

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1062319	(X3) Date Survey Completed 03/07/2024
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory director (LD), the laboratory did not ensure that all the testing personnel (TP) who tested patient samples performed the PT. Findings: 1. The laboratory currently has three TP listed on the "Laboratory Personnel Report" (CMS-209). 2. A review of bacteriology PT attestation worksheets from 2022 and 2023 showed that the attestation worksheet from one of four PT events, "2023 PT Bacti_Viral 2", was not signed by the TP. The PT was performed by one of the three TP performing bacteriology PT in three of three events which were signed. 3. During an interview on 03/07/2024 at 11:45 AM, the LD confirmed that PT samples were not tested each year by all the staff who perform patient testing to ensure accurate and reliable patient test results.</p>
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory</p>

director (LD), the laboratory failed to ensure that the individual testing or examining the samples and the LD signed the PT attestation statements, attesting that PT specimens were run in the same manner as patient samples Findings: 1. A review of bacteriology PT records from 2022 through 2023 showed that in one of four events, the attestation statement was not signed by the LD or the testing person (TP) who performed the PT. 2. During an interview on 03/07/2024 at 11:45 AM, the LD confirmed that the attestation statement was not signed by the LD or the TP, attesting to the routine integration of the samples into the patient workload using the laboratory's routine methods.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

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.

This STANDARD is not met as evidenced by:

I. Based on procedure manual, manufacturer's package insert, 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," "Limitations of the Procedure" states, "The Taxo A disc test is presumptive, and a positive result should be followed with more specific physiological and/or serological tests." 2. The procedure "Updated Procedures for In House Group A Strep Culture Plates" states "Effective immediately all positive throat cultures will be reported as 'presumptive positive' instead of 'positive.'" 3. Random review of patient records showed that two of two patients' throat cultures were reported as "positive", not "presumptive positive." 4. During an interview on 03/07/2024 at 11:45 AM, the LD confirmed that the laboratory reports "presumptive positive" strep test results as "positive" and did not follow written procedures for reporting bacteriology testing. II. Based on review of the procedure manual and the culture media manufacturer's instructions for use (IFU) and interview with testing personnel (TP), the laboratory's procedure for performing throat cultures did not include instructions for allowing the culture media to reach room temperature before inoculation. Findings: 1. The laboratory performs bacteriology testing for group A beta-hemolytic streptococci on throat swabs. 2. The IFU for the "Group A Beta Strep Agar," under "Method of Use" states, "Prior to inoculation, the medium should be brought to room temperature"; however the laboratory's procedure, "Throat Cultures for Streptococcus" did not state that the agar plate must be at room temperature before inoculation. 3. During an interview on 03/07/2024 at 10:20 AM, TP #1 stated that they were not aware that the agar plates had to be at room temperature before inoculation. 4. During an interview on 03/07/2024 at 11:45 AM, the LD confirmed that the laboratory's procedure for performing throat cultures did not follow the manufacturer's IFU.