

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2112275	(X3) Date Survey Completed 02/18/2020
Name of Provider or Supplier Annapolis Pediatrics - Edgewater	Street Address, City, State 3158 Braverton Street Suite 110, Edgewater, 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: Based on standard operating procedure manual (SOPM) and laboratory patient log review and interview with the technical consultant (TC), the laboratory did not follow written procedures for performing bacteriology testing. Findings: 1. The laboratory performs bacteriology testing on throat swabs for Group A streptococci. A review of the procedure, "Strep Cultures" shows that testing personnel are to interpret the growth on the plate at "18-24 hrs." 2. A review of "Strep A-Rapid/Culture Patient Logs" from January, 2018 to December, 2019 showed that testing personnel also perform a "48HR READ" on throat culture plates before reporting the test results. 3. During an interview on 1/29/20 at 11:45 AM, the TC confirmed that the written SOPM did not accurately reflect the actual practice of the laboratory.</p>
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: I. Based on standard operating procedure manual (SOPM) review and interview with the technical consultant (TC), the laboratory did not ensure that the SOPM was signed</p>

and dated by the laboratory director (LD). Findings: 1. The laboratory changed directors on 1/1/20. A review of the current SOPM showed that the procedures were not approved (signed and dated) by the current LD. 2. During an interview on 1/29/20 at 11:45 AM, the TC confirmed that the SOPM was not signed and dated by the new LD. II. Based on standard operating procedure manual (SOPM) review and interview with the technical consultant (TC), the laboratory did not ensure that the SOPM was updated when changes to the laboratory occurred. Findings: 1. The laboratory discontinued use of their hematology instrument on 1/15/18. A review of the SOPM showed that the procedure, "Review of Daily Quality Control Results" included a section on "Daily Review for CBC analysis." 2. During an interview on 1/29/20 at 11:45 AM, the TC confirmed that the SOPM was not updated and approved by the laboratory director.