

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2022328	(X3) Date Survey Completed 04/29/2026
Name of Provider or Supplier Sovereign Laboratory Services, Llc	Street Address, City, State 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
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</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 review and evaluate PT results obtained from the College of American Pathologists (CAP) for Pharmacogenetics tests and American Proficiency Institute (API) for Microbiology tests from 1/10/24 to 4/29/26. The findings include: 1. Surveyor review of the PT records revealed the following analytes had Code 11 (not graded) results that were not reviewed or evaluated for API 2025 Microbiology - 3rd event as follows: a) Molecular Resist. Genes - Urine CTX-M for samples UIT-12, 13 and 15. b) Molecular Resist. Genes - Urine NDM for samples UIT-12, 13 and 15. c) Molecular Resist. Genes - Urine vanA for samples UIT-11, 12, 13, and 14. d) Molecular Resist. Genes - Urine vanB for samples UIT-11, 12, 13, 14 and 15. e) Molecular Resist. Genes - Urine VIM for samples UIT-12, 13 and 15. 2. Surveyor review of the PT records revealed the following analytes had Code 27 (Lack of participant or referee consensus) results that were not reviewed or evaluated for event CAP PGX-A 2025 as follows: a) CYP2D6 Genotype, for samples PXG-01, 02, and 03. 3. Surveyor review of the PT records revealed the following analytes had Code 11 (not graded) results that were not reviewed or evaluated for API 2025 Microbiology - 2nd event as follows: a) Molecular Resist. Genes - Urine CTX-M for samples UIT-06, 07, 09, and 10. b) Molecular Resist. Genes - Urine vanA for samples UIT-06, 07, 08, and 10. c) Molecular Resist. Genes - Urine vanB for samples UIT-06, 07, 08, 09 and 10. d) Molecular Bacti-STI Treponema Pallidum, for sample STI-06. e) Molecular Resist. Genes - Urine NDM for samples UIT-06, and 09. f) Molecular Resist. Genes - Urine VIM for samples UIT-06, and 09. 4. Surveyor review of the PT records revealed the</p>

following analytes had Code 11 (not graded) results that were not reviewed or evaluated for API 2025 Microbiology - 1st event as follows: a) Molecular Bacti Urine Citrobacter spp. for sample UTI-01. b) Molecular Bacti Urine Proteus spp. for sample UTI-02. c) Molecular Resist. Genes - Urine CTX-M for samples UTI-02, 03, and 04.

5. Surveyor review of the PT records revealed the following analytes had Code 26 (Educational challenge) results that were not reviewed or evaluated for event CAP PGX-A 2025 as follows: a) CYP2B6 Clinical Manage, for samples PXG-01, 02, and 03. b) CYP2B6 Predicted Pheno, for samples PXG-01, 02, and 03. c) CYP2C19 Clinical Manage, for samples PXG-01, 02, and 03. d) CYP2C19 Predicted Pheno, for samples PXG-01, 02, and 03. e) CYP2C9 Predicted Pheno, for samples PXG-01, 02, and 03. f) CYP2C9 / VKORC1 Clinical, for samples PXG-01, 02, and 03. g) CYP2D6 Clinical Manage, for samples PXG-01, 02, and 03. h) CYP2D6 Predicted Pheno, for samples PXG-01, 02, and 03. i) CYP3A4 Predicted Pheno, for samples PXG-01, 02, and 03. j) CYP3A5 Predicted Pheno, for samples PXG-01, 02, and 03. k) SLCO1B1 Clinical Manage, for samples PXG-01, 02, and 03. l) VKORC1 Predicted Pheno, for samples PXG-01, 02, and 03.

6. Surveyor review of the PT records revealed the following analytes had Code 11 (not graded) results that were not reviewed or evaluated for API 2024 Microbiology - 3rd event as follows: a) Molecular Resist. Genes - Urine CTX-M for samples UIT-11, 13, 14 and 15. b) Molecular Resist. Genes - Urine vanA/B for samples UIT-11, 12, 13, and 14.

7. Surveyor review of the PT records revealed the following analytes had Code 11 (not graded) results that were not reviewed or evaluated for API 2024 Microbiology - 2nd event as follows: a) Molecular Bacti-STI Treponema Pallidum, for sample STI-06. b) Molecular Resist. Genes - Urine CTX-M for samples UIT-06, 09, and 10. c) Molecular Resist. Genes - Urine NDM for samples UIT-06, and 09. d) Molecular Resist. Genes - Urine vanA for samples UIT-06, 07, 08 and 10. e) Molecular Resist. Genes - Urine vanB for samples UIT-06, 07, 08, 09 and 10. f) Molecular Resist. Genes - Urine VIM for samples UIT-06, and 09.

8. Surveyor review of the PT records revealed the following analytes had Code 26 (Educational challenge) results that were not reviewed or evaluated for event CAP PGX-B 2024 as follows: a) CYP2B6 Clinical Manage, for samples PXG-04, 05, and 06. b) CYP2B6 Genotype, for samples PXG-04, 05, and 06. b) CYP2B6 Predicted Pheno, for samples PXG-01, 02, and 03. c) CYP2C19 Clinical Manage, for samples PXG-01, 02, and 03. d) CYP2C19 Predicted Pheno, for samples PXG-01, 02, and 03. e) CYP2C9 Predicted Pheno, for samples PXG-01, 02, and 03. f) CYP2C9 Predicted Activ, for samples PXG-01, 02, and 03. g) CYP2D6 Clinical Manage, for samples PXG-01, 02, and 03. h) CYP2D6 Predicted Pheno, for samples PXG-01, 02, and 03. i) CYP2D6 Predicted Activ, for samples PXG-01, 02, and 03. j) CYP3A4 Predicted Pheno, for samples PXG-01, 02, and 03. k) CYP3A5 Predicted Pheno, for samples PXG-01, 02, and 03. l) SLCO1B1 Clinical Manage, for samples PXG-01, 02, and 03.

9. Surveyor review of the PT records revealed the following analytes had Code 27 (Lack of participant or referee consensus) results that were not reviewed or evaluated for event CAP PGX-B 2024 as follows: a) CYP2D6 Genotype, for sample PXG-05.

10. Surveyor review of the PT records revealed the following analytes had Code 26 (Educational challenge) results that were not reviewed or evaluated for event CAP PGX-A 2024 as follows: a) CYP2B6 Clinical Manage, for samples PXG-01, 02, and 03. b) CYP2B6 Genotype, for samples PXG-01, 02, and 03. b) CYP2B6 Interpretation, for samples PXG-01, 02, and 03. c) CYP2C19 Clinical Manage, for samples PXG-01, 02, and 03. d) CYP2C19 Interpretation, for samples PXG-01, 02, and 03. e) CYP2C9 Predicted Activ, for samples PXG-01, 02, and 03. f) CYP2C9 / VKORC1 Clinical, for samples PXG-01, 02, and 03. g) CYP2D6 Clinical Manage, for samples PXG-01, 02, and 03. h) CYP2D6 Interpretation, for samples PXG-01, 02, and 03. i) CYP2D6 Predicted Activ, for samples PXG-01, 02, and 03. j) CYP3A4 Interpretation, for samples PXG-01, 02, and 03. k) CYP3A5 Interpretation, for

samples PXG-01, 02, and 03. 1) SLCO1B1 Clinical Manage, for samples PXG-01, 02, and 03. 11. The TS confirmed on 4/28/26 at 11:10 am, the laboratory did not review and evaluate all PT results obtained from CAP.