

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0244200	(X3) Date Survey Completed 07/18/2018
Name of Provider or Supplier Novant Health Eastover Pediatrics	Street Address, City, State 517 South Sharon Amity Road, Charlotte, 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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of 2016, 2017, and 2018 quality control records, and interview with the TC (technical consultant) 7/18/18, the laboratory failed to follow the manufacturer's instructions for performance of throat cultures. The BD BBL Taxo A Discs product insert states "INTENDED USE BD BBL Taxo A discs are for the presumptive identification of group A beta-hemolytic streptococci based on susceptibility to a low level of bacitracin. Discs are intended for use with pure cultures, with the exception noted under 'Specimens'. ... SPECIMENS BD BBL Taxo A discs are not for use directly with clinical specimens or other sources containing mixed flora. ... However, the BBL Group A Selective Strep Agar with 5% Sheep Blood (ssA) plate, which may be used for the primary isolation of group A streptococci from throat specimens, was designed specifically for use with the BD BBL Taxo A disc. ..." Review of 2016, 2017, and 2018 quality control records revealed the laboratory had received sheep blood agar plates, but had not received any Selective Strep Agar plates. During interview at approximately 11:35 a.m., the TC confirmed the laboratory uses only sheep blood agar plates. She stated the laboratory had never used Selective Strep Agar plates as specified by the bacitracin disc instructions for presumptive identification of group A strep from throat cultures.</p>
D6014	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii)</p>

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, review of the laboratory's policies and procedures, review of 2017 and 2018 quality control records, and interview with the TC (technical consultant) 7/18/18, the laboratory director failed to ensure testing personnel were performing the throat culture procedure as required for accurate and reliable results. The BD BBL Taxo A Discs product insert states "INTENDED USE BD BBL Taxo A discs are for the presumptive identification of group A beta-hemolytic streptococci based on susceptibility to a low level of bacitracin. Discs are intended for use with pure cultures, with the exception noted under 'Specimens'. ... SPECIMENS BD BBL Taxo A discs are not for use directly with clinical specimens or other sources containing mixed flora. ... However, the BBL Group A Selective Strep Agar with 5% Sheep Blood (ssA) plate, which may be used for the primary isolation of group A streptococci from throat specimens, was designed specifically for use with the BD BBL Taxo A disc. ..." The laboratory's "Throat Cultures for Group A Streptococcus" procedure states "... IV. EQUIPMENT Sheep Blood Agar ... V. PROCEDURE ... 16. ... cultures are made by rolling the swab onto one side of the SBA (sheep blood agar) plate ... 17. ... Place a Bacitracin disc at the junction of the primary and secondary streaks as noted. ..." The laboratory director failed to ensure the laboratory's procedure was consistent with the manufacturer's instructions for use of the bacitracin discs. Review of 2016, 2017, and 2018 quality control records revealed the laboratory had received sheep blood agar plates, but had not received any Selective Strep Agar plates. The laboratory director failed to ensure that the throat culture media used by the laboratory was the media specified by the manufacturer (Selective Strep Agar) for use with the bacitracin discs. During interview at approximately 11:35 a.m., the TC confirmed the laboratory uses only sheep blood agar plates. She stated the laboratory had never used Selective Strep Agar plates as specified by the bacitracin disc instructions for presumptive identification of group A strep from throat cultures. The laboratory performs approximately 3400 throat cultures per year for the presumptive identification of group A Streptococcus.