Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0657854	11/12/2020
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
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of Bactec MGIT 960 daily maintenance QC log sheets and interview with Testing Personnel #4 (TP#4), the laboratory failed to record the temperatures of the Bactec MGIT 960 for 32 of 169 days reviewed from January 2020 to August 2020. Findings include: 1. The Bactec MGIT 960 daily maintenance QC log sheet states: - "Perform daily, except on weekends and holidays." - "Perform even if no testing is being performed that day." 2. On the date of survey 11/12/2020, review of the Bactec MGIT 960 daily maintenance QC log sheet revealed, the laboratory did not document temperatures for the following days from January 2020 to August 2020: - 1 of 22 days in March 2020. - 3 of 22 days in April 2020. - 1 of 20 days in May 2020. - 3 of 21 days in June 2020. - 16 of 23 days in July 2020. - 8 of 21 days in August 2020. 3. TP#4 confirmed the findings above on 11/12/2020 at 11:12 a.m.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

	This STANDARD is not met as evidenced by: Based on review of the Iris ichem VELOCITY Urine Chemistry System maintenance cards, Iris ichem VELOCITY Urine Chemistry System maintenance records and interview with the Testing personnel (TP #1), the laboratory failed to perform and document quarterly (3 of 4) maintenance for the Iris Ichem VELOCITY Urine Chemistry System in 2019. Findings include: 1. The Iris Ichem VELOCITY Urine Chemistry System maintenance cards state, "Quarterly maintenance, run iChem Velocity CalChek reflectance Strips". 2. On the day of survey, 11/12/2020, review of Iris ichem VELOCITY Urine Chemistry System maintenance records revealed, quarterly maintenance of the iChem Velocity CalChek reflectance Strips were performed 3 of 4 times in 2019. -The laboratory performed and documented maintenance for the iChem Velocity CalChek reflectance Strips on 04/09/2019, 09/23 /2019 and on 12/19/2019. 3. TP #1 confirmed the findings above on 11/12/2020 at 12: 35 p.m..
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of quality control records and interview with Technical Supervisor (TS) #3, the laboratory failed to perform a negative and positive controls, each day of patient testing for the Meridian Bioscience Illumigene Herpes simplex virus (HSV) 1 & 2 and the Meridian Bioscience Illumigene Bordetella pertussis/parapertussis testing performed from 09/26/2018 to the day of survey. Findings include: 1. On the day of survey, 11/12/2020, review of the Meridian Bioscience Illumigene HSV 1&2 and the Meridian Bioscience Illumigene Bordetella pertussis/parapertussis quality control records revealed, that laboratory did not perform a positive and negative controls each day of patient testing for HSV 1 & 2 and Bordetella pertussis/parapertussis testing performed from 09/26/2018 to 11/12/2020. 2. From (9/26/2018 to 6/25/19) 290 tests were analyzed on the Meridian Bioscience Illumigene for HSV 1&2. 3. From (6/26/19 to 11/12/2020) the follow volume of tests were analyzed on the Meridian Bioscience Illumigene: - HSV 1&2: 530 - Bordetella pertussis/parapertussis: 1 4. TS #3 confirmed the findings above on 11/12/2020 around 1:45 pm.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on review of the hematology refrigerator #28 temperature records and

	interview with the technical supervisor (TS) #1, the laboratory failed to document all corrective actions taken when the hematology refrigerator exceeded acceptable ranges in 2019. Findings include: 1. The hematology refrigerator #28 temperature document states, "If the temperature is not within the acceptable range notify a supervisor". "Mark "CA" box to indicate that a corrective action is on file with the section supervisor". 2. On the day of survey, 11/12/2020, review of the hematology refrigerator #28 temperature records revealed, the following number of days temperatures were below the acceptable range (2 to 8 degrees Celsius) in 2019. - 2 of 22 days in August. - 6 of 20 days in September. 3. The TS #1 could not provide correction actions documented for temperatures out of range in 2019. 4. The hematology refrigerator #28 housed moderate level hematology and urinalysis testing reagents and controls. 5. The TS#1 confirmed the finding above on 11/12/2020 around 11:40 am.