

<p>Statement of Deficiencies</p>	<p>(X1) Provider/Supplier/CLIA Identification Number 49D0991967</p>	<p>(X3) Date Survey Completed 09/30/2025</p>
<p>Name of Provider or Supplier Richmond Pediatrics Associates, Inc</p>	<p>Street Address, City, State 7521 Right Flank Road - Suite 100, Mechanicsville, VA</p>	
<p>For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.</p>		

<p>(X4) ID Prefix Tag</p>	<p>Summary Statement of Deficiencies</p>
<p>D0000</p>	<p>An announced CLIA recertification survey was conducted at Richmond Pediatric Associates, INC on September 30, 2025 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:</p>
<p>D2026</p>	<p>BACTERIOLOGY CFR(s): 493.823(d)</p> <p>(d)(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a pre-survey review of Centers for Medicare and Medicaid Services CLIA Survey Summary Report (CMS 0096D), the laboratory's proficiency testing (PT) records, College of American Pathologists (CAP) PT Corrective Action Form instructions, lack of documentation, and interview, the laboratory failed to document employment of technical evaluations/remedial actions per PT vendor's instructions after an unsatisfactory 2024 Bacteriology Event 2 (one of six events reviewed) during the survey timeframe of August 24, 2023-September 30, 2025. Findings include: 1. Review of the CMS 0096D report revealed the following unsatisfactory score: CAP 2024 Event 2 - Bacteriology Analyte Code 0005: Scored 20%. 2. Review of the laboratory's PT records (2023 Event 3, 2024 Events 1-3, 2025 Events 1-2), a total of six events, revealed no evidence that the laboratory conducted remedial action evaluation or documentation of technical assistance for the following unsatisfactory event: CAP 2024 Bacteriology Throat Culture Event 2 - Scored 20% Challenge TC-06</p>

reported Negative for Group A Strep, Intended Response Positive; Challenge TC-07 reported Positive Group A Strep, Intended Response Negative; Challenge TC-09 reported Negative for Group A Strep, Intended Response Positive; Challenge TC-10 reported Negative for Group A Strep, Intended Response Positive; four of the five challenge samples were scored as unacceptable. 3. The inspector requested to review remedial action records for the unacceptable responses outlined above (noted as assayed on 8/16/24). The laboratory manager provided record of repeat assays performed on 10/2/24. The laboratory manager stated on 9/30/25 at 4:30 PM, "I rerun the throat culture samples when we get failures from CAP". The inspector inquired regarding documentation for self grade of the repeated samples and remedial action such as patient look back during the timeframe of the unsuccessful event. No documentation was available. 4. Review of CAP's PT Exception Investigation instructions revealed the following sections for remedial documentation for unacceptable analytes or unsatisfactory event results: Survey information, Clerical, Procedural, Analytical Technical checklist, Specimen Handling checklist, PT Material checklist, Conclusion, Corrective Action Documentation, and Review of Patient Results in Response to PT failure, Lab Director Review/Approval signature requirement. The inspector inquired regarding any documentation utilizing CAP's instructions. No additional documentation was available for review. 5. An exit interview with the laboratory manager on 9/30/25 at 5 PM confirmed the above findings.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

This STANDARD is not met as evidenced by:

Based on a review of proficiency testing (PT) records, College of American Pathologists (CAP) exception investigation instructions, lack of documentation, and interview, the laboratory director (LD) failed to ensure a corrective action plan was established/followed for six (6) unacceptable Throat Culture results submitted on three (3) of 6 Bacteriology modules and two (2) unacceptable Hematology analyte results submitted on 2 of 6 Complete Blood Count (CBC) modules reviewed for the survey timeframe of August 24, 2023 to September 30, 2025. Findings include: 1. Review of the laboratory's CAP Bacteriology PT records (2023 Event 3, 2024 Events 1-3, 2025 Events 1-2), a total of 6 events, revealed no evidence of remedial evaluation for 6 unacceptable throat culture challenges noted on the following 3 events: CAP 2024 Event 2 # TC-06 reported Negative for Group A Strep, Intended Response Positive; CAP 2024 Event 2 # TC-07 reported Positive Group A Strep, Intended Response Negative; CAP 2024 Event 2 # TC-09 reported Negative for Group A Strep, Intended Response Positive; CAP 2024 Event 2 # TC-10 reported Negative for Group A Strep, Intended Response Positive; CAP 2024 Event 3 # TC-14 reported Positive Group A Strep, Intended Response Negative; CAP 2025 Event 2 # TC-08 reported Positive Group A Strep, Intended Response Negative. 2. Review of the laboratory's CAP CBC PT records (2023 Event 3, 2024 Events 1-3, 2025 Events 1-2), a total of 6 events, revealed no evidence of remedial evaluation for the following unacceptable analyte challenges noted on the following 2 events: CAP 2024 Event 1 # FH1-03 Red Blood Cell (RBC) count reported as 7.40 with acceptable range 2.33-2.63; CAP 2025 Event 2 # FH1-10 Hemoglobin (HGB) count reported as 6.4 with acceptable range 6.5-27.2. 3. Review of CAP's PT Exception Investigation instructions revealed ten

parameters for remedial documentation for investigating unacceptable analyte scores and/or unsatisfactory events (Cross Reference D 2026). 4. The inspector inquired regarding documentation utilizing CAP's PT corrective action instructions for the unacceptable Bacteriology and Hematology results outlined above and requested to review the LD approved proficiency testing policy. No policy was available. The laboratory manager stated on 9/30/25 at 5 PM, "Our quality assurance policy has a statement that we will conduct corrective action but we do not have a PT policy with specifics." 5. An exit interview with the laboratory manager on 9/30/25 at 5 PM confirmed the above findings.