

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0213045	(X3) Date Survey Completed 04/30/2019
Name of Provider or Supplier Bethesda Pediatrics	Street Address, City, State 11325 Seven Locks Rd, Potomac, 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 technical consultant (TC), the laboratory did not ensure that all the testing personnel who tested patient samples performed the PT. Findings: 1. The laboratory currently has 6 testing personnel listed on the "Laboratory Personnel Report (CMS-209)" who perform hematology testing. 2. A review of hematology PT attestation worksheets from 2018 and 2019 showed that PT was performed by the same testing person in 3 of 4 events; and 3. During an interview on 4/30/19 at 1:00 PM, the TC 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>
D5445	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p>

This STANDARD is not met as evidenced by:
Based on record review and interview with the technical consultant (TC), the laboratory failed to ensure that the laboratory's Individual Quality Control Plan (IQCP) was complete. Findings: 1. Record review showed that the laboratory's (IQCP) for strep selective agar quality control was not present at the time of the survey. The TC provided a copy of the Plan of Correction from the last survey on 4/5/17 which included some information but was not a complete IQCP. 2. During an interview on 4/30/19 at 1:00 PM, the TC stated that the IQCP and supporting documentation had been sent with the Plan of Correction from the survey on 4/5/17 but that the laboratory did not retain a copy of the laboratory's IQCP.