

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2074207	(X3) Date Survey Completed 07/24/2018
Name of Provider or Supplier New Jersey Interventional	Street Address, City, State 3 Cornwall Drive, East Brunswick, NJ	
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
D2015	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to maintain all PT records for Urine Toxicology tests performed with the College of American Pathologists (CAP) in the C- 2017 and A - 2018 events. The finding includes: 1. The laboratory did not have the attestation page for PT results in event UT-A 2018. 2. The laboratory did not have the attestation page and work records for PT results in event UT-C 2017 and UT-A 2018. 2. The TS confirmed on 7/24/18 at 10:00 am that all PT records were not maintained.</p>
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p>

	<p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Reports, Instrument Data Base and interview with the Technical Supervisor (TS), the laboratory failed to retain records for Urine Toxicology performed on the AbSciex Triple Quad 6500 from November 2017 thru March 2018. The findings include: 1. A review of the instrument history revealed Quality Control, Calibration, Internal Standards and Patient Results were not retained for the time period above. 2. The TS stated at the time of the survey the above records were not available as printed results or on a back up drive. 3. The TS confirmed on 7/24/18 at 2:10 pm that work records were not retained.</p>
<p>D5401</p>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory failed to establish a policy for manual integration of Urine Toxicology chromatography peaks from November 2017 to the date of survey. The TS confirmed on 7/24/18 at 1:20 pm that the laboratory did not establish the above policy.</p>
<p>D5441</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)</p> <p>(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of work records and interview with the Technical Supervisor (TS), the laboratory failed to have a Hydrolysis control procedure to monitor the accuracy of the analytic process for Urine Toxicology tests run on the ABSciex Triple Quad 6500 from November 2017 to the date of survey. The TS confirmed on 7/24/18 at 2:10 pm that the laboratory did not have a Hydrolysis control procedure .</p>
<p>D5467</p>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(9)(g)</p>

	<p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- When using calibration material as a control material, use calibration material from a different lot number than that used to establish a cut-off value or to calibrate the test system. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual, Calibrators, Controls and interview with the Technical Supervisor (TS), the laboratory failed to use different lot numbers of calibrators to make the calibrator and control for Urine Toxicology tests from November 2017 to the date of the survey. The TS confirmed on 7/24/18 at 11:10 am the laboratory did not use different lot numbers.</p>
<p>D5779</p>	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(a)</p> <p>Corrective action policies and procedures must be available and followed as necessary to maintain the laboratory's operation for testing patient specimens in a manner that ensures accurate and reliable patient test results and reports.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual and interview with the Technical Supervisor (TS), the laboratory failed to have a Corrective Action (CA) procedure for failed Quality Control to ensure accurate and reliable patient results from November 2017 to the date of the survey . The TS confirmed at 1:45 pm on 7/24/18 the laboratory did not have the above CA procedure.</p>
<p>D5805</p>	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report (FR) and interview with the Technical Supervisor (TS), the laboratory failed to ensure that the Test Report Date (TRD) was accurate on the FR from November 2017 to the date of survey. The finding includes: 1. The TRD changed to the date of reprint date of the FR. 2. The TS confirmed on 7/24 /18 at 2:30 pm that the TRD changed when FR was reprinted.</p>
<p>D6086</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)</p>

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS) the Laboratory Director failed to ensure that PS were adequate to perform Toxicology testing for Urine Drug Confirmatory tests on the AbSciex Triple Quad 6500 from November 2017 to the date of survey. The findings include: 1. A review of the stability study revealed the laboratory did not evaluate stability of frozen and refrigerated samples. 2. A method comparison was not performed 3. The review of the PS for Analytical Specificity (AS) evaluating matrix interference did not state how matrix interference was evaluated. 4. The TS confirmed on 7/24/18 at 1:40 pm that the LD did not ensure the PS were adequate.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the Laboratory Director (LD) failed to ensure that all PT results obtained from the College of American Pathologists (CAP) were reviewed and evaluated by the appropriate staff in the calendar year 2017. The finding includes: 1. There was no review of CAP results for Urine Toxicology event UT-C 2017. 2. The TS confirmed on 7/24/18 at 10:10 am that the laboratory did not review and evaluate all PT results.