Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2074207	12/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
New Jersey Interventional	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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) 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. This STANDARD is not met as evidenced by: Based on the lack of Analytical Reference Standards (ARS) material and interview with the Technical Consultant (TC) the laboratory failed to retain the lot number and expiration dates of the ASR material used to prepare the Master Mix used for Urine Toxicology Confirmation tests from 7/24/18 to the date of survey. The TC confirmed on 12/30/20 at 12:00 pm ASR lot numbers and expirations dates were not retained.
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 Procedure Manual (PM) and interview with the Technical Consultant (TC), the laboratory failed to have all procedures needed for Urine Toxicology confirmation tests run on the AB Sciex Triple Quad 6500 from 7/24 /18 to the date of the survey. The findings include: 1. The laboratory receives Master Mix from a reference laboratory. 2. The laboratory failed to have a procedure for the transportation of Master Mix from the reference laboratory to their facility. 3. The TC confirmed on 12/30/19 at 11:50 am that the laboratory did not have the above procedure.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on surveyor review of the Temperature Logs (TL), Heat Block (HB), Manufactures Package Insert (MPI) and interview with the Technical Consultant (TC), the laboratory failed to define an acceptable temperature range for the HB used for Urine Toxicology confirmation tests from 7/24/18 to the date of survey. The finding includes: 1. A review of the TL revealed an acceptable temperature range to be between 50 and 60 degrees Celsius (C) but the MPI stated the temperature must be 55C. 2. The TC confirmed on 12/30/19 at 11:00 am that the laboratory did not define an appropriate HB temperature.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation of reagents and interview with the Technical Consultant (TC), the laboratory failed to discard expired reagents used for Urine Toxicology confirmation tests from May 2019 to the date of the survey. The findings include: 1) Observation of the refrigerator revealed that seven bottles of unopened

	Rapid Hydrolysis buffer had expired. 2) Two bottles expired 5/2019 and five bottles expired 9/2019. 3) Approximately 330 patients run and reported. 4) The TC confirmed on 12/30/19 at 12:10 pm that the laboratory did not discard the expired reagent.
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 surveyor review of the Procedure Manual (PM), and interview with the Technical Consultant (TC), the laboratory failed to establish a procedure for verification of Quality Control material from 7/24/18 until the date of survey. The TC confirmed on 12/30/19 at 1:30 pm that the laboratory did not establish a procedure for QC verification.