Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	09D2186500	04/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
George Washington University Public Health Lab	800 22nd Street Nw Suite 1800, Washington, DC	

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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the specimen rejection procedure and interview with the technical supervisor (TS), the laboratory failed to ensure that step by step instructions were available for documenting rejected specimens. Findings: 1. The laboratory recently changed LIS systems. 2. The current LIS systems does not give lab personnel the option to document specimen rejection electronically in the database as the previous LIS system. 3. The TS stated on 4/20/22 at 2:30 PM that lab personnel can document specimen rejection in the lab Teams chat for review. 4. The lab did not update the rejection policy with step-by-step instructions for documenting specimen rejections

	with the new LIS system through Teams chats. 5. The TS confirmed 4/20/22 at 2:30 PM that the lab failed to update the rejection policy with step-by-step instructions for documenting specimen rejections with the new LIS system through the Teams chats.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the quality assessment (QA) procedure and interview with the technical supervisor (TS), the laboratory director (LD) failed to ensure that all lab personnel were informed of QA meeting minutes performed during daily lab huddles. Findings: 1. The LD failed to have a tracking mechanism in place to ensure all lab personnel was informed of QA meeting minutes when not present during the daily lab huddle. 2. The TS stated on 4/20/22 at 2:00 PM that the lab has daily huddles to discuss lab testing. 3. The TS documented the huddle minutes and the names of lab personnel present during the meeting. 4. The TS did not inform lab personnel that was not present during the daily huddle the QA meeting minutes nor the information that was shared during the daily QA huddle. 5. The TS confirmed on 4/20/22 at 2:00 PM that a tracking mechanism was not in place to ensure all lab personnel was informed of QA meeting minutes when not present during the daily lab huddle.