

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D0213045	(X3) Date Survey Completed 11/19/2021
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
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality assessment (QA) records and interview with the technical consultant (TC), the laboratory failed to document the personnel performing the QA reviews and when the QA reviews were performed. Findings: 1. Every month the laboratory performed a "Quality Assessment Review" of random patients' charts, test results, and final reports and documented the findings on a standard form. 2. The completed "Quality Assessment Review" forms did not include the signature of the personnel performing the review or the dates the reviews were performed. 3. During the exit interview on 11/19/2021 at 1:00 PM, the TC confirmed that the completed "Quality Assessment Review" forms were not signed and dated by the personnel performing the reviews.</p>
D6054	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the technical</p>

consultant (TC), the laboratory failed to document the annual competency assessments of the physicians evaluating results for patient throat cultures. Findings: 1. The laboratory had no records of annual competency assessments for the physicians evaluating results for patient throat cultures. 2. During the exit interview on 11/19/2021 at 1:00 PM, the TC confirmed that the laboratory did not document annual competency assessments for the physicians evaluating results for patient throat cultures.