Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D1085624	03/04/2022
Name of Provider or Supplier	**Street Address, City, State**	
Prince Georges County Health Dept Std Stat Lab	3003 Hospital Drive Ste 3048, Cheverly, MD	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) and quality control (QC) records and interview with the testing personnel (TP), the laboratory failed to perform serum pregnancy PT using the laboratory's routine methods in three of seven PT events. Findings: 1. The TP stated that external QC was performed for serum pregnancy testing each day patient testing was performed. 2. The serum pregnancy QC results were recorded on a log that included the date of testing, lot numbers, expiration dates, QC results and TP initials. 3. Attestation sheets, which included the dates the serum pregnancy PT was performed, were reviewed for seven PT events from 2020 to 2022. 4. There was no record that external QC was performed on the days when PT samples were tested for three of the seven serum pregnancy PT events reviewed (2020 Q1, 2020 Q2 and 2022 Q1). 5. During the survey on 03/04/2022 at 2:50 pm, the TP confirmed that external QC was not always recorded on the log on days that PT samples were tested
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 rapid plasma reagin (RPR) worksheets and interview with the testing personnel, the laboratory's standard operating procedure (SOP) did not include written instructions for the frequency of performing the revolutions per minute (rpm) for the rotator and calibration of the needle used for the adding RPR antigen suspension. Findings: 1. The RPR worksheets showed that the rotator rpms were performed daily for each of the two rotators and the needle calibration was performed weekly and with a new vial of RPR antigen suspension reagent. 2. During the survey on 03/04/2022 at 2:50 pm, the testing personnel confirmed that the SOP did not include written instructions for the frequency of performing rotator rpms and needle calibration. 43123 Based on review of the rapid plasma reagin (RPR) worksheets and interview with the testing personnel, the laboratory's standard operating procedure (SOP) did not include written instructions for the frequency of performing the revolutions per minute (rpm) for the rotator and calibration of the needle used for the adding RPR antigen suspension. Findings: 1. The RPR worksheets showed that the rotator rpms were performed daily for each of the two rotators and the needle calibration was performed weekly and with a new vial of RPR antigen suspension reagent. 2. During the survey on 03/04/2022 at 2:50 pm, the testing personnel confirmed that the SOP did not include written instructions for the frequency of performing rotator rpms and needle calibration.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on review of gram stain records and interview with the testing personnel, the laboratory did not ensure that the record system included when each new lot of the gram stain slides were put into use for quality control. Findings: 1. Review of the gram stain records showed that the lot number and expiration dates were recorded on the inventory worksheet, but not when the new lot was put into use. 2. During the survey on 03/04/2022 at 2:50 pm, the testing personnel confirmed that the gram stain records did not indicate when the new lot was put into use to ensure that the old lot was not used past the recorded expiration date. 43123

D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the "Quarterly Lab Manual Review" worksheet and interview with the testing personnel, the laboratory director did not ensure that the quarterly review was done every three months. Findings: 1. The "Quarterly Lab Manual Review" worksheet lists the following months to record the quarterly review- January, April, September, and December. 2. The worksheets for 2020, 2021, and 2022 were reviewed. There was only a signature next to the month on each worksheet. There was no date of the actual review. There are six months between April and September and zero months between December and January. The documentation failed to ensure that the review was performed on a quarterly basis. 3. During the survey on 03/04/2022 at 2:50 pm, the testing personnel confirmed that the documentation on the "Quarterly Lab Manual Review" worksheet did not ensure that the review was performed quarterly.