

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0863830	(X3) Date Survey Completed 05/02/2025
Name of Provider or Supplier Rva Peds	Street Address, City, State 7000 Patterson Avenue, Richmond, VA	
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
D0000	An announced CLIA recertification survey was conducted at RVA Peds on May 1, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The inspection included an offsite follow up interview with the clinical supervisor on 5 /2/25. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows and include the following Condition under 42 CFR part 493 CLIA Regulation: D6063 -42 CFR. 493.1421 Condition Testing Personnel.
D2121	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on a review of hematology proficiency testing (PT) documentation, and an interview, the laboratory failed to ensure that the Complete Blood Count (CBC) PT module's hemoglobin (Hgb) analyte results were returned to College of American Pathologists (CAP) for five (5) of 5 challenge samples on one (1) of 5 events reviewed on the date of the inspection, May 1, 2025. Findings include: 1. Review of the laboratory's CAP PT documentation (2023 Event 3, 2024 Events 1-3, 2025 Event 1), a total of 5 hematology events, revealed that the laboratory failed to submit and received "failure to participate" analyte scores for the following CBC module: 2024 Event 3 - 0% Hgb scores for 5 of 5 challenges (samples- FH-11, FH-12, FH-13, FH-14, and FH-15). 2. An interview with the clinical supervisor on 5/1/25 at 4 PM confirmed the above findings.</p>
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on a pre-survey review of the Center of Medicare and Medicaid Services CASPER 0096D Report (CMS CASPER), laboratory's proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to document a review/evaluation of five (5) of 5 Hemoglobin (Hgb) results on their 2024 College of American Pathologists (CAP) Hematology PT Event 3 report as reviewed on the date of the inspection on May 1, 2025. Findings include: 1. During a pre-survey review of the laboratory's CMS CASPER 0096D report revealed unsatisfactory analyte scores reported by CAP for the 2024 Event 3 Hematology Analyte Number 0795: HGB (NON-WAIVED) - Score 0%. 2. Review of the laboratory's CAP hematology PT documentation (2023 Event 3, 2024 Events 1-3, 2025 Event 1), a total of 5 events, revealed 2024 CAP Event 3's samples Hgb FH-11, Hgb FH-12, Hgb FH-13, Hgb FH-14, and Hgb FH-15 resulted as zero for "absence of laboratory response". 3. Review of the laboratory's 2024 Event 3 PT records revealed Complete Blood Count (CBC) analyzer reports included printed Hgb results for the PT challenge samples outlined above. The inspector requested to review documentation of a self evaluation for the hemoglobin results. The clinical supervisor stated on 5/2/25 at 3:30 PM, "We submitted the CBC results for that event but we failed to enter the five hemoglobin results. We ran the complete CBC for each PT vial but did not report the hemoglobin. We did not check our results with the peer results." 4. An exit interview with the clinical supervisor on 5/2/25 at 4:00 PM confirmed the above findings.

D6063

LABORATORY TESTING PERSONNEL
CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form, testing personnel records, and interviews, the laboratory failed to retain documentation of education qualifications for one of seven testing personnel responsible for reporting moderate complexity Complete Blood Count hematology patient test results during the twenty-two months reviewed (timeframe: 7/11/23 - 5/1/25). See D6065.

D6065

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; or (b)(2) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical

technology, or nursing from an accredited institution; or (b)(3) Meet the requirements in 493.1405(b)(3)(i)(B), (b)(4)(i)(B), (b)(4)(i)(C) or (b)(5)(i)(B); or (b)(4) Have earned an associate degree in a chemical, biological, clinical or medical laboratory science, or medical laboratory technology or nursing from an accredited institution; or (b)(5) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least a duration of 50 weeks and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(6)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of the Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel (TP) records, and interviews, the laboratory failed to maintain documentation of education qualifications for one (1) of seven (7) TP as noted on the date of the inspection, May 1, 2025. Findings include: 1. Review of the CMS 209 report revealed 7 TP listed as qualified to perform moderate complexity Complete Blood Count (CBC) patient testing utilizing the laboratory's Abbott Emerald hematology analyzer. 2. Review of the laboratory personnel files revealed no documentation of education qualifications for TP A. The inspector requested to review documentation of TP A's diploma of education or official transcript record. The documentation was not available for review. (See Personnel Code Sheet.) 3. An exit interview on 5/1/25 at 4 PM and a follow up offsite interview with the clinical supervisor on 5/2/25 at 11 AM confirmed the above findings.