Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657854	07/07/2026
Name of Provider or Supplier	**Street Address, City, State**	
Public Health Lab City Of Philadelphia	1930 South Broad Street, Philadelphia, PA	

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
D0000	An onsite complaint survey was conducted on 7/7/2026 at Public Health Lab City of Phila by the Pennsylvania State Agency. The complaint was found to be unsubstantiated.
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 lack of documentation and interview with the Quality Officer (QO), the laboratory failed to establish and follow a competency assessment (CA) procedure to assess the competency of 1 of 5 Technical Supervisor (TS) for their supervisory responsibilities performed from 2/26/2025 to 7/7/2026. Findings Include: 1. On the day of survey, 7/7/2026 at 11:30 am, the laboratory failed to provide a competency assessment procedure to assess the competency of 1 of 5 TS (CMS 209, TS # 5 dated 7 /7/2026) for their supervisory responsibilities performed in the laboratory from 2/26 /2025 to 7/7/2026. 2. The laboratory failed to provide CA records for TS #5 for their supervisory responsibilities performed from 2/26/2025 to 7/7/2026. 3. The QO confirmed the findings above on 7/7/2026 at 3:00 pm.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score

	for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records and interview with the Quality Officer (QO), the laboratory failed to verify the accuracy of the PT results obtained for 1 of 3 API Microbiology testing events in 2025. Findings Include: 1. On the day of survey, 07/07/2026 at 09:45 am, review of the laboratory's API PT records revealed that the laboratory did not verify the accuracy for the following analytes that were not scored by the PT agency for 1 of 3 API Microbiology PT events performed in 2025: - API 2025 (2nd event): GCB-01 Group B Strep - API 2025 (2nd event): UR-06 Urine Culture A MIC/ZONE diameter - API 2025 (2nd Event): UR-07 Urine Culture A MIC/Zone diameter 2. The QO confirmed the findings above on 07/07/2026 at 2:50pm.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) (b)(1)(i) Establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (b)(1)(ii) Perform and document the maintenance activities specified in paragraph b(1)(i) of this section. This STANDARD is not met as evidenced by: Based on record review, lack of documentation and interview with the Quality Officer (QO), the laboratory failed to perform and document weekly maintenance for 1 of 1 Diasorin Liaison and 1 of 1 Abbott Alinity instruments used to perform Chemistry testing from 02/26/2025 to 07/07/2026. Findings Include: 1. The laboratory's Diasorin Liaison Maintenance Log stated, "Weekly: Make cleaning solution, Auto clean Procedure, Shutdown analyzer, Clean pipettor probes, Check Inventory." 2. The laboratory's Abbott Alinity Maintenance Log stated, "Weekly: Manual Clean Pipettor Probe, Manual Clean Wash Zone Probes, Manual Clean Wash Cup." 3. On the day of survey, 07/07/2026 at 11:10 am, review of maintenance records for 1 of 1 Diasorin Liaison and 1 of 1 Abbott Alinity instruments revealed the laboratory failed to document weekly maintenance tasks performed for 1 out of 4 weeks for the following months in 2025 and 2026: - April 2025 (Diasorin Liaison) - July 2025 (Diasorin Liaison) - March 2026 (Diasorin Liaison) - June 2026 (Abbott Alinity) 4. The laboratory performed 227,521 Chemisty tests in 2025 (CMS 116, estimated annual volume, dated 07/07/2026). 5. The QO confirmed the findings above on 07/07/2026 at 2:45pm.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on lack of documentation, and interview with the Quality Officer (QO), the

	laboratory failed to evaluate twice a year the relationship between test results using different methodologies/instruments for urinalysis and microbiology examinations for 2 of 2 years from 7/10/2024 to 7/7/2026. Findings include: 1. On the day of the survey, 7/7/2026 at 2:00 pm, the laboratory failed to provide documentation for the evaluation performed twice a year to monitor and evaluate the relationship between the following methodologies/instruments used for urinalysis and microbiology examinations for 2 of 2 years from 7/10/2024 to 7/7/2026: - Manual Urine Microscopic vs Automated Urine Microscopic - Biofire Fourplex vs Cepheid 2. The QO confirmed the findings above on 7/7/2026 at 3:00 pm.