Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2022328	03/21/2019
Name of Provider or Supplier	**Street Address, City, State**	
Sovereign Laboratory Services, Llc	680 Kinderkamack Road, Oradell, 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	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (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. 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 the attestation statements signed by the analyst and laboratory director for Drug Monitoring for Pain Management (DMPM) tests performed with the College of American Pathologists (CAP) in the DMPM- B2017 and DMPM- A2018 events. The TS confirmed on 3/21 /19 at 10:20 am that the above attestation statements were not maintained.
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 of the Laboratory equipment and interview with the Laboratory Director (LD), the laboratory failed to ensure protection from chemical hazards at the time of the survey. The finding includes: 1. Observation of the hood used to exhaust fumes from histology reagents revealed the exhaust pipe was not attached to the hood. 2. The LD confirmed on 3/21/19 at 1:30 pm that the laboratory did not ensure protection from chemical hazards.
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: Based on surveyor review of the Competency Assessment (CA) records and interview with the Technical Supervisor (TS), the laboratory failed to evaluate competency accurately on the TS from 4/25/17 to the date of the survey. The TS confirmed on 3/21 /19 at 10:50 am that the CA was not performed accurately.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: a) Based on the lack of a Procedure Manual (PM) for the Leica ASP6025 tissue processor interview with the Laboratory Director (LD), the laboratory failed to have a written procedures for Tissue processing on the Leica ASP6025 from July 2018 to the date of the survey. The LD confirmed on 3/21/19 at 2:00 pm that the laboratory did not have procedures for Tissue processing. 35471 b) Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow their policy for Environmental Monitoring (EM) from 4/25/17 to the date of the survey. The finding includes: 1. The PM stated the grossing and histology area of the laboratory will have EM annually but there was no documented evidence this occurred. 2. The TP #3 listed on CMS form 209 confirmed on 3/21/19 at 2:50 pm the PM was not followed.
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 and interview with the Testing Personnel (TP), the laboratory failed to establish a procedure for using and preparing samples for the Cytospin from 4/25/17 to the date of the survey. The TP #3 confirmed on 3/21/19 at 2:15 pm that the laboratory did not establish the above procedure.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of Reagent Package Insert (RPI) and interview with the Testing Personnel (TP), the laboratory failed to follow RPI instructions for Free Prostate Specific Antigen (PSA), Total PSA tests performed on the Beckman Coulter Access 2 analyzer for maintaining specimen integrity from 4/25/17 to the date of survey. The finding includes: 1. The RPI stated "If the serum sample is to be assayed within 24 hours after collection, the specimen should be stored in a refrigerator at 2 ro 8 degrees Celsius, Specimens held for longer times should be frozen at -20 degrees Celsius or colder" but the laboratory did not ensure that Free PSA and Total PSA specimens were frozen if assayed after 24 hours. 2. On 3/16/19, four out of four patient samples were run and reported for Total PSA test after 24 hours of collection which was not frozen. 3. The TP was unaware of the RPI instructions. 4.The TP # 3 listed on CMS form 209 confirmed on 3/21/19 at 1:30 pm that RPI instruction was not followed.
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 Testing Personnel

	(TP), the laboratory failed to check the expiration date for reagents used for Histopathology tests on the date of the survey. The finding includes: 1. Reagents were expired as below: a. Colorbond Reagent - 6/17 b. Cytology Spray - 12/18 c. Blue Morgan Marker 6/16 d. Saccomanno (2) - 2/19 e. 37% Formaldehyde - 2/19 2. The TP #3 listed on CMS form 209 confirmed on 3/21/19 at 2:30 pm that the laboratory had expired reagents.
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 lack of Calibration Records (CR) and interview with the Testing Personnel (TP), the laboratory failed to calibrate the Ohaus Scout Pro Balance annually as per manufacturers instructions from 4/25/17 to the date of the survey. The TP #3 listed on CMS form 209 confirmed on 3/21/19 at 2:45 pm that calibration of the Ohaus Scout Pro Balance was not performed.
D5805	TEST REPORT CFR(s): 493.1291(c) 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. 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 report Urine Drug confirmation test results accurately from 4/25/17 to the date of survey. The finding includes: 1. The laboratory performed non Food and Drug Administration cleared tests and there was no statement stating "The performance characteristics of this test were determined by (Laboratory Name). It has not been cleared or approved by the U.S. Food and Drug Administration" on FR. 2. The TS confirmed on 3/21/19 at 11:30 am that Urine Drug confirmation tests were not reported accurately.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT

	CFR(s): 493.1299(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 postanalytic systems specified in 493.1291. 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 correct problems in the postanalytic system from 4/25/17 to the date of the survey. The findings include: 1. The laboratory reported comments below on Urine Drug confirmation tests on the FR: a. " This test is a qualitative screening assay. It is not designed to be quantitative." b. Note: "This test provides only preliminary test results and are considered "presumptive in nature. A more specific method should be used in order to obtain a confirmed analytical result. LC-MS/MS is the preferred confirmation method." 2. The FR for Urine Drug confirmatory tests included numerical values performed on the LCMS. 3. The TS confirmed on 4/25/17 at 12:20 pm that laboratory failed to correct problems on the FR.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) 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 (LD) failed to ensure that PS were adequate to perform Urine Toxicology confirmatory tests on the AB Sciex Triple Quad MD from 4/25/17 to the date of survey. The findings include: 1. The PS did not have a date on them as to when they were approved or performed. 2. The validation of the hydrolysis control did not include validation of: a. Optimal Enzyme Concentration b. Temperature of the Heat Block c. Time on the Heat Block 3. There was no criteria to review chromatography. 4. There was no criteria for manual integration. 5. The TS confirmed on 3/21/19 at 12:10 pm that the LD did not ensure the PS were adequate.