Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	11D2108401	01/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Priority Toxicology Laboratories	6781 Londonderry Way, Suite 4, Union City, GA	

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	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 25, 2018. The laboratory was found not in compliance with all applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation and an interview with the Technical Supervisor (TS), the laboratory failed to assure that the fire extinguishers were maintained in a fully charged and operable condition and kept in a designated area at all times except during use. The findings include: 1. An observation of the laboratory's fire extinguishers revealed that it had not been inspected and certified by a fire protection equipment company since January 2016. 2. The TS confirmed on January 25, 2018, at 1:15 PM, in the breakroom, that the fire extinguisher had not been inspected and certified since 2016.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: A review of the procedure manual and interview with the Technical Supervisor (TS), determined that the laboratory failed to have a separate competency assessment for their toxicology and chemistry panels for 2017. The findings include: 1. A review of testing personnel records revealed that a competency assessment was performed on testing personnel but the assessment included both the toxicology and chemistry test panels. 2. The laboratory must monitor each individual's competency and identify remedial training for each test procedure performed in the laboratory. 3. An interview with the Technical Supervisor (TS), in the breakroom on January 25, 2018 at 11:30 AM, confirmed that the laboratory did not have separate competency assessments for each test performed in the laboratory.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on surveyor review of proficiency test (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to have a written proficiency test procedure and policy for performing and evaluating their non-regulated toxicology analytes for 2017. The findings include: 1. The laboratory had no written policy or procedure for proficiency testing of their non-regulated toxicology analytes for 2017. The laboratory is enrolled in a CMS approved PT provider for their regulated toxicology analytes. 2. The laboratory must verify the accuracy of the test or procedure twice annually for their non-regulated analytes. 3. An interview with the Technical Supervisor (TS), in the break room on 1/25/18 at 11:30 AM, confirmed that the laboratory did not have a written policy and procedure for evaluating proficiency for their non-regulated toxicology analytes for 2017.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

	This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory procedure manual and interview with the Technical Supervisior (TS), the laboratory failed to establish a procedure for column and quality control (QC) validation for the AB Sciex QTRAP LC-MS/MS analyzer for 2016 and 2017. The findings include: 1. The laboratory had no record of a procedure showing the column validation process for the QTRAP LC-MS/MS analyzer. The manufacturer's instructions require that a new column must be validated prior to testing to confirm its accuracy and sensitivity. 2. The laboratory did not have a procedure detailing how their in-house quality control is prepared and validated for their toxicology panel. 3. The Technical Supervisor confirmed on 1/25/18 at 11:00 AM, in the breakroom, that the laboratory did not have procedures for their QC preparation/validation or column validation for the AB Sciex QTRAP LC-MS/MS analyzer.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of maintenance records and interview with the Technical Supervisor (TS), the laboratory failed to perform preventative maintenance for the CLC 800 Chemistry Analyzer from 2016 through January 2018. The laboratory failed to perform calibration for the Thermo Scientific Pico Centrifuge and the Rainin pipets for 2016, 2017, and 2018. Also, the laboratory failed to perform and document maintenance for the water bath that is used to incubate patient samples for 2017. The findings include: 1. The laboratory failed to perform preventative maintenance for the CLC 800 Chemistry Analyzer for 2016 through January 2018. The manufacturer requires that preventative maintenance be performed on a semi-annual and annual basis for the analyzers. The laboratory has records for monthly maintenance but not for preventative maintenance. 2. The laboratory had no record of calibrations being performed for the centrifuge or pipets for 2016, 2017, and 2018. 3. Review of laboratory records revealed there was no documentation of maintenance being performed on the water bath from 2016 through December 2017. 4. Water baths used for testing and/or incubations must be maintained and cleaned by the testing personnel. 5. An interview with the TS, in the breakroom on 1/25/18 at approximately 12:30 PM, confirmed no preventative maintenance records were available for the CLC 800 Chemistry Analyzer for 2016, 2017, & 2018. Also, the TS confirmed that no calibrations were performed on the Thermo Scientific Centrifuge and Rainin Pipets for 2016, 2017, & 2018. The TS also confirmed that maintenance for the water bath was not documented.
D6085	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3) The laboratory director must ensure that the test methodologies selected have the capability of providing the quality of results required for patient care.

	This STANDARD is not met as evidenced by: Based on review of laboratory records and initial method validation records, the Laboratory Director (LD) failed to ensure testing systems provided quality laboratory results for the AB Sciex QTRAP LC-MS/MS and CLC 800 Chemistry analyzers. The findings include: 1. A review of validation records revealed that the Laboratory Director failed to approve and sign off on the validation for the AB Sciex QTRAP LC-MS/MS and CLC 800 Chemistry analyzers in 2017. 2. All test methods should have the capability of providing the quality of results required for patient care, and needs to be approved and signed by the Laboratory Director prior to patient testing. 3. The Technical Supervisor (TS) confirmed on 01/25/2018 at 12:30 PM in the breakroom, that the laboratory performed patient testing on the AB Sciex QTRAP LC-MS/MS and CLC 800 Chemistry analyzers without validation approval from the Laboratory Director.