

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1025461	(X3) Date Survey Completed 10/09/2018
Name of Provider or Supplier Farmville Pediatrics	Street Address, City, State 3444 S Contentnea Steet, Farmville, NC	
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	<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 laboratory's procedure manual and laboratory manager interview 10/09/18, the laboratory's procedure manual was not complete and current for the testing performed. The laboratory performs urine cultures using Trypticase Soy Agar (TSA) 5% media and throat cultures using Group A Selective Strep Agar media. Review of laboratory procedure manual revealed the laboratory has two procedures entitled "CULTI-LOOPS" used for the quality control (QC) procedures for TSA 5% media and Group A Selective Strep Agar media. The procedures describe the principle of culti-loops, the precautions of culti-loops, the storage of culti-loops and</p>

the procedure for culti-loops. The procedures fail to meet the requirements for (QC) of TSA 5% media and Group A Selective Strep Agar media. For example: 1. "CULTI-LOOPS" procedure #1 does not indicate it is a QC procedure for TSA 5% media (ie urine cultures). The only mention of TSA 5% media is under... "PROCEDURE"..... Direct Streak Method:2. Warm appropriate plated media (TSA 5%) to 37 degrees Celcius (C)." The procedure fails to include the frequency of QC for TSA 5% media; including sterility and condition requirements and the criteria used to determine if all QC is acceptable. 2. "CULTI-LOOPS" procedure #2 does not indicate it is a QC procedure for Group A Selective Strep Agar media (ie throat cultures). The procedure does not state what media is to be used in the procedure. For example, the frequency of QC is stated" 9. Plate subculture and test Taxo-A disc with each new lot number of plates/A discs." The procedure fails to include sterility and condition QC requirements, the frequency of sterility and condition QC, and the criteria used to determine if all QC is acceptable. Review of laboratory procedure manual revealed procedure "Throat Culture" (BBL DISCS FOR GROUP A STREPTOCOCCI) which included the throat culture procedure for patient specimens and the QC requirements for Taxo-A discs only. Interview with Laboratory Manager at approximately 1:30 p. m. confirmed the QC procedures for TSA 5% media and Group A Selective Strep Agar media were not complete.

D5477

CONTROL PROCEDURES
CFR(s): 493.1256(e)(4)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of laboratory logs and laboratory manager interview 10/09/18, the laboratory failed to document and/or perform sterility checks for Group A Selective Strep Agar media and Trypticase Soy Agar (TSA) 5% media, and failed to perform quality control (QC) on Group A Selective Strep Agar for each new lot number and/or shipment. The laboratory uses Healthlink StrepSelect AGAR media for throat cultures and BBL TSA II 5% SB media for urine cultures. Review of laboratory logs "E. Coli and Pyogenes/A Disc" and "Media Label Book" revealed no documentation of sterility checks for TSA 5% media. The laboratory does document a growth and no growth result for each new lot number and/or shipment, but it is not documented as a sterility check. Review of laboratory logs "E. Coli and Pyogenes/A Disc" and "Media Label Book" revealed the laboratory failed to perform sterility checks on Healthlink StrepSelect AGAR media since time of last survey 11/18/16. Review of laboratory logs "E. Coli and Pyogenes/A Disc" and "Media Label Book" revealed no documentation of quality control or sterility check for BBL TSA II 5% SB media, Lot # 7208609, expiration (exp) 11/15/17. Approximately 30 patients were affected. Review of laboratory logs "E. Coli and Pyogenes/A Disc" and "Media Label Book" revealed quality control had not been performed on the following lot numbers of Healthlink StrepSelect AGAR: 1. Lot # 1703013, received 03/07/17, exp 05/08/17; approximately 41 patients were affected. 2. Lot # 1705905, received 04/04/17, exp 06/06/17; approximately 32 patients were affected. 3. Lot # 1705905, received 04/18/17,

exp 06/06/17; approximately 33 patients were affected. 4. Lot # 1717703, received 08/21/17, exp 10/02/17, approximately 49 patients were affected. 5. Lot # 1731000, received 12/27/17, exp 04/15/18, approximately 30 patients were affected. 6. Lot # 1736005, received 01/30/18, exp 04/17/18, approximately 30 patients were affected. 7. Lot # 1818308, received 09/11/18, exp 10/22/18, approximately 30 patients were affected. Interview with Laboratory Manager at approximately 1:30 p.m. confirmed the laboratory had not been performing sterility checks on Healthlink StrepSelect AGAR media and BBL TSA II 5% SB media. She stated she was not aware that sterility checks were required for media. She also confirmed quality control had not been documented and/or performed for the above noted lot numbers of media.