

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 08D0662985	(X3) Date Survey Completed 08/30/2023
Name of Provider or Supplier Delaware Public Health Laboratory	Street Address, City, State 30 Sunnyside Road, Smyrna, DE	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of laboratory personnel competency assessment records and an interview with the Quality Manager, the laboratory failed to establish written policies and procedures to assess Technical Supervisors (TS) for competency in 2021 and 2022. Findings Included: 1. The personnel form CMS-209 filled out by the laboratory at the time of the survey listed 4 TS technical supervisors for the laboratory. 2. Review of the Quality Plan Micro, section 9.1 competency assessment, revealed, that the laboratory did not establish a TS competency assessment policy. 2. Interviews with Quality Manager on 8/30/2023 at 11:45 am confirmed they did not establish a written policy to assess TS for competency.</p>
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on a observation of the Tuberculosis (TB) laboratory and interview with technical supervisor (TS) #3, the laboratory failed to monitor the room temperature of the TB laboratory that stores calibration vials, test medium and tubes that require conditions for storage from 2021 to 2023. Findings Included: 1. Review of the Isensix temp track map on 08/29/2023, revealed the TB laboratory was not monitored by the system. 2. On August 30, 2023, a tour of the TB laboratory revealed, the follow BD Bactec MGIT supplies require to be stored at 2 to 25 degrees Celsius per the manufacturer: - Mycobacteria Growth Incubator Tubes - Lot# 3061954 - 3 of 3 boxes. - Susceptibility Test Medium - Lot# 3025516 - 4 of 4 boxes. - Calibration Vials - Lot# 3032627 - 1 of 1 box. 3. Interviews with TS #3 confirmed on 8/30/2023 at 10:00 am, the laboratory does not monitor the room temperature of the TB laboratory.

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 a observation of the laboratories, lack of records and an interview with technical supervisor (TS) #2 and #3, the laboratory failed to perform maintenance for 6 of 7 traceable timers observed in the laboratory on August 29, 2023 and August 30, 2023. Findings Included: 1. The laboratory could not provide a procedure for the performance for maintenance check for timers used for clinical testing. 2. On August 29, 2023 and August 30, 2023 the following timers were observed that were due to maintenance in the Virology and Tuberculosis (TB) laboratories: - Fisher Scientific Traceable - S/N#140799247 - Due 12/09/2016. - Fisher Scientific Traceable - S/N#111473801 - Due 04/22/2013. - Fisher Brand Traceable - S/N#192552834 - Due 10/10/2021. - Fisher Brand Traceable - S/N#192552809 - Due 10/10/2021. - Fisher Brand Traceable - S/N#160303283 - Due 03/23/2018. - Fisher Brand Traceable - S/N#160203235 - Due 03/23/2018. - Fisher Brand Traceable - S/N#160303276 - Due 03/23/2018. 3. Interviews with TS#2 and TS #3 on 8/30/2023 at 10:30 am confirmed the laboratory does not have a policy for the maintenance of timers in use.

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. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
Based on a review laboratory records and an interview with the Quality Manager and technical supervisor (TS) #2, the laboratory failed to perform comparison studies every 6 month for 11 out of 11 Thermo Scientific ABI Fast 7500 Fast DX analyzers used to analyze virology tests. Findings Included: 1. On August 30, 2023 the laboratory could not provide comparison studies performed every 6 month for 11 out

of 11 Thermo Scientific ABI Fast 7500 Fast DX analyzers. 2. Interviews with the Quality Manager and TS#2 on 8/30/2023 at 1:00 pm confirmed comparison studies were not performed every 6 months to compare the Thermo Scientific ABI Fast 7500 Fast DX analyzers that run the same test.