

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D1017002	(X3) Date Survey Completed 06/25/2019
Name of Provider or Supplier Bay Pediatric Center Llc,The	Street Address, City, State 606 Dutchman'S Lane, Easton, 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
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> <p>This STANDARD is not met as evidenced by: Based on review of the 2018 and 2019 records showing receipt of the selective strep test media (SSA media) into the laboratory (lab) and interview with the technical consultant on the day of survey, the lab did not document all quality control procedures performed when recording the receipt of the SSA media into the laboratory for patient testing. Findings: 1. The lab receives already prepared selective strep agar for patient throat culture testing; 2. The lab documents (on a log) the receipt and condition of the agar delivered to the lab; and 3. In 2018 and 2019 the person receiving the agar and observing acceptability for use, did not initial these activities on the log to show who performed the checks of the agar when received by the lab.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p>

This STANDARD is not met as evidenced by:

Based on interview with the technical consultant (TC) on the day of survey, the TC did not document competency assessments made for testing personnel who performed Group A strep testing using selective strep agar and taxo A disks (group A strep testing). Findings: 1. The physicians interpret the results of the Group A strep testing; 2. The technical consultant monitors the proficiency testing results, quality control (media check log) records and patient test records; and 3. The annual competency review showing that the activities were performed, is not documented for each physician interpreting the results of the Group A strep testing.