Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657854	09/07/2022
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
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 Assuarance Officer (QA), the laboratory failed to verify the accuracy for 1 of 4 Mycobacteriology Culture Susceptibilites in 2021. Findings Include: 1. On the day of survey, 09/07/2022 at 10:11 am, review of 2021 API proficiency testing records revealed that the laboratory did not verify the accuracy for the following analytes that were not graded by the proficiency testing agency: - API 2021 Mycobacteriology 1st Event: Mycobacteriology Culture Susceptibility Testing for Pyrazinamide was not graded due to lack of particpants. 2. The QA Officer confirmed the findings above on 09/07/2022 around 03:00 pm.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. 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 Assurance Officer (QA), the laboratory failed to document the evaluation and verification activities for 2 of 3 events of Chemistry

	Core and 1 of 3 events of Microbiology for the Unacceptable Proficiency Testing (PT) for 2021. Findings Include: 1. On the day of survey, 09/07/2022 at 10:11 am, a review of API proficiency testing records revealed that the laboratory received an unacceptable grade for the following PT events. - 50% on API 2021 1st event Chemistry Core: PSA Testing Abbott Architect i2000SR. - 80% on API 2021 2nd event Chemistry Core: LDL Cholesterol (measured) (mg/dL). - 80% on API 2021 1st event Microbiology Core: Gram Stain. 2. The laboratory failed to provide documentation of the evaluation and verification activities for the above PT events. 3. The QA Officer confirmed the findings above on 09/07/2022 at 03:10 PM.
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 review of the ALCOR iSED analyzer validation records and interview with the Technical Supervisor (TS)#3, the Laboratory Director (LD) failed to approve the performance specification procedures used to determine the accuracy and precision for the Erythrocyte Sedimentation Rate (ESR) testing performed on the ALCOR iSED before reporting patient test results from April 2022 to the date of survey. Findings Include: 1. On the day of survey, 09/07/2022 at 11:00 am, review of the ALCOR iSED validation records revealed that the LD did not review and approve the validation studies for the ALCOR iSED performed on 04/07/2022. 2. The TS#3 confirmed the findings above on 09/07/2022 around 3:00 p.m.