

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2022328	<b>(X3) Date Survey Completed</b> 01/10/2024
<b>Name of Provider or Supplier</b> Sovereign Laboratory Services, Llc	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 General Supervisor (GS), the laboratory failed to maintain all work records and signed attestation records for Molecular Bacteriology Urine tests from American Proficiency Institute Associates (API) in the calendar years 2022 and 2023. The findings include: 1. Work records and signed attestation records for the 3rd PT event in 2022 were not maintained. 2. Work records and signed attestation records for all PT events in the calendar year 2023 were not maintained. 3. The GS confirmed on 1/9/24 at 1:35 pm work and attestation records were not maintained for PT events as mentioned above.</p>
<b>D2021</b>	<p><b>BACTERIOLOGY</b> CFR(s): 493.823(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories</p>

failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS) the laboratory failed to participate in PT for Molecular Bacteriology Urine tests from the American Proficiency Institute (API) for the 1st event of 2023 for Bacteriology. The GS confirmed on 1/9/24 at 12:00 pm the laboratory failed to participate in PT for Molecular Bacteriology Urine tests from API for the 1st event of 2023 for Bacteriology.

**D3009**

**FACILITIES**  
CFR(s): 493.1101(c)

The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the laboratories NJ State License, Proficiency Testing (PT) and interview with the State of New Jersey Proficiency Provider Program lead, the Laboratory Director (LD) failed to be in compliance with New Jersey Administrative code N.J.A.C. 8:44-2.5(b)3. The finding includes: 1. N.J.A.C. 8:44-2.5 (b)3. states Laboratories shall: iii. Maintain records of all proficiency testing results in surveys in which they participate and make such records, including results, interpretations and cumulative performance data routinely available to the Department of Health and Senior Services. 2. The LD failed to make PT chemistry and endocrinology data routinely available to the Department of Health and Senior Services.

**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 General Supervisor (GS) the laboratory failed to follow its policies and procedures for assessing the competency of Testing Personnel (TP) in calendar years 2022 and 2023. The findings include: 1. The laboratory CA policy stated: "it is the policy of the Lab to perform and document employee training/competence at the following intervals after initial training has been documented." 6 months, at 1 year and annually thereafter. 2. 2 out of 4 TP did not have an annual CA performed in 2023. 3. 3 out of 4 TP did not have a 6 month CA performed after initial training. 4.

	<p>The GS confirmed on 1/9/24 at 11:00 am, the laboratory failed to follow the CA policy.</p>
<b>D5221</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: A) Based on surveyor review of the Proficiency Testing (PT) records and interview with the General Supervisor (GS) the laboratory failed to review coded results for Special Chemistry and endocrinology Testing performed with the College of American Pathologists (CAP) in the calendar year 2022 and 2023 event VITD-A 2022 and Y-A 2023. The findings include: 1. The laboratory received coded results (Code 28 - Response qualifies with a great than or less than sign: unable to quantitative) results for 25 O-H Vitamin D. a) 25 OH Vitamin D samples VITD-01, VITD-03 were coded 28, there was no documented evidence of peer group comparison performed. 2. The laboratory received coded results (Code 11-unable to analyze) results for Prolactin and Testosterone. b) Prolactin and Testosterone samples Y-01, Y-02, and Y-03 were coded 11, there was no documented corrective action taken. 3. The GS confirmed on 1/9/24 at 11:00 am that there was no corrective action performed aforementioned coded analytes. B) Based on surveyor review of the PT records and interview with the GS, the laboratory failed to evaluate all analyte scores for Molecular Bacteriology Urine tests for the 2nd event in the calendar year 2023 from the American Proficiency Institute (API). The findings include; 1. Sample Identification (ID) UTI-08 had a result of "not graded see note 11." 2. There was not documented evidence of evaluation or corrective action performed. 3. The GS confirmed on 1/9/24 at 1:00 pm, all analyte scores were not evaluated. 48354</p>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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 General Supervisor (GS) the laboratory failed to have a procedure for performing Thyroid-Stimulating Hormone (TSH) testing on the date of survey. The GS confirmed on 1/9/24 at 10:30 am that the laboratory failed to have a procedure for TSH.</p>
<b>D5415</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p>

This STANDARD is not met as evidenced by:  
Based on surveyor observation of Quality Control (QC) material in use, review of the Liquid Assayed Immunoassay Plus Control Kit Manufacture Package Insert (MPI) and interview with the General Supervisor (GS), the laboratory failed to put expiration dates on QC material for Routine Chemistry and endocrinology tests at the time of survey. The findings include: 1. The expiration date of the QC material shortens once opened. 2. The laboratory had an open date of 11/14/23 with no expiration date on current QC in use. 3. The MPI states All analytes had 14 day stability except fore Estrodial which had 5 days stability. 4. The analyzer had not performed patient testing since October 2023. 5. The laboratory was conducting performance specification with expired QC. 6. No patients where affected. 7. The GS confirmed on 1/9/24 at 11:45 am the laboratory failed to put expiration dates on the control material.

**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 Test Reports (TR) for Clinical Cytogenetics and Molecular Polymerase Chain Reaction (PCR) for Urinary Tract Infection (UTI) tests and interview with the Technical Supervisor (TS) the laboratory failed to ensure the TR included all the required information from 1/8/24 to the date of survey. The findings include: 1. TR did not include the required statement for tests that have not been FDA-cleared or approved which is "The performance characteristics of this test were determined by Sovereign Laboratory Services, LLC. It has not been cleared or approved by the U.S. Food and Drug Administration". 2. The TS confirmed on 1/9/24 at 12:00 pm, the laboratory failed to ensure the TR included all the required information.

**D5807**

**TEST REPORT**  
CFR(s): 493.1291(d)

Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:  
Based on the surveyor review of the Final Reports (FR), and interview with the General Supervisor (GS), the laboratory failed to have accurate Reference Interval (RI) for Endocrinology tests on the date of survey. The findings include: 1. A review of five FR revealed as follows: a. Three FRs had an RI of .01-16 ng/ml for

testosterone b. Two FR's had no RI for testosterone. c. Two FR's had no RI for prolactin. d. .Two FR's had PSA RI as 0.005-150 ng/ml while one FR had 0-4 ng/ml  
2. The GS confirmed on 1/10/24 at 1:00 pm that laboratory failed to have accurate RI.

**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 General Supervisor (GS), the Laboratory Director (LD) failed to ensure that PS were adequate to perform Endocrinology and Chemistry tests performed on the Beckman Coulter Access 2 analyzer on the date of survey. The findings include: 1. The laboratory failed to perform accuracy, precision and linearity. 2. The laboratory failed to perform a normal patient range study. 3. The GS confirmed on 1/9/24 at 11:15 am that not all PS were adequate.

**D6093**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality control 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 surveyor review of the Quality Control (QC) records and interview with the General Supervisor (GS), the Laboratory Director failed to ensure that the laboratory maintained the QC program on the date of the survey. The findings include; 1. QC was only reviewed on a daily basis. 2. There was no documented evidence that the laboratory reviewed QC for shifts and/or trends. 3. The GS confirmed on 1/9/24 at 12:00 PM, the laboratory did not review monthly quality control records.