Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	29D2135892	11/17/2021
Name of Provider or Supplier	**Street Address, City, State**	
Psychiatric Management Llc	2725 S Jones Blvd Ste 107, Las Vegas, NV	

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	This Statement of Deficiencies was created as a result of an on-site CLIA recertification survey conducted at your facility on November 16-17, 2021. The findings and conclusions of any investigation by the Division of Public and Behavioral Health shall not be construed as prohibiting any criminal or civil investigations, actions or other claims for relief that may be available to any party under applicable federal, state, or local laws.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the director approved policy entitled "Proficienty (sic) Testing," the lack of laboratory records of twice per year verification of accuracy for the following analytes not included in the College of American Pathologists (CAP) Drug Monitoring for Pain Management (DMPM) Proficiency Testing (PT) enrollment for 2019, 2020 and 2021: MDEA, Mephedrone, Methylphenidate, Ritalinic Acid, Nordiazapam, Secobarbital, Flurazepam, Metaxalone, Zaleplon, Zolpidem, Amitriptyline, Cuclobenzaprine, Desipramine, Doxepin, Duloxetine, Nortriptyline, JWH-018 Pentanoic acid, JWH-073 Butanoic acid, JWH-073 Hydroxybutyl, Mitragynine, Baclofen, Clonidine, Ketamine, Naphyrone, Norketamine, Norpseudoephedrine, Naloxone, Naloxone Glucoronide, Naltrexone, Morphine 3 Glucuronide, and Morphine 6 Glucuronide, the laboratory failed to perform twice per year verification of accuracy for analytes not included in commercially available

	proficiency testing enrollment (refer to D5217), a review of the College of American Pathologists (CAP) Drug Monitoring for Pain Management (DMPM) Proficiency Testing (PT) 2020 and 2021 laboratory evaluation reports and corrective action documentation, the laboratory failed to perform appropriate corrective action for the confirmation of the analytes that were outside the acceptable ranges established by the CAP Proficiency Testing program(Refer to D5221), a review of the director approved policy entitled "Quality Assurance," and a review of the Monthly Director Visit Quality Assurance Review records between the dates of April, 2019, and October, 2021), the laboratory failed to follow written policies and procedures to monitor, assess, and correct problems identified in the general laboratory systems. (refer to D5291) The laboratory performs approximately 432,016 toxicology tests annually.
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 a review of the director approved policy entitled "Proficienty (sic) Testing," a review of the proficiency testing records, and an interview with the laboratory supervisor, the laboratory failed to ensure that the accuracy of the analytes not included in the College of American Pathologists (CAP) Drug Monitoring for Pain Management (DMPM) Proficiency Testing (PT) survey was verified twice per year during 2019, 2020, and 2021. Findings include: 1. The director approved policy entitled "Proficienty (sic) Testing," in section "II. Policy", sub-section "B." stated, "Tests for which compatible proficiency testing material in (sic) not available from an approved program the laboratory is required to verify twice annually the accuracy of the tests. This will be accomplished by exchange of specimens required for the test with an outside licensed laboratory in the community who performs the test for which there is no proficiency testing materials available. The exchange of data will be used to verify the accuracy of the instrument." 2. There were no records for the twice per year verification of accuracy performed in 2019, 2020, and 2021 for the following analytes that were not included in the CAP DMPM proficiency testing survey: MDEA, Mephedrone, Methylphenidate, Ritalinic Acid, Nordiazapam, Secobarbital, Flurazepam, Metaxalone, Zaleplon, Zolpidem, Amitriptyline, Cyclobenzaprine, Desipramine, Doxepin, Duloxetine, Nortriptyline, JWH-018 Pentanoic acid, JWH-073 Butanoic acid, JWH-073 Hydroxybutyl, Mitragynine, Baclofen, Clonidine, Ketamine, Naphyrone, Norketamine, Norpseudoephedrine, Naloxone, Naloxone Glucoronide, Naltrexone, Morphine 3 Glucuronide, and Morphine 6 Glucuronide. 3. During an interview conducted on November 16, 2021 at approximately 1:30 PM, the laboratory supervisor confirmed that no records of twice per year verification of accuracy for 2019, 2020, and 2021 were available for review at the time of the survey. The laboratory performs approximately 432,016 toxicology tests annually.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by:

Based on a review of the director approved policy entitled "Proficienty (sic) Testing," a review of the laboratory College of American Pathologists (CAP) Drug Monitoring for Pain Management (DMPM) Proficiency Testing (PT) records for 2020 and 2021, a review of the 2021 DMPM-A re-run analyzer print out for the event one specimens, and an interview with the laboratory supervisor, the laboratory failed to perform and document effective corrective action for the 2020 DMPM-B test event two, and the 2021 DMPM-A test event one quantitative urine drug testing results, and the laboratory failed to review and document an evaluation of the participant summary for the 2020 DMPM-B test event two ungraded test result for specimen number DMPM-06. Findings include: 1. The director approved policy entitled "Proficienty (sic) Testing," in section "II. Policy", sub-section "G." stated, "All out of range results will be investigated and all corrective action documented. If the assigned proficiency test score falls below 100%, corrective action will include reviewing of instrument control and calibration data, review of instrument maintenance logs, and verification of analyte accuracy." 2. A review of the 2020 DMPM-B CAP PT report revealed that for specimen DMPM-06, the quantitative result for Morphine was outside the limit of acceptability. The result reported was 6457.9 ng/ml. The limit of acceptability for morphine identified on the CAP report was 2929.1-6088.1 ng/ml. 3. A review of the 2020 DMPM-B CAP PT report revealed that for specimen DMPM-07, the quantitative result for oxymorphone was outside the limit of acceptability. The result reported was 717.2ng/ml. The limit of acceptablility for oxymorphone identified on the CAP report was 332.5-661.7 ng/ml. 4. A review of the document entitled "DMPM-B 2020 Corrective Action" revealed that specimens DMPM-06 and DMPM-07 were reanalyzed. The document stated that the DMPM-06 morphine result was still out of range, and would be monitored going forward. The document stated that the DMPM-07 oxymorphone result obtained upon repeat was acceptable. There were no records retained of the repeat of the test specimens to verify that the DMPM-07 oxymorphone result obtained upon repeat analysis was acceptable. 5. A review of the 2020 DMPM-B CAP PT report revealed that there was no documentation of the Participant Summary review to evaluate the specimen number DMPM-06 result for N-Desmethyltramadol which was not graded due to insufficient peer group data. 6. A review of the 2020 DMPM-B Participant Summary for specimen number DMPM-06 revealed that the detection of N-Desmethyltramadol reported to CAP was a false positive. 7. A review of the 2020 DMPM-B Participant Summary for specimen number DMPM-06 revealed that the detection of O-Desmethyltramadol was present in the specimen. The laboratory failed to detect and report O-Desmethyltramadol present in specimen number DMPM-06. 8. The document entitled "DMPM-B 2020 Corrective Action" stated that no patients were affected by the unacceptable PT results for the DMPM-B 2020 test event because all of the analytes were detected during the survey. 9. A review of the 2021 DMPM-A CAP PT test event one revealed that for specimen DMPM-01, the results for Amphetamine, Alprazolam, Butalbital, Alpha-Hydroxyalprazolam, and Hydromorphone were outside the acceptable ranges. The Amphetamine result reported was 4924.7 ng/ml. The acceptable range for Amphetamine was 1073.1-2051.4 ng/ml. The Alprazolam result reported was 794.1 ng /ml. The acceptable range for Alprazolam was 140.6-275.1 ng/ml. The Butalbital result reported was 5399.1 ng/ml. The acceptable range for Butalbital was 1189.5-2673.7 ng/ml. The Alpha-Hydroxyalprazolam result reported was 4969.9 ng/ml. The acceptable range for Alpha-Hydroxyalprazolam was 839.5-1943.1 ng/ml. The Hydromorphone result reported was 1701.0 ng/ml. The acceptable range for Hydromorphone was 352.5-654.8 ng/ml. 10. A review of the analyzer print out for the re-analysis of the 2021 DMPM-A CAP PT specimen DMPM-01 after the preventative maintenance and cleaning of the rails was performed on the analyzer revealed that the results for Amphetamine, Alprazolam, Butalbital, Alpha-Hydroxyalprazolam, and

Hydromorphone remained outside the acceptable ranges. The Amphetamine repeat result was 2283.58 ng/ml. The acceptable range for Amphetamine was 1073.1-2051.4 ng/ml. The Alprazolam repeat result was 347.31 ng/ml. The acceptable range for Alprazolam was 140.6-275.1 ng/ml. The Butalbital repeat result was 3043.51 ng/ml. The acceptable range for Butalbital was 1189.5-2673.7 ng/ml. The Alpha-Hydroxyalprazolam repeat result was 1957.64 ng/ml. The acceptable range for Alpha-Hydroxyalprazolam was 839.5-1943.1 ng/ml. The Hydromorphone repeat result was 759.55 ng/ml. The acceptable range for Hydromorphone was 352.5-654.8 ng/ml. 11. A review of the 2021 DMPM-A CAP PT test event one revealed that for specimen DMPM-02, the results for Amphetamine, Benzoylecgonine, and Methadone were outside the acceptable ranges. The Amphetamine result reported was 2123.3 ng/ml. The acceptable range for Amphetamine was 1012.8-2077.0 ng/ml. The Benzoylecgonine result reported was 1517.0 ng/ml. The acceptable range for Benzoylecgonine was 658.6-1223.3 ng/ml. The Methadone result reported was 331.7 ng/ml. The acceptable range for Methadone was 131.5-286.1 ng/ml. 12. A review of the analyzer print out for the re-analysis of the 2021 DMPM-A CAP PT specimen DMPM-02 after the preventative maintenance and cleaning of the rails was performed on the analyzer revealed that the results for Amphetamine, and Benzoylecgonine remained outside the acceptable ranges. The Amphetamine repeat result was 2283.58 ng/ml. The acceptable range for Amphetamine was 1073.1-2051.4 ng/ml. The Benzoylecgonine repeat result was 1231.96 ng/ml. The acceptable range for Benzoylecgonine was 658.6-1223.3 ng/ml. The re-analysis revealed that the Delta-9-THC-COOH that was initially acceptable was no longer acceptable on the repeat analysis of the specimen. The repeated result for the Delta-9-THC-COOH was 242.48 ng/ml. The acceptable range for Delta-9-THC-COOH was 90.3-236.8 ng/ml. 13. A review of the 2021 DMPM-A CAP PT test event one revealed that for specimen DMPM-03, the results for Diazepam, Nordiazepam, Oxazepam, Pregabalin, Codeine, and Morphine were outside the acceptable ranges. The Diazepam result reported was 143.6 ng/ml. The acceptable range for Diazepam was 32.9-71.1 ng/ml. The Nordiazepam result reported was 1285.1 ng/ml. The acceptable range for Nordiazepam was 325.4-628.3 ng/ml. The Oxazepam result reported was 2554.9 ng /ml. The acceptable range for Oxazepam was 579.6-1261.7 ng/ml. The Pregabalin result reported was 9.7 ng/ml. The acceptable range for Pregabalin was 2.2-7.0 ng/ml. The Codeine result reported was 4304.4 ng/ml. The acceptable range for Codeine was 1217.7-2546.6 ng/ml. The Morphine result reported was 848.9 ng/ml. The acceptable range for Morphine was 201.3-374.0 ng/ml. 14. A review of the analyzer print out for the re-analysis of the 2021 DMPM-A CAP PT specimen DMPM-03 after the preventative maintenance and cleaning of the rails was performed on the analyzer revealed that the results for Pregabalin remained outside the acceptable range. The Pregabalin repeat result was 5867.69 ng/ml. The acceptable range for Pregabalin was 2.2-7.0 ng/ml. 15. A review of the document entitled, "2021 DMPM-A Corrective Action" revealed that specimens DMPM-01, DMPM-02, and DMPM-03 were re-analyzed after preventative maintenance and cleaning of the rails was performed. The document stated, "On the repeat, specimen DMPM-03 and 3 drugs from DMPM-02 were all reported as acceptable. DMPM-01 and DMPM-02 still had some drugs that that (sic) were higher in concentration than expected from the CAP results." The document failed to address the specific analytes that remained outside the acceptable ranges, nor did it address the initally acceptable DMPM-02 Delta-9-THC-COOH that was outside the acceptable range upon repeat analysis. The document went on to state, "No patients were affected from the CAP findings. All analytes were detected qualitatively." 16. The findings were confirmed during an interview with the laboratory supervisor conducted on November 16, 2021 at approximately 2:00 PM. The laboratory performs approximately 432,016 toxicology tests annually.

D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on a review of the director approved policy entitled, "Quality Assurance," a review of the Monthly Director Visit Quality Assurance Review records between the dates of April, 2019 and October, 2021, a review of the College of American Pathologists (CAP) Proficiency Testing records for the 2020 and 2021 Drug Monitoring for Pain Management (DMPM) test events, a review of the director approved policy entitled, "Proficienty (sic) Testing," and an interview with the laboratory supervisor, the laboratory failed to ensure that the established written policies and procedures were followed to monitor, assess, and when indicated, correct problems identified in the general laboratory systems. Findings include: 1. A review of the Monthly Director Visit Quality Assurance Review records between the dates of April, 2019 and October, 2021 revealed that the established quality assessment plan failed to detect and correct the failure to perform and maintain the records of the twice per year verification of accuracy for the following analytes that are not included in the CAP DMPM Proficiency Testing enrollment as specifed in the director approved policy entitled "Proficienty (sic) Testing": MDEA, Mephedrone, Methylphenidate, Ritalinic Acid, Nordiazapam, Secobarbital, Flurazepam, Metaxalone, Zaleplon, Zolpidem, Amitriptyline, Cyclobenzaprine, Desipramine, Doxepin, Duloxetine, Nortriptyline, JWH-018 Pentanoic acid, JWH-073 Butanoic acid, JWH-073 Hydroxybutyl, Mitragynine, Baclofen, Clonidine, Ketamine, Naphyrone, Norketamine, Norpseudoephedrine, Naloxone, Naloxone Glucoronide, Naltrexone, Morphine 3 Glucuronide, and Morphine 6 Glucuronide. 2. In the section of the Monthly Director Visit Quality Assurance Review documents between the dates of April, 2019 and October, 2021 entitled, "II. Proficiency Testing," there is no reference to the need to perform twice per year verification of accuracy for the analytes not included in the CAP DMPM Proficiency Testing enrollment or reference to a review of twice per year verification of accuracy for those analytes. 3. A review of the Monthly Director Visit Quality Assurance Review records between the dates of September, 2020 and October, 2021 revealed that the Monthly Director Visit Quality Assurance Review forms failed to accurately document the results of the 2020 CAP DMPM-B and the 2021 DMPM-A in order to ensure that appropriate corrective action was taken for the proficiency testing failures. The Monthly Director Visit Quality Assurance Review records for the months of September, October, and November, 2020 stated that the CAP Survey 2020 DMPM-B test event evaluation received a score of 100%. The Monthly Director Visit Quality Assurance Review records for the months of April, 2021 through October, 2021 stated that for the 2021 DMPM-A test event evaluation was "Good Pass." 4. The director approved policy entitled, "Quality Assurance," in the section entitled "Principle"stated, "The purpose of this procedure is two-fold: (1) to provide an ongoing, planned and systematic process to monitor, evaluate, and improve the quality and appropriateness of laboratory services provided. (2) To assure that services provided are optimally safe, efficient and effective within the limits set by available resources." The section entitled, "X. Communicate Results" stated, "A monthly report will be generated and will include aspects of care that have been monitored and the results evaluation process, the action plan and it's (sic)

	implementation, and the measurable improvements in quality that have been achieved. This is the Director Visit Report, which is reviewed with laboratory employees each month for quality assurance purposes." 5. The findings were confirmed during an interview with the laboratory supervisor on November 17, 2021 at approximately 9:00 AM. The laboratory performs approximately 432,016 toxicology tests annually.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, 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 analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of the laboratory maintenance logs for the AB Sciex 4500 lc-ms /ms analyzer between the dates of April, 2019 and June, 2020, the laboratory failed to ensure that the weekly maintenance was performed on two of four weeks during the month of September, 2020 (refer to D5433). Based on a review of the director approved policy and procedure entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure," a random patient audit for the urine drug confirmation testing on the dates of March 20, 2020, May 29, 2020, and June 26, 2021, a lack of records of calibration of the AB Sciex 4500 urine drug confirmation testing, and an interview with the laboratory supervisor, the laboratory failed to perform the calibration of the AB Sciex 4500 lc-ms/ms with each patient analysis run as specified in the director approved policy and procedure (refer to 5437) and to perform calibration verification at least every six months (refer to D5439). Based on a review of the director approved policy entitled, "Quality Assurance," and a review of the Director Monthly Visit Quality Assurance Review between the months of April, 2019 and October, 2021, the laboratory failed to ensure that the established policies and procedures were effective to detect and correct problems in the laboratory analytical systems (refer to D5791). The laboratory performs approximately 432,016 toxicology tests annually.
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: Based on a review of the laboratory maintenance logs for the AB Sciex 4500 Liquid Chromatography/Mass Spectrometry (LC-MS/MS) analyzer between the dates of April, 2019 and June, 2021, and an interview with the laboratory supervisor, the laboratory failed to ensure that the weekly maintenance was performed on two of four

	weeks during the month of September, 2020. Findings include: 1. A review of the maintenance log for the AB Sciex 4500 LC-MS/MS analyzer between the dates of April, 2019 and June 2021 revealed that the weekly maintenance to clean the front end was not performed between the dates of September 14, 2020 and October 2, 2020. 2. The finding was confirmed during an interview with the laboratory supervisor conducted on November 16, 2021 at approximately 2:00 PM. The laboratory performs approximately 432,016 toxicology tests annually.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on a random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021, a review of the director approved policy and procedure entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure," and an interview with the laboratory supervisor, who spoke with and relayed the information from the former testing technologist during the survey, the laboratory failed to ensure that the calibration of the urine drug confirmatory tests was performed with each patient run, in accordance with the director approved policy and procedure. Findings include: 1. A random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021 revealed that there were no records of the calibration for the AB Sciex 4500 lc-ms/ms analyzer with each patient sample run. 2. The director approved policy entitled, "LC /MS/MS AB Sciex 4500 Analytic Procedure," in the section entitled, "Sample Preparation for Calibration, Quality Control, and Patient Samples," in step 1 entitled, "For Calibration and Quality Control samples," part a. "Calibration and Quality Control solutions are prepared per the Calibrator and QC protocol. They are stored frozen (-20 degrees C) in 2 mL amber vials with 10 uL of pooled blank urine and either 10 uL of calibration or QC solution in each labeled vial." Part b stated, "From the -20 degree Celsius freezer, remove a 7-vial set of calibrators and a 3-vial set of QC (A, B, and C) and one known blank sample. These will be processed in parallel to the patient samples." 3. The laboratory supervisor relayed that the former testing technologist stated that each day of testing, a System Suitability test was performed, but that calibration was only performed annually after the preventative maintenance during an interview conducted on November 16, 2021 at approximately 2:30 PM. The laboratory performs approximately 432,016 toxicology tests annually.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021, a review of the director approved policy and procedure entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure," and an interview with the laboratory supervisor, who spoke with and relayed the information from the former testing technologist during the survey, the laboratory failed to ensure that the calibration verification of the urine drug confirmatory testing was performed at least once every six months. Findings include: 1. A random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021, revealed that there were no records of the calibration for the AB Sciex 4500 lc-ms/ms analyzer with each run of patient samples. 2. The director approved policy entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure," in the section entitled, "Sample Preparation for Calibration, Quality Control, and Patient Samples," in step 1 entitled, "For Calibration and Quality Control samples," part a. "Calibration and Quality Control solutions are prepared per the Calibrator and QC protocol. They are stored frozen (-20 degrees C) in 2 mL amber vials with 10 uL of pooled blank urine and either 10 uL of calibration or QC solution in each labeled vial." Part b stated, "From the -20 degree Celsius freezer, remove a 7-vial set of calibrators and a 3-vial set of QC (A, B, and C) and one known blank sample. These will be processed in parallel to the patient samples." 3. The laboratory supervisor relayed that the former testing technologist stated that each day of testing, a System Suitability test was performed, but that calibration was only performed annually after the preventative maintenance was performed during an interview conducted on November 16, 2021 at approximately 2:30 PM. The laboratory performs approximately 432,016 toxicology tests annually.
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 a random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021, a review of the September 2020 monthly maintenance log for the AB Sciex 4500 LC-MS/MS analyzer, a review of the director approved policy entitled "LC/MS/MS AB Sciex 4500 Analytic Procedure," a review of the director approved policy entitled "Quality Assurance," a review of the Monthly Director Visit Quality Assurance Review between the dates of April, 2019 and October, 2021, and an interview with the laboratory supervisor, who spoke to and relayed the information from the former testing technologist during the survey, the laboratory failed to ensure that the established written policies and procedures were followed to monitor, assess, and when indicated, correct problems identified in the laboratory analytic systems for the urine drug screen confirmation testing. Findings include: 1. A random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021 revealed that the laboratory failed to perform calibration of the AB Sciex 4500 LC-MS/MS analyzer with each patient run for the urine drug screen confirmation testing in accordance with the director approved policy and procedure entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure." During an interview with the laboratory supervisor, who spoke to and relayed the information from the former testing technologist during the survey, it was stated that calibration was performed annually after the preventive maintenance was completed for the analyzer. 2. A random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021 revealed that the laboratory failed to perform calibration verification of the AB Sciex 4500 LC-MS/MS analyzer at least every six months. The director approved policy and procedure entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure" stated that a 7-point calibration was to be performed with each patient run. During an interview with the laboratory supervisor, who spoke to and relayed the information from the former testing technologist during the survey, on November 16, 2021 at approximately 2:30 PM, it was stated that calibration was performed annually after the preventive maintenance was completed for the analyzer. 3. A review of the laboratory maintenance logs between the dates of April, 2019 and June, 2021 for the AB Sciex 4500 LC-MS/MS analyzer revealed that the weekly maintenance was not performed for two of four weeks in the month of September, 2020. 4. The director approved policy entitled, "Quality Assurance," in the section entitled "Principle"stated, "The purpose of this procedure is two-fold: (1) to provide an ongoing, planned and systematic process to monitor, evaluate, and improve the quality and appropriateness of laboratory services provided. (2) To assure that services provided are optimally safe, efficient and effective within the limits set by available resources." The section entitled, "X. Communicate Results" stated, "A monthly report will be generated and will include aspects of care that have been monitored and the results evaluation process, the action plan and it's (sic) implementation, and the measurable improvements in quality that have been achieved. This is the Director Visit Report, which is reviewed with laboratory employees each month for quality assurance purposes." 5. A review of the Monthly Director Visit Quality Assurance Review

	records between the dates of April 2019 and October, 2021 revealed that the quality assessment program failed to detect and correct the failure to perform the test calibration with each patient run for the AB Sciex 4500 Urine Drug Screen confirmation testing, the failure to perform calibration verification at least every 6 months, and the failure to perform weekly maintenance on the AB Sciex 4500 LC-MS /MS analyzer. The laboratory performs approximately 432,016 toxicology tests annually.
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 a review of the director approved policy and procedure entitled, "LC/MS /MS AB Sciex 4500 Analytic Procedure," a random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021, the director failed to ensure that the established policy and procedure was followed to ensure that the results of the urine drug screen confirmation testing were accurate and reliable (refer to D6087), a review of the director approved policy entitled "Proficienty (sic) Testing," a review of the proficiency testing records, and an interview with the laboratory supervisor, the director failed to ensure that the accuracy of the analytes not included in the College of American Pathologists (CAP) Drug Monitoring for Pain Management (DMPM) Proficiency Testing (PT) survey was verified twice per year during 2019, 2020, and 2021 (refer to D6089). A review of the laboratory College of American Pathologists (CAP) Drug Monitoring for Pain Management (DMPM) Proficiency Testing (PT) records for 2020 and 2021, a review of the 2021 DMPM-A re-run analyzer print out for the event one specimens, and an interview with the laboratory supervisor, the director failed to ensure that the laboratory performed and documented effective corrective action for the 2020 DMPM-B test event two, and the 2021 DMPM-A test event one quantitative urine drug testing results, and the director failed to ensure that the laboratory reviewed and documented an evaluation of the participant summary for the 2020 DMPM-B test event two ungraded test result for specimen number DMPM-06 (refer to D6092), a review of the director approved policy entitled, "Quality Assurance," a review of the Monthly Director Visit Quality Assurance Review records between the dates of April, 2019 and October, 2021, a review of the College of American Pathologists (CAP) Proficiency Testing records for the 2020 and 2021 Drug Monitoring for Pain Management (DMPM) test events, a review of the September 2020 monthly maintenance log for the AB Sciex 4500 lc-ms/ms analyzer, a review of the director approved policy entitled "LC/MS/MS AB Sciex 4500 Analytic Procedure," and an interview with the laboratory supervisor, who also spoke to and relayed the information from the former testing technologist during the survey, the director failed to ensure that the established written policies and procedures were followed to monitor, assess, and when indicated, correct problems identified in the general laboratory systems and the laboratory analytic systems for the urine drug screen confirmation testing (refer to D6094), a review the laboratory personnel records for the testing personnel highest level of education, and training and competency assessment, and an interview with the laboratory supervisor, the director failed to

	ensure that one of one testing personnel performing the LC-MS/MS urine confirmation drug testing had the appropriate education, training, and demonstrated their ability to perform all testing operations reliably to provide and report accurate results (refer to D6102). The laboratory performs approximately 432,016 toxicology tests annually.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of the director approved policy and procedure entitled, "LC/MS /MS AB Sciex 4500 Analytic Procedure," a random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021, and an interview with the laboratory supervisor, who spoke to and relayed the information from the former testing technologist during the survey, the director failed to ensure that the established policy and procedure was followed to ensure that the results of the urine drug screen confirmation testing were accurate and reliable. Findings include: 1. The director approved policy entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure," in the section entitled, "Sample Preparation for Calibration, Quality Control, and Patient Samples," in step 1 entitled, "For Calibration and Quality Control samples," part a. "Calibration and Quality Control solutions are prepared per the Calibrator and QC protocol. They are stored frozen (-20 degrees C) in 2 mL amber vials with 10 uL of pooled blank urine and either 10 uL of calibration or QC solution in each labeled vial." Part b stated, "From the -20 degree Celsius freezer, remove a 7-vial set of calibrators and a 3-vial set of QC (A, B, and C) and one known blank sample. These will be processed in parallel to the patient samples." 2. A random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021 revealed that there were no records of the calibration for the AB Sciex 4500 lc-ms/ms analyzer with each patient sample analysis run. 3. The laboratory supervisor, who spoke with, and relayed the information from the former testing technologist durng the survey stated that each day of testing a System Suitability test was performed, but that calibration was only performed annually after the preventative maintenance during an interview conducted on November 16, 2021 at approximately 2:30 PM. The laboratory performs approximately 432,016 toxicology tests annually.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a review of the director approved policy entitled "Proficienty (sic) Testing," a review of the proficiency testing records, and an interview with the laboratory supervisor, the director failed to ensure that the accuracy of the analytes not included

	in the College of American Pathologists (CAP) Drug Monitoring for Pain Management (DMPM) Proficiency Testing (PT) survey was verified twice per year during 2019, 2020, and 2021. Findings include: 1. The director approved policy entitled "Proficienty (sic) Testing," in section "II. Policy", sub-section "B." stated, "Tests for which compatible proficiency testing material in (sic) not available from an approved program the laboratory is required to verify twice annually the accuracy of the tests. This will be accomplished by exchange of specimens required for the test with an outside licensed laboratory in the community who performs the test for which there is no proficiency testing materials available. The exchange of data will be used to verify the accuracy of the instrument." 2. There were no records for the twice per year verification of accuracy performed in 2019, 2020, and 2021 for the following analytes that were not included in the CAP DMPM proficiency testing survey: MDEA, Mephedrone, Methylphenidate, Ritalinic Acid, Nordiazapam, Secobarbital, Flurazepam, Metaxalone, Zaleplon, Zolpidem, Amitriptyline, Cyclobenzaprine, Desipramine, Doxepin, Duloxetine, Nortriptyline, JWH-018 Pentanoic acid, JWH-073 Butanoic acid, JWH-073 Hydroxybutyl, Mitragynine, Baclofen, Clonidine, Ketamine, Naphyrone, Norketamine, Norpseudoephedrine, Naloxone, Naloxone Glucoronide, Naltrexone, Morphine 3 Glucuronide, and Morphine 6 Glucuronide. 3. During an interview conducted on November 16, 2021 at approximately 1:30 PM, the laboratory supervisor confirmed that no records of twice per year verification of accuracy for 2019, 2020, and 2021 were available for review at the time of the survey. The laboratory performs approximately 432,016 toxicology tests annually.
D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on a review of the director approved policy entitled "Proficienty (sic) Testing," a review of the laboratory College of American Pathologists (CAP) Drug Monitoring for Pain Management (DMPM) Proficiency Testing (PT) records for 2020 and 2021, a review of the 2021 DMPM-A re-run analyzer print out for the event one specimens, and an interview with the laboratory supervisor, the director failed to ensure that the laboratory performed and documented effective corrective action for the 2020 DMPM-B test event two, and the 2021 DMPM-A test event one quantitative urine drug testing results, and the director failed to ensure that the laboratory reviewed and documented an evaluation of the participant summary for the 2020 DMPM-B test event two ungraded test result for specimen number DMPM-06. Findings include: 1. The director approved policy entitled "Proficienty (sic) Testing," in section "II. Policy", sub-section "G." stated, "All out of range results will be investigated and all corrective action documented. If the assigned proficiency test score falls below 100%, corrective action will include reviewing of instrument control and calibration data, review of instrument maintenance logs, and verification of analyte accuracy." 2. A review of the 2020 DMPM-B CAP PT report revealed that for specimen DMPM-06, the quantitative result for Morphine was outside the limit of acceptability. The result reported was 6457.9 ng/ml. The limit of acceptability for morphine identified on the CAP report was 2929.1-6088.1 ng/ml. 3. A review of the 2020 DMPM-B CAP PT report revealed that for specimen DMPM-07, the quantitative result for oxymorphone was outside the limit of acceptability. The result reported was 717.2ng/ml. The limit of acceptablility for oxymorphone identified on the CAP report was 332.5-661.7 ng

/ml. 4. A review of the document entitled "DMPM-B 2020 Corrective Action" revealed that specimens DMPM-06 and DMPM-07 were reanalyzed. The document stated that the DMPM-06 morphine result was still out of range, and would be monitored going forward. The document stated that the DMPM-07 oxymorphone result obtained upon repeat was acceptable. There were no records retained of the repeat of the test specimens to verify that the DMPM-07 oxymorphone result obtained upon repeat analysis was acceptable. 5. A review of the 2020 DMPM-B CAP PT report revealed that there was no documentation of the Participant Summary review to evaluate the specimen number DMPM-06 result for N-Desmethyltramadol which was not graded due to insufficient peer group data. 6. A review of the 2020 DMPM-B Participant Summary for specimen number DMPM-06 revealed that the detection of N-Desmethyltramadol reported to CAP was a false positive. 7. A review of the 2020 DMPM-B Participant Summary for specimen number DMPM-06 revealed that the detection of O-Desmethyltramadol was present in the specimen. The laboratory failed to detect and report O-Desmethyltramadol present in specimen number DMPM-06. 8. The document entitled "DMPM-B 2020 Corrective Action" stated that no patients were affected by the unacceptable PT results for the DMPM-B 2020 test event because all of the analytes were detected during the survey. 9. A review of the 2021 DMPM-A CAP PT test event one revealed that for specimen DMPM-01, the results for Amphetamine, Alprazolam, Butalbital, Alpha-Hydroxyalprazolam, and Hydromorphone were outside the acceptable ranges. The Amphetamine result reported was 4924.7 ng/ml. The acceptable range for Amphetamine was 1073.1-2051.4 ng/ml. The Alprazolam result reported was 794.1 ng/ml. The acceptable range for Alprazolam was 140.6-275.1 ng/ml. The Butalbital result reported was 5399.1 ng /ml. The acceptable range for Butalbital was 1189.5-2673.7 ng/ml. The Alpha-Hydroxyalprazolam result reported was 4969.9 ng/ml. The acceptable range for Alpha-Hydroxyalprazolam was 839.5-1943.1 ng/ml. The Hydromorphone result reported was 1701.0 ng/ml. The acceptable range for Hydromorphone was 352.5-654.8 ng/ml. 10. A review of the analyzer print out for the re-analysis of the 2021 DMPM-A CAP PT specimen DMPM-01 after the preventative maintenance and cleaning of the rails was performed on the analyzer revealed that the results for Amphetamine, Alprazolam, Butalbital, Alpha-Hydroxyalprazolam, and Hydromorphone remained outside the acceptable ranges. The Amphetamine repeat result was 2283.58 ng/ml. The acceptable range for Amphetamine was 1073.1-2051.4 ng/ml. The Alprazolam repeat result was 347.31 ng/ml. The acceptable range for Alprazolam was 140.6-275.1 ng/ml. The Butalbital repeat result was 3043.51 ng/ml. The acceptable range for Butalbital was 1189.5-2673.7 ng/ml. The Alpha-Hydroxyalprazolam repeat result was 1957.64 ng/ml. The acceptable range for Alpha-Hydroxyalprazolam was 839.5-1943.1 ng/ml. The Hydromorphone repeat result was 759.55 ng/ml. The acceptable range for Hydromorphone was 352.5-654.8 ng/ml. 11. A review of the 2021 DMPM-A CAP PT test event one revealed that for specimen DMPM-02, the results for Amphetamine, Benzoylecgonine, and Methadone were outside the acceptable ranges. The Amphetamine result reported was 2123.3 ng/ml. The acceptable range for Amphetamine was 1012.8-2077.0 ng/ml. The Benzoylecgonine result reported was 1517.0 ng/ml. The acceptable range for Benzoylecgonine was 658.6-1223.3 ng/ml. The Methadone result reported was 331.7 ng/ml. The acceptable range for Methadone was 131.5-286.1 ng/ml. 12. A review of the analyzer print out for the re-analysis of the 2021 DMPM-A CAP PT specimen DMPM-02 after the preventative maintenance and cleaning of the rails was performed on the analyzer revealed that the results for Amphetamine, and Benzoylecgonine remained outside the acceptable ranges. The Amphetamine repeat result was 2283.58 ng/ml. The acceptable range for Amphetamine was 1073.1-2051.4 ng/ml. The Benzoylecgonine repeat result was 1231.96 ng/ml. The acceptable range for Benzoylecgonine was 658.6-1223.3 ng/ml.

	The re-analysis revealed that the Delta-9-THC-COOH that was initially acceptable was no longer acceptable on the repeat analysis of the specimen. The repeated result for the Delta-9-THC-COOH was 242.48 ng/ml. The acceptable range for Delta-9-THC-COOH was 90.3-236.8 ng/ml. 13. A review of the 2021 DMPM-A CAP PT test event one revealed that for specimen DMPM-03, the results for Diazepam, Nordiazepam, Oxazepam, Pregabalin, Codeine, and Morphine were outside the acceptable ranges. The Diazepam result reported was 143.6 ng/ml. The acceptable range for Diazepam was 32.9-71.1 ng/ml. The Nordiazepam result reported was 1285.1 ng/ml. The acceptable range for Nordiazepam was 325.4-628.3 ng/ml. The Oxazepam result reported was 2554.9 ng/ml. The acceptable range for Oxazepam was 579.6-1261.7 ng/ml. The Pregabalin result reported was 9.7 ng/ml. The acceptable range for Pregabalin was 2.2-7.0 ng/ml. The Codeine result reported was 4304.4 ng /ml. The acceptable range for Codeine was 1217.7-2546.6 ng/ml. The Morphine result reported was 848.9 ng/ml. The acceptable range for Morphine was 201.3-374.0 ng/ml. 14. A review of the analyzer print out for the re-analysis of the 2021 DMPM-A CAP PT specimen DMPM-03 after the preventative maintenance and cleaning of the rails was performed on the analyzer revealed that the results for Pregabalin remained outside the acceptable range. The Pregabalin repeat result was 5867.69 ng/ml. The acceptable range for Pregabalin was 2.2-7.0 ng/ml. 15. A review of the document entitled, "2021 DMPM-A Corrective Action" revealed that specimens DMPM-01, DMPM-02, and DMPM-03 were re-analyzed after preventative maintenance and cleaning of the rails was performed. The document stated, "On the repeat, specimen DMPM-03 and 3 drugs from DMPM-02 were all reported as acceptable. DMPM-01 and DMPM-02 still had some drugs that that (sic) were higher in concentration than expected from the CAP results." The document failed to address the specific analytes that remained outside the acceptable ranges, nor did it address the initally acceptable DMPM-02 Delta-9-THC-COOH that was outside the acceptable range upon repeat analysis. The document went on to state, "No patients were affected from the CAP findings. All analytes were detected qualitatively." 16. The findings were confirmed during an interview with the laboratory supervisor conducted on November 16, 2021 at approximately 2:00 PM. The laboratory performs approximately 432,016 toxicology tests annually.
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 a review of the director approved policy entitled, "Quality Assurance," a review of the Monthly Director Visit Quality Assurance Review records between the dates of April, 2019 and October, 2021, a review of the College of American Pathologists (CAP) Proficiency Testing records for the 2020 and 2021 Drug Monitoring for Pain Management (DMPM) test events, a review of the director approved policy entitled, "Proficienty (sic) Testing," a random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021, a review of the September 2020 monthly maintenance log for the AB Sciex 4500 lc-ms/ms analyzer, a review of the director approved policy entitled "LC /MS/MS AB Sciex 4500 Analytic Procedure," and an interview with the laboratory

supervisor, who also spoke to and relayed the information from the former testing technologist during the survey, the director failed to ensure that the established written policies and procedures were followed to monitor, assess, and when indicated, correct problems identified in the general laboratory systems and the laboratory analytic systems for the urine drug screen confirmation testing. Findings include: 1. The director approved policy entitled, "Quality Assurance," in the section entitled "Principle"stated, "The purpose of this procedure is two-fold: (1) to provide an ongoing, planned and systematic process to monitor, evaluate, and improve the quality and appropriateness of laboratory services provided. (2) To assure that services provided are optimally safe, efficient and effective within the limits set by available resources." The section entitled, "X. Communicate Results" stated, "A monthly report will be generated and will include aspects of care that have been monitored and the results evaluation process, the action plan and it's (sic) implementation, and the measurable improvements in quality that have been achieved. This is the Director Visit Report, which is reviewed with laboratory employees each month for quality assurance purposes." 2. A review of the Monthly Director Visit Quality Assurance Review records between the dates of April, 2019 and October, 2021 revealed that the established quality assessment plan failed to detect and correct the failure to perform and maintain the records of the twice per year verification of accuracy for the following analytes that are not included in the CAP DMPM Proficiency Testing enrollment as specifed in the director approved policy entitled "Proficienty (sic) Testing": MDEA, Mephedrone, Methylphenidate, Ritalinic Acid, Nordiazapam, Secobarbital, Flurazepam, Metaxalone, Zaleplon, Zolpidem, Amitriptyline, Cyclobenzaprine, Desipramine, Doxepin, Duloxetine, Nortriptyline, JWH-018 Pentanoic acid, JWH-073 Butanoic acid, JWH-073 Hydroxybutyl, Mitragynine, Baclofen, Clonidine, Ketamine, Naphyrone, Norketamine, Norpseudoephedrine, Naloxone, Naloxone Glucoronide, Naltrexone, Morphine 3 Glucuronide, and Morphine 6 Glucuronide. 3. In the section of the Monthly Director Visit Quality Assurance Review documents between the dates of April, 2019 and October, 2021 entitled, "II. Proficiency Testing," there was no reference to the need to perform twice per year verification of accuracy for the analytes not included in the CAP DMPM Proficiency Testing enrollment or reference to a review of twice per year verification of accuracy for those analytes. 4. A review of the Monthly Director Visit Quality Assurance Review records between the dates of September, 2020 and October, 2021 revealed that the Monthly Director Visit Quality Assurance Review forms failed to accurately document the results of the 2020 CAP DMPM-B and the 2021 DMPM-A in order to ensure that appropriate corrective action was taken for the proficiency testing failures. The Monthly Director Visit Quality Assurance Review records for the months of September, October, and November, 2020 stated that the CAP Survey 2020 DMPM-B test event evaluation received a score of 100%. The Monthly Director Visit Quality Assurance Review records for the months of April, 2021 through October, 2021 stated that for the 2021 DMPM-A test event evaluation was "Good Pass." 5. A random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021 revealed that the laboratory failed to perform calibration of the AB Sciex 4500 LC-MS/MS analyzer with each patient run for the urine drug screen confirmation testing in accordance with the director approved policy and procedure entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure." During an interview with the laboratory supervisor, who spoke to and relayed the information from the former testing technologist during the survey, it was stated that calibration was performed annually after the preventive maintenance was completed for the analyzer. 6. A random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug

	confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021 revealed that the laboratory failed to perform calibration verification of the AB Sciex 4500 LC-MS/MS analyzer at least every six months. The director approved policy and procedure entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure" stated that a 7-point calibration was to be performed with each patient run. During an interview with the laboratory supervisor, who spoke to and relayed the information from the former testing technologist during the survey, on November 16, 2021 at approximately 2:30 PM, it was stated that calibration was performed annually after the preventive maintenance was completed for the analyzer. 7. A review of the laboratory maintenance logs for the AB Sciex 4500 LS-MS/MS analyzer revealed that the weekly maintenance was not performed for two of four weeks in the month of September, 2020. 8. A review of the Monthly Director Visit Quality Assurance Review records between the dates of April 2019 and October, 2021 revealed that the quality assessment program failed to detect and correct the failure to perform the test calibration with each patient run for the AB Sciex 4500 Urine Drug Screen confirmation testing, the failure to perform calibration verification at least every 6 months, and the failure to perform weekly maintenance on the AB Sciex 4500 LC-MS /MS analyzer during the month of September, 2020. The laboratory performs approximately 432,016 toxicology tests annually.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the laboratory personnel records for the testing personnel highest level of education, and training and competency assessment, and an interview with the laboratory supervisor, the director failed to ensure that one of one testing personnel performing the LC-MS/MS urine confirmation drug testing had the appropriate education, initial training and competency assessment, and that the testing personnel demonstrated their ability to perform all testing operations reliably to provide and report accurate results. Findings include: 1. There were no records of the highest level of education, and initial training and competency assessment for the one of one testing personnel in the performance of the AB Sciex 4500 LC-MS/MS urine drug confirmation testing who was employed by the laboratory between the dates of April 2019 and June, 2021. 2. The laboratory supervisor confirmed the finding during an interview conducted on November 16, 2021 at approximately 11:00 AM. The laboratory performs approximately 432,016 toxicology tests annually.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart.

	This CONDITION is not met as evidenced by: Based on a review of the laboratory personnel records and an interview with the laboratory director, and the laboratory supervisor, the laboratory did not have personnel that met the qualifications of the technical supervisor between the dates of February 1, 2021 and July 1, 2021 (refer to D6111), a review of the laboratory personnel records for the testing personnel training and competency assessment, a random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021, a review of the director approved procedure entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure," the technical supervisor failed to identify training needs and ensure that one of one testing personnel performing the LC-MS/MS urine confirmation drug testing demonstrated their ability to perform the LC-MS/MS urine drug confirmation testing reliably to provide and report accurate results. (refer to D6120) The laboratory performs approximately 432,016 toxicology tests annually.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or Possesses qualifications that are equivalent to those required for such certification. (c) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, the individual functioning as the technical supervisor must-- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; and (c)(5)(ii) Have at least 4 years of laboratory training or experience, or

both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology. (d) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycobacteriology, the individual functioning as the technical supervisor must-- (d)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor or podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology; or (d)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycobacteriology. (e) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of mycology, the individual functioning as the technical supervisor must-- (e)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (e)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (e)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (e)(3)(ii) Have at least 1 year of laboratory training or experience, or both in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (e)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology; or (e)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (e)(5)(ii) Have at least 4 years of

laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of mycology. (f) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of parasitology, the individual functioning as the technical supervisor must-- (f)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (f)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (f)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; (f)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (f)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (f)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology; or (f)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (f)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of parasitology. (g) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of virology, the individual functioning as the technical supervisor must-- (g)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (g)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (g)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (g)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (g)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology; or (g)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (g)(5)(ii) Have at least 4 years of

laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of virology. (h) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, the individual functioning as the technical supervisor must- (h)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (h)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (h)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (h)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of diagnostic immunology; or (h)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (h)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology; or (h)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (h)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of diagnostic immunology. (i) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of chemistry, the individual functioning as the technical supervisor must-- (i)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (i)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (i)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (i)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of chemistry; or (i)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (i)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry; or (i)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (i)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of chemistry. (j) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of hematology, the individual functioning as the technical supervisor must-- (j)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (j)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (j)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy,

or podiatry in the State in which the laboratory is located; and (j)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of hematology (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (j)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (j)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of hematology; or (j)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (j)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology; or (j)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (j)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of hematology. (k)(1) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must-- (k)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (k)(1)(ii) Meet one of the following requirements-- (k)(1)(ii)(A) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (k)(1)(ii)(B) Be certified by the American Society of Cytology to practice cytopathology or possess qualifications that are equivalent to those required for such certification; (l) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must-- (l)(1) Meet one of the following requirements: (l)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (l)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; (l)(1)(ii) An individual qualified under 493.1449(b) or paragraph (l)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (l)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (l)(2) For tests in dermatopathology, meet one of the following requirements: (l)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(2)(i)(B) Meet one of the following requirements: (l)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology or possess qualifications that are equivalent to those required for such certification; or (l)(2)(ii) An individual qualified under 493.1449(b) or paragraph (l)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (l)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (l)(3) For tests in ophthalmic pathology, meet one of the following requirements: (l)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (l)(3)(i)(B) Must meet

one of the following requirements: (l)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (l)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology or possess qualifications that are equivalent to those required for such certification and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (l)(3)(ii) An individual qualified under 493.1449(b) or paragraph (1)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (1)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (m) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (m)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located and-- (m)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (m)(2) Be certified in oral pathology by the American Board of Oral Pathology or possess qualifications for such certification; or (m)(3) An individual qualified under 493.1449(b) or paragraph (m)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraphs (b) or (m)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (n) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of radiobioassay, the individual functioning as the technical supervisor must-- (n)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (n)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (n)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (n)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(3)(i) Have an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution; and (n)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of radiobioassay; or (n)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (n)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay; or (n)(5)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (n)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the specialty of radiobioassay. (o) If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either-- (o)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (o)(1)(ii) Have training or experience that meets one of the following requirements: (o)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or

both, in the specialty of histocompatibility; or (o)(2)(i) Have an earned doctoral degree in a biological or clinical laboratory science from an accredited institution; and (o)(2)(ii) Have training or experience that meets one of the following requirements: (o)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (o)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (o)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (p) If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must-- (p)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (p)(1)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (p)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, or clinical laboratory science from an accredited institution; and (p)(2)(ii) Have 4 years of training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (q) If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of immunohematology, the individual functioning as the technical supervisor must-- (q)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (q)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (q)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (q)(2)(ii) Have at least one year of laboratory training or experience, or both, in high complexity testing for the specialty of immunohematology. Note: The technical supervisor requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service. For example, an individual, who has a doctoral degree in chemistry and additionally has documentation of 1 year of laboratory experience working concurrently in high complexity testing in the specialties of microbiology and chemistry and 6 months of that work experience included high complexity testing in bacteriology, mycology, and mycobacteriology, would qualify as the technical supervisor for the specialty of chemistry and the subspecialties of bacteriology, mycology, and mycobacteriology.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory personnel records and an interview with the laboratory director, and the laboratory supervisor, the laboratory did not have personnel that met the qualifications of the technical supervisor between the dates of February 1, 2021 and July 1, 2021. Findings include: 1. The laboratory director assumed the position of director effective February 1, 2021. The director confirmed during an interview conducted on November 17, 2021 at approximately 11:00 AM he did not posess a minimum of one year of laboratory training, or experience or both in high complexity testing within the specialty of toxicology. 2. There were no records for one of one testing personnel who performed the AB Sciex 4500 lc-ms/ms urine drug confirmatory testing availabe at the time of the survey to verify the highest level of education and experience in high complexity testing within the specialty of toxicology in order to determine if the laboratory had a person meeting the qualifications required for the Technical Supervisor between the dates of February 1, 2021 and June 30, 2021 when the testing personnel left the employment of the

	laboratory. The laboratory supervisor confirmed that the personnel records were not available at the time of the survey. The laboratory performs approximately 432,016 toxicology tests annually.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on a review of the laboratory personnel records for the testing personnel training and competency assessment, a random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021, a review of the director approved procedure entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure," and an interview with the laboratory supervisor, the technical supervisor failed to identify training needs and ensure that one of one testing personnel performing the LC-MS/MS urine confirmation drug testing demonstrated their ability to perform the LC-MS/MS urine drug confirmation testing reliably to provide and report accurate results. Findings include: 1. There were no records of semi-annual training and competency assessment during the first year of employment, and annual training and competency assessment thereafter for the one of one testing personnel in the performance of the AB Sciex 4500 LC-MS/MS urine drug confirmation testing who was employed by the laboratory between the dates of April 2019 and June, 2021. 2. A review of the director approved policy and procedure entitled, "LC/MS/MS AB Sciex 4500 Analytic Procedure," in the section entitled, "Sample Preparation for Calibration, Quality Control, and Patient Samples," in step 1 entitled, "For Calibration and Quality Control samples," part a. "Calibration and Quality Control solutions are prepared per the Calibrator and QC protocol. They are stored frozen (-20 degrees C) in 2 mL amber vials with 10 uL of pooled blank urine and either 10 uL of calibration or QC solution in each labeled vial." Part b stated, "From the -20 degree Celsius freezer, remove a 7-vial set of calibrators and a 3-vial set of QC (A, B, and C) and one known blank sample. These will be processed in parallel to the patient samples." 3. A random patient audit of seven patients between the dates of July 3, 2019 and July 5, 2021, three of whom were tested for urine drug confirmation on the dates of March 20, 2020, May 29, 2020 and June 26, 2021 revealed that there were no records of the calibration for the AB Sciex 4500 LC-MS /MS analyzer urine drug confirmation testing with each patient sample analysis run, in accordance with the director approved procedure.. 4. The Technical Supervisor did not identify the failure of testing personnel to perform the LC-MS/MS calibration with each patient sample analysis run, and to retrain the testing personnel in the correct performance of the procedure. 5. The laboratory supervisor confirmed the finding during an interview conducted on November 16, 2021 at approximately 11:00 AM. The laboratory performs approximately 432,016 toxicology tests annually.