/2016) revealed the laboratory would process urine specimens received through the United States Postal Service, at an ambient air temperature for up to 7 days after collection. This was a modification of manufacturer's instructions stating samples were acceptable for up to 3 days after collection if refrigerated. 3. A review

	of the laboratory's establishment studies for its modified FDA-approved tests, revealed the laboratory did not include ambient air transport stability for 7 days as part of its studies for sample stability, transport, or storage. 4. A random sampling of final patient confirmation reports revealed the following 17 of 30 specimens were processed after ambient air transport from 5/05/2021-5/19/2021: a. Patient ID: P000620 b. Patient ID: P000243 c. Patient ID: 001427 d. Patient ID: 000061 e. Patient ID: 001138 f. Patient ID: 001433 g. Patient ID: 000826 h. Patient ID: P000225 i. Patient ID: 000812 j. Patient ID: 000892 k. Patient ID: 000389 l. Patient ID: P000396 m. Patient ID: 000119 n. Patient ID: 001361 o. Patient ID: P000088 p. Patient ID: 000084 q. Patient ID: 001322 6. In an interview with the laboratory general supervisor at 2:25 PM on 5/26/2021, in the laboratory, the supervisor was asked to provide documentation of 7 day ambient air stability studies for urine specimens. No documentation was provided. This confirmed the above findings. II. Based on laboratory's stability studies, laboratory test requisitions, final confirmation patient reports, and staff interview, the laboratory failed to follow its own policy for specimen acceptability for urine LC/MS analysis for 1 of 30 specimens reviewed from May 2021. Findings Included: 1. Review of laboratory stability studies revealed the following: Urine Stability for LC/MS Room Temperature and 2-8 C - 14 days 2. Random review of laboratory's final confirmation patient reports for May 2021, revealed the following specimen tested after 14 days: Patient ID: 001433 Collection Date: 4/17/21; Test Date: 5/05/2021; Elapsed number of days: 18 days 3. In an interview with the general supervisor at 3:00 PM on 5/26/2021, in the laboratory, the supervisor was asked to define the acceptance criteria for urine prior to LC/MS analysis. The general supervisor stated urine specimens collected more than 14 days prior to testing would be rejected. The supervisor was presented with the above findings and confirmed the 1 of 30 urine specimens from May 2021, for LC/MS analysis, should have been rejected prior to testing. This confirmed the above findings. IV. Based on laboratory's stability studies, laboratory test requisitions, final confirmation patient reports, and staff interview, the laboratory failed to follow its own policy for urine specimen acceptability for testing on the Sysmed IR-500 for 10 of 30 specimens reviewed from May 2021. Findings Included: 1. Review of laboratory's stability studies revealed the following: Urine Stability for IR-500 Room Temperature and 2-8 C - 7 days 2. Random review of laboratory's final confirmation patient reports for May 2021, revealed the following specimens tested after 7 days: a. Patient ID: 001433 Collection Date: 4/17/21; Test Date: 5/05/2021; Elapsed number of days:18 days b. Patient ID: 001509 Collection Date: 4/25/21; Test Date: 5/05/2021; Elapsed number of days:10 days c. Patient ID: 000812 Collection Date: 5/01/21; Test Date: 5/12/2021; Elapsed number of days:11 d. Patient ID: 000892 Collection Date: 5 /03/21; Test Date: 5/12/2021; Elapsed number of days:9 days e. Patient ID: 000389 Collection Date: 5/03/21; Test Date: 5/12/2021; Elapsed number of days:9 days f. Patient ID: P000396 Collection Date: 5/03/21; Test Date: 5/12/2021; Elapsed number of days:9 days g. Patient ID: 000061 Collection Date: 4/22/21; Test Date: 5/05/2021; Elapsed number of days:13 days h. Patient ID: 001427 Collection Date: 4/26/21; Test Date: 5/05/2021; Elapsed number of days:9 days i. Patient ID: 001138 Collection Date: 4/22/21; Test Date: 5/05/2021; Elapsed number of days:13 days j. Patient ID: 000826 Collection Date: 4/22/21; Test Date: 5/05/2021; Elapsed number of days:13 days 3. In an interview with the general supervisor at 3:00 PM on 5/26/2021, in the laboratory, the supervisor was asked to define the acceptance criteria for urine prior to IR-500 analysis. The general supervisor stated urine specimens collected more than 14 days prior to testing would be rejected. The supervisor was presented with the above findings and confirmed 10 of 30 urine specimens from May 2021, for IR-500 analysis, should have been rejected prior to testing. This confirmed the above findings. Word Key: LC/MS- Liquid Chromatography Mass Spectrometry

D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation, review of Synermed IR Series GPR 560 Urine Creatinine reagent package insert, laboratory Reagent/Calibration log, patient records and staff interview, the laboratory failed to monitor the revised expiration date for 1 of 1 Synermed IR Series GPR 560 Urine Creatinine reagent currently in use. Findings Included: 1. Review of the manufacturer's package insert for Synermed IR Series GPR 560 Urine Creatinine revealed the following: "Reagent Preparation and Storage ... ... All assay components should be stored at 0-4 C and are stable until the expiration date on the product label when not in use. In-use reagent is stable for 30 days." 2. During a tour of the lab at 4:15 PM on 5/26/21, the inspector observed 1 Synermed IR Series GPR 560 Urine Creatinine reagent currently on board the Synermed IR 500 analyzer. Lot Number: 1401; Expiration Date: 2/10/21 3. Review of the laboratory's Reagent /Calibration Log revealed the last lot of reagent loaded onto the Synermed IR-500 analyzer: Date- 12/01/20 Lot Number: 1401; Expiration Date: 02/10/21 Thus, the onboard reagent expired on 12/31/2020. 4. Review of patient records revealed the laboratory processed 108 patient specimens after the revised in use expiration date (12 /31/2020) of the Synermed IR Series GPR 560 Urine Creatinine reagent. 5. In an interview with the general supervisor at 4:20 PM on 5/26/2021, in the laboratory, the supervisor was asked if the Synermed IR Series GPR 560 Urine Creatinine reagent expiration date was revised once placed into use. The supervisor stated the expiration date had not been revised when the reagent was put into use. This 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: I. Based on review of the laboratory's policy, review of the laboratory's establishment studies, and staff interview, it was revealed the laboratory failed to ensure establishment studies were complete prior to patient testing. Findings included: 1. A review of the laboratory's test menu revealed the facility utilized the following

	modified FDA-approved tests to perform toxicology screening: Lin-Zhi Barbiturate Enzyme Immunoassay Lin-Zhi Benzodiazepines Enzyme Immunoassay Lin-Zhi Buprenorphine Enzyme Immunoassay Lin-Zhi Cannabinoids Enzyme Immunoassay Lin-Zhi Cocaine Metabolite Enzyme Immunoassay Lin-Zhi Ecstasy Enzyme Immunoassay Lin-Zhi Methadone Enzyme Immunoassay Lin-Zhi Oxycodone Enzyme Immunoassay Lin-Zhi Opiate Enzyme Immunoassay Lin-Zhi Phencyclidine Enzyme Immunoassay Lin-Zhi Propoxyphene Enzyme Immunoassay 2. A review of the laboratory's establishment studies for the identified assays revealed the laboratory failed to have documentation of performing: Specimen ambient air stability studies (see also D5311 I). 3. The laboratory was asked to provide documentation of performing the required studies. No documentation was provided. 4. In an interview with the general supervisor at 3:00 PM on 5/26/2021, in the laboratory, the supervisor confirmed the laboratory did not perform the specimen ambient air and post-extraction studies. This confirmed the above findings. II. Based on review of the laboratory's policies, review of the laboratory's establishment studies for its laboratory developed tests and staff interview, it was revealed the laboratory failed to have documentation of performing stability studies to support its post-extraction patient specimen stability for testing on the Sciex 4000 LC/MS analyzer. Findings Included: 1. Review of laboratory policy, "Quantitative Determination of Drugs and Metabolites in Urine via LC-MS/MS (Urine Drug Confirmation- Panel A) Pain Care Option "(Reviewed by the laboratory director on 5/20/2021) stated the following: " ...11. Samples are now ready for analysis by LCMS/MS. Store vials in the refrigerator if not able to analyze immediately." 2. A review of the laboratory's establishment studies for its laboratory developed tests, revealed the laboratory did not include post-extraction stability storage as part of its studies. 3. In an interview with the general supervisor at 3:00 PM on 5/26/2021, in the laboratory, the supervisor was asked to provide documentation of stability studies for post-extraction of patient specimens. No documentation was provided. This confirmed the above findings. Word Key: LC/MS-Liquid Chromatography Mass Spectrometry
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: I. Based on laboratory maintenance logs, and staff interview, the laboratory failed to perform monthly maintenance for the IR 500 analyzer for 5 of 15 months (February 2020 - April 2021). Findings Included: 1. Review of laboratory maintenance logs titled, "IR 500 Maintenance Schedule" revealed the following months where monthly maintenance was not documented for "1 pipette full of bleach in diluter well" : June 2020; July 2020; October 2020; November 2020; February 2021 2. In an interview with the general supervisor at 2:50 PM on 5/26/2021, in the laboratory, the supervisor was asked if monthly maintenance was performed on the Synermed IR 500 analyzer. The general supervisor stated monthly maintenance was performed, and the missing monthly maintenance entries for 5 of 15 months (February 2020 - April 2021), were transcription errors. When the supervisor was asked to provide another form of documentation that monthly maintenance was performed, no documentation was provided. This confirmed the above findings. II. Based on laboratory maintenance logs, and staff interview, the laboratory failed to perform 3 month maintenance for the

	Synermed IR 500 analyzer for 4 of 6 months (January 2020 - April 2021). Findings Included: 1. Review of laboratory maintenance logs titled, "IR 500 Maintenance Schedule" revealed the following months 3 month maintenance was performed (January 2020- April 2021): September 2020; January 2021 Thus, the laboratory exceeded 3 months when performing maintenance on the Synermed IR 500 analyzer. 2. In an interview with the general supervisor at 2:52 PM on 5/26/2021, in the laboratory, the supervisor was asked if 3 month maintenance was performed on the Synermed IR 500 analyzer. The general supervisor stated 3 month maintenance was performed, and the missing maintenance entries for 4 of 6 months (January 2020 - April 2021), were transcription errors. When the supervisor was asked to provide another form of documentation that 3 month maintenance was performed, no documentation was provided. This confirmed the above findings.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: I. Based on laboratory policy, laboratory monthly maintenance logs, and staff interview, the laboratory failed to document performance of monthly maintenance for the Sciex 4000 LC/MS analyzer for 10 of 12 months in 2020. Findings Included: 1. Review of the laboratory policy, "5. Maintenance and Service" (Approved by the laboratory director on 1/12/2018), stated the following: " ... 5.2. Monthly- Clean spray cone and ion transfer tube every month. Verify Instrument performance." 2. Review of laboratory maintenance logs titled, "Monthly Sciex 4000 LC/MS Maintenance Log" revealed the following months where monthly maintenance was not performed: a. January 2020 Clean Ion chamber: No b. February 2020 Clean Ion chamber: No c. March 2020 Clean Ion chamber: No f. June 2020 Clean Ion chamber: No g. July 2020 Clean Ion chamber: No h. August 2020 Clean Ion chamber: No i. October 2020 Clean Ion chamber: No j. November 2020 Clean Ion chamber: No 3. In an interview with the general supervisor at 2:55 PM on 5/26/2021, in the laboratory, the supervisor was asked if monthly maintenance was performed on the LC/MS analyzer. The general supervisor stated monthly maintenance was performed, and the "No" selected for monthly maintenance on 8 of 10 maintenance logs in 2020, were transcription errors. When the supervisor was asked to provide another form of documentation that monthly maintenance was performed, no documentation was provided. This confirmed the above findings. II. Based on laboratory policy, review of maintenance records, and staff interview, the laboratory failed to perform quarterly maintenance for the Sciex 4000 LC/MS analyzer for 1 event in 2020. Findings Included: 1. Review of the laboratory policy, "5. Maintenance and Service" (Approved by the laboratory director on 1/12/2018), stated the following: " ...5.3 Quarterly Replace roughing pump oil. Perform tuning and calibration of the instrument after oil change." 2. Review of laboratory maintenance logs titled, "Monthly Sciex 4000 LC/MS Maintenance Log" revealed the following event where quarterly maintenance was not performed: June 2020 Change the roughing pump oil: No 3. In an interview with the general supervisor

	at 2:55 PM on 5/26/2021, in the laboratory, the supervisor was asked if monthly maintenance was performed on the LC/MS analyzer. The general supervisor stated quarterly maintenance was performed, and the "No" selected for quarterly maintenance on 1 event of 2020, was a transcription error. When the supervisor was asked to provide another form of documentation that quarterly maintenance was performed, no documentation was provided. This confirmed the above findings. Word Key: LC/MS- Liquid Chromatography Mass Spectrometry
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control policy, review of laboratory's quality control records from January 2020-May 2021, and staff interview, it was revealed the laboratory failed to have documentation of verifying 12 of 12 new lots of control prior to placing them into service. Findings Included: 1.Review of the laboratory's policy titled, "Quality Control Policy"(Approved by the laboratory director on 11/15/2017) revealed the laboratory failed to define a procedure for lot to lot verification of new quality control lots before placing them into use. 2. Review of the laboratory's records, "IR 500 QC Log" revealed the following quality controls in use: a. M1-Benzoylecgonine, PCP, Oxazepam, Secobarbital, MEthD b. M2-Benzoylecgonine, PCP, Oxazepam, Secobarbital, MEthD c. T1, T2 - Cannabinoid d. O1, O2- Opiate e. U1, U2- Urine Creatinine 3. Further review of the laboratories quality control log revealed the following new lots placed into use: a. M1 Lot Number: 031912-98; Exp. Date: 12/03/20 b. M2 Lot Number: 031912-99; Exp. Date: 12/03/20 c. T1 Lot Number: 1910073; Exp. Date: 04/10/21 Lot Number: 200080; Exp. Date: 02/26/22 d. T2 Lot Number: 1910075; Exp. Date: 04/10/21 Lot Number: 200082; Exp. Date: 02/26/22 e. U1 Lot Number: 1620011-CON; Exp. Date: 01/16/21 Lot Number: 052006-50; Exp. Date: 06/05/21 f. U2 Lot Number: 1620012-CON; Exp. Date: 01/16/21 Lot Number: 052006-300; Exp. Date: 06/05/21 g. O1 Lot Number: 1908079; Exp. Date: 08/09/21 h. O2 Lot Number: 1908081; Exp. Date: 08/09 /21 3. The laboratory was asked to provide documentation of lot to lot verification for the 12 new lots put into use. No documentation was provided. 4. In an interview with the general supervisor at 3:00 PM on 5/26/2021, in the laboratory, the general supervisor stated no lot to lot verifications were performed for new quality control lots before putting them into use. This confirmed the above findings.
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 the Centers for Medicare and Medicaid Services (CMS) 209 form, laboratory policy, laboratory personnel records for 2018-2020 and confirmed in interview, the technical supervisor failed to perform two competency assessments in the first year of patient testing for 1 of 1 testing persons (TP-1) for the high complexity Sciex 4000 and Synerned IR-500 chemistry analyzers. Findings included: 1. Review of the CMS209 signed by the laboratory director on 05/17/2021 revealed 1 testing person (TP-1) who performed high complexity toxicology testing on the Sciex 4000 and Synerned IR-500 chemistry analyzers. 2. Review of the laboratory policy titled, "Personnel Competency Assessment" (signed by the laboratory director 05/26 /2021) stated, "Laboratory staffs who conduct the pre-analytical, analytical, and post-analytical phases of testing will be monitored as it applies to their specific duties, at six months and annually, to assure that they are competent and maintain their competency to process specimen, and/or perform test procedures and/or report test results promptly and proficiently ..." 3. Review of the personnel records from 2018-2020 revealed the following training and competency documentation for high complexity on the Sciex 4000 and Synerned IR-500 chemistry analyzers: Testing Person-1; Initial Training 06/09/2018 The next competency assessment was performed 06/07/2019 The next competency assessment was performed 06/07/2020. The technical supervisor failed to perform two competency assessments for Testing Person-1 in the first year of patient testing for the high complexity Sciex 4000 and Synerned IR-500 chemistry analyzers. 4. During an interview on 05/26/2021 at 09: 30am in the hallway outside of the laboratory, the technical supervisor was asked to provide documentation of two competency assessments in the first year of patient testing for Testing Person-1. No documentation was provided. This confirmed the findings.