

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D1085624	<b>(X3) Date Survey Completed</b>  06/18/2019
<b>Name of Provider or Supplier</b>  Prince Georges County Health Dept Std Stat Lab	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the written procedure manual and interview with testing personnel, the laboratory did not have step by step instructions for all laboratory procedures performed by the lab. Findings: I. 1. The laboratory did not have a procedure for ordering quality control (QC) slides that are pre- prepared for testing when performing gram stain procedures. 2. The gram stain procedure states that QC is performed by slides that have been prepared in house. 3. The testing person stated that they stopped preparing QC slides in house last year when performing gram staining procedures and started ordering the QC slides already prepared for testing. 4. The</p>

testing personnel confirmed that the laboratory did not have a written procedure for ordering QC slides when performing gram staining procedures. II. 1. The gram stain procedure states that monthly correlation reports are performed between the patient gram stain results and the confirmation culture result. 2. The testing person stated that the gram stain monthly correlation reports are performed electronically and not on paper anymore. 3. The laboratory did not have written procedures for performing the electronic gram stain patient monthly correlation report. 4. The testing personnel confirmed the laboratory did to have a procedure for performing the monthly correlation report. III. 1. The laboratory did not have a written procedure for performing RPR's with the Sure-Vue test kit. 2. The laboratory written procedure for performing the RPR test with the Macro-Vue RPR Card test states to rehydrate the QC cards when performing the test. Reagents are impregnated on the card that react when positive specimen is added to the card. 3. The testing personnel stated that they now use the Sure-Vue kit with three separate reagents that are added to the RPR test card when performing the QC. The reagents have three different levels of reactivity when added to patient specimen. 4. The testing personnel confirmed that the laboratory did not have a written procedure for performing the RPR test with the Sure-Vue RPR test kit. IV. 1. The RPR procedure nor the serum pregnancy procedure states how long to centrifuge the patient specimen and rotations per minute (RPM) prior to performing the test. 2. The testing personnel stated that they follow the "centrifuge usage procedure". 3. The "centrifuge usage procedure" states on the centrifuge turn to "#5" for the RPM's needed for serum separation and set the timer for 10-15 mins. 4. The written procedure did not specify the RPM's nor the exact spin time for serum separation when performing the RPR and the serum pregnancy test. 5. The testing personnel stated that they spin specimens for 10 minutes at 5000 RPM's . 6. The testing personnel confirmed that the RPM's and specimen centrifuge time for the RPR and serum pregnancy test was not included in the written procedure.

**D6019**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
 CFR(s): 493.1407(e)(4)(iv)

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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:  
 Based on review of proficiency testing (PT) records and interview with the testing personnel, the laboratory director did not ensure that corrective action procedures were followed when PT results were shown to be unacceptable. Findings: 1. The laboratory did not perform corrective action procedures for the Gram Stain 2018 non chemistry Q2 PT performance report. 1. The laboratory Gram Stain PT performance report for the 2018 non chemistry Q2 showed a "?" for sample #4. 2. The laboratory reported result was "gram-positive" for sample #4 and the majority in the peer group reported result was "gram-negative" 3. The performance report ledger states that "?" score may not give an accurate result for the specimen in question due the lack of peer group (consensus) participation and was not graded. 4. The PT procedure states that when the submitting labs result is the majority the test should be repeated and the if

the result is the same the PT agency should be notified. 4. The testing personnel stated that they were unaware of the "?" and confirmed that corrective action procedures were not performed.