

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  21D1107054	<b>(X3) Date Survey Completed</b>  06/27/2019
<b>Name of Provider or Supplier</b>  Annapolis Pediatrics	<b>Street Address, City, State</b>  1630 Main Street, Chester, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> 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 nursing supervisor, the laboratory did not ensure that all the testing personnel who tested patient samples performed the PT. Findings: 1. The laboratory currently has 5 testing personnel listed on the "Laboratory Personnel Report (CMS-209)" who perform bacteriology testing. 2. A review of bacteriology PT attestation worksheets from 6 events from 2017 to 2019 showed that PT was performed by the same testing person in 5 of 6 events. 3. During an interview on 6/27/19 at 12:00 PM, the nursing supervisor 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>
<b>D3037</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the laboratory staff, the laboratory did not ensure that a copy of all PT documents were maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of PT records for 6 events from 2017 through 2019 showed that PT reports were not available at the time of the survey for the 2nd PT event of 2018 in</p>

bacteriology. 2. During an interview on 6/27/19 at 12:00 PM, the laboratory staff confirmed that the PT reports were unavailable for the above listed PT events.

**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:

Based on standard operating procedure manual (SOPM) and laboratory patient log review and interview with the nursing supervisor, the laboratory did not follow written procedures for performing bacteriology testing. Findings: 1. The procedure "Transporting Specimens" in the SOPM states, "Any culture performed in the Kent Island office on Thursday Friday will be transported to the Annapolis office for reading on Saturday and Sunday." 2. During an interview at 11:40 AM, the nursing supervisor stated that the courier still transports throat culture specimens to the Annapolis office, but "if specimens are plated after the courier picks up on Friday, a nurse comes in on Saturday or Sunday to read the cultures" at the Kent Island office "instead of transporting cultures to Annapolis." 3. During an interview on 6/27/19 at 12:00 PM, the nursing supervisor confirmed that the written SOPM did not accurately reflect the actual practice of the laboratory.

**D5805**

**TEST REPORT**

CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:

Based on review of the procedure manual, final patient reports in the laboratory information system (LIS), and interview with the nursing supervisor, the laboratory failed to ensure that the final test report included the name and address of the laboratory where throat cultures were interpreted. Findings: 1. According to the procedure "Transporting Specimens," "Any culture performed in the Kent Island office on Thursday Friday will be transported to the Annapolis office for reading on Saturday and Sunday." 2. Random review of the cultures being sent to the Annapolis office on Thursdays and Fridays showed that a throat culture collected and plated on 7/19/18 was sent to the Annapolis office on 7/20/18. The final patient reports in the LIS did not indicate that the final interpretation was performed at the Annapolis office. 3. During an interview on 6/27/19 at 12:00 PM, the nursing supervisor confirmed that the name and address of the laboratory where throat cultures were interpreted was not included on patient final reports.