

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0227320	<b>(X3) Date Survey Completed</b> 07/27/2021
<b>Name of Provider or Supplier</b> Pediatric Associates Of Richmond	<b>Street Address, City, State</b> 7240 Patterson Ave, Suite 100, Richmond, VA	
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>D0000</b>	An announced CLIA Validation survey was conducted at the Pediatric Associates of Richmond on July 27, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows: The laboratory is performing COVID-19 testing and in compliance with the applicable COVID-19 reporting requirements.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&amp;P), lack of documentation, and interview, the laboratory did not have an established P&amp;P for performing competency assessments on testing personnel at the date of the survey on 07/27/21. Findings include: 1. Review of the available P&amp;P's revealed lack of documentation of a policy for performing competency assessments on testing personnel performing patient testing in the specialty of hematology and subspecialty of bacteriology. 2. During an exit interview with the laboratory director and primary testing personnel on 07/27/21 at approximately 2:30 PM, the document was not available upon request for review, in addition, the above-specified findings were confirmed.</p>
<b>D5403</b>	<p><b>PROCEDURE MANUAL</b> CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,</p>

storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

A. Based on the review of available policy and procedures (P&P), lack of documentation and interview, the laboratory failed to provide an established P&P for the performance and interpretation of results for the BD-BBL Taxo A disc procedures to include quality control (QC) at the date of survey on 07/27/21. Findings include: 1. Review of the available P&P revealed lack of documentation of a systematic policy for the performance and interpretation of results for the BD-BBL Taxo A discs utilized to perform media QC procedures and to screen patients for Streptococcus pyogenes, Group A Strep infections. 2. During an exit interview with the laboratory director and primary testing personnel on 07/27/21 at approximately 2:30 PM, the document was not available upon request for review, in addition, the above-specified findings confirmed. B. Based on the review of available policy and procedures (P&P), lack of documentation and interview, the laboratory failed to provide an established P&P for the performance and interpretation of results for the BD-BBL Group A Selective Strep Agar with 5% Sheep Blood (ssA) quality control (QC) procedures at the date of survey on 07/27/21. Findings include: 1. The laboratory utilizes the ssA Agar to screen patients for Streptococcus pyogenes, Group A Strep infections. Review of the available P&P revealed lack of documentation of a systematic policy for the performance and interpretation of results for the QC procedures performed on the BD-BBL ssA Agar. 2. During an exit interview with the laboratory director and primary testing personnel on 07/27/21 at approximately 2:30 PM, the document was not available upon request for review, in addition, the above-specified findings were confirmed.

**D6046**

**TECHNICAL CONSULTANT RESPONSIBILITIES**

CFR(s): 493.1413(b)(8)

(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.

This STANDARD is not met as evidenced by:

Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview, the Technical Consultant (TC) failed to perform and document review of the annual competency

assessments for eighteen (18) of 18 TP in the calendar years of 2019 and 2020. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of technical consultant and that there were a total of 18 TP performing patient testing in 2019 and 2020. See attached TP code sheet. 2. Review of the TP records revealed lack of documentation by the TC of performance and review of the annual competency assessments for all 18 of the TP (TP A-R). 3. An exit interview with the primary TP and TC on 07/27/21 at approximately 2:30 PM confirmed the findings.