

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2112275	(X3) Date Survey Completed 09/30/2022
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
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the laboratory supervisor (LS), the laboratory director failed to ensure that the laboratory was enrolled in a PT program that met the criteria of subpart I for testing in the specialty of bacteriology. Findings: 1. The laboratory performed throat cultures to screen for the presence of group A streptococcus bacteria which is a regulated test in subpart I in the code of federal regulations (CFR) found at 42 CFR 493.911. 2. The laboratory performed urine colony counts which is an unregulated test as it is not listed in subpart I. 3. The requirements in subpart I for bacteriology regulated testing is to test "a minimum of five samples per testing event" with "at least three testing events at approximately equal intervals per year." 4. The laboratory was enrolled in a PT program that included three testing events per year but evaluated two PT samples for group A streptococcus antigen, which is a waived test, two PT samples for urine colony count, which is an unregulated test, and two PT samples for throat culture, which is a regulated test. 5. The laboratory was not enrolled in a PT program that tested a minimum of five throat culture PT samples three times per year. 6. During the survey on 09/01/2022 at 12:45 PM, the LS confirmed that the laboratory was not enrolled in a PT program that included five samples per PT event for throat culture screening for group A streptococcus which is a regulated test.</p>