

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0664387	(X3) Date Survey Completed 09/03/2021
Name of Provider or Supplier Pediatric Care Center,The	Street Address, City, State 5612 Spruce Tree Ave, Bethesda, 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
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 procedure manual, laboratory reagent package insert, and patient log record review and interview with the laboratory director (LD), the laboratory did not follow the manufacturer's instructions for performing bacteriology testing. Findings: 1. The laboratory is performing presumptive identification of group A streptococcus on throat cultures, using Taxo A discs which are impregnated with low levels of Bacitracin. 2. During an interview at 10:30 AM on the day of the survey, the LD stated that the laboratory evaluates the culture plates at 24 and 48 hours after inoculation. This was confirmed with a review of the "Sophia 2 Strep A+ FIA Test and Culture Log" (patient log) from January to August, 2021. 3. The laboratory's "Throat Cultures For Diagnosis of Streptococcus Pyogenes (Group A Beta Hemolytic Streptococcus)" procedure states, "The sensitivity of the test can be increased by incubating all negative cultures for a total of 48 hours." 4. Review of the package insert for the "BD BBL Taxo A Discs" showed that culture plates must be incubated "at 35 to 37 degrees C for 18 to 24 hours" before being read or interpreted. 5. During an interview on 9/3/2021 at 1:00 PM the LD confirmed that the laboratory did not follow the manufacturer's instructions for performing throat cultures.</p>