

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0688729	(X3) Date Survey Completed 04/18/2018
Name of Provider or Supplier Carolina Pediatrics Of Wilmington	Street Address, City, State 715 Medical Center Drive, Wilmington, 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 procedure manual 4/18/18, the laboratory's procedure manual failed to include all required information. Findings: 1. The laboratory's procedure manual failed to include pediatric hematology normal values or reference ranges. 2. The laboratory's procedure manual failed to include and define critical values for the Medonic M-series hematology analyzer. For example: a. How panic values are defined, and the ranges for various analytes. b. How they are verified. c.</p>

How they are reported to the providers. 3. The laboratory's procedure manual failed to include a downtime procedure to follow if the Medonic M-series hematology analyzer was inoperable.

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 policy, review of 2016, 2017 and 2018 microbiology quality control records and interview with testing personnel (TP) 04/18/18, the laboratory failed to perform and document quality control and sterility checks for the BBL Group A Selective Strep Agar as required for each new lot number or shipment received. The laboratory uses BBL Group A Selective Strep agar as media for throat culture testing. The laboratory examines each "package" for product deterioration, and saves the new "lot number sticker" in a log book to document examination. Review of laboratory policy "THROAT CULTURE POLICY AND PROCEDURE" revealed the procedure includes only the examination of physical characteristics and the quality control to perform for a new lot number of BBL TAXO DISCS. It does not include sterility or quality control for growth checks as required for each new lot number or shipment of BBL Group A Selective Strep Agar. Review of 2016, 2017, and 2018 microbiology quality control records revealed no documentation of sterility or quality control for growth checks on each new lot number or shipment of BBL Group A Selective Strep Agar. During exit interview at approximately 2:30 p.m., TP #1 confirmed the laboratory had not performed sterility or quality control for growth checks on each new lot number or shipment of BBL Group A Selective Strep Agar. She stated, "no one has ever told us we needed to do this".