

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1062319	(X3) Date Survey Completed 02/25/2020
Name of Provider or Supplier Hirsch Pediatrics Llc	Street Address, City, State 15235 Shady Grove Road Ste 105, Rockville, 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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by:</p> <p>I. Based on standard operating procedure manual (SOPM) and patient record review and interview with the laboratory director (LD), the laboratory did not follow written procedures for performing bacteriology testing. Findings: 1. The procedure "Throat Cultures for Streptococcus" states that after placing the bacitracin disk on the inoculated culture plate, to "Invert the plate and incubate at 35 degrees C for 18-24 hours"; and 2. The package insert from the "BD BBL Taxo Discs for Differentiation of Group A Streptococci" states, "Incubate plates(s)" "for 18 to 24 hours." 3. During an interview at 10:00 AM, the testing person stated that strep cultures which are plated on a Friday are not read until the following Monday because the office is not open on weekends. 4. Random review of patient records showed that "Patient A's" throat culture was plated on 2/7/20 and interpreted on 2/10/20 which is beyond the 18-24 hour time frame for interpreting the throat cultures. 3. During an interview on 2/25/20 at 11:15 AM, the LD confirmed that throat cultures were not interpreted within 18-24 hours as specified in the written SOPM. II. Based on standard operating procedure manual (SOPM) and patient record review and interview with the laboratory director (LD), the laboratory did not follow written procedures for performing bacteriology testing. Findings: 1. The package insert from the "BD BBL Taxo Discs for Differentiation of Group A Streptococci," "Intended Use" states, "Taxo A discs are for the presumptive identification of group A beta-hemolytic streptococci based on susceptibility to a low level of bacitracin"; and 2. The procedure "Throat Cultures for Streptococcus," "Table 1" states that if "beta hemolysis is present" on the culture plate</p>

and the "growth is inhibited by the bacitracin disc" that test results should be reported as "Presumptive Positive for Group A beta Streptococcus." 3. Random review of patient records showed that "Patient A's" throat culture was reported as "Positive" on 2/10/20, not "presumptive positive." 4. During an interview on 2/25/20 at 11:15 AM, the LD confirmed that the laboratory reports "presumptive positive" strep test results as "positive" and did not follow written procedures for performing bacteriology testing.