Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0233388	07/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Clinch Valley Physicians Associates, Llc	398 Clinic Road, Cedar Bluff, 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 Clinch Valley Physicians Associates on July 8, 2026 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:
D2128	HEMATOLOGY CFR(s): 493.851(e) (e)(1) For any unsatisfactory analyte or test performance or 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) For any unacceptable analyte or testing event score, 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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to document remedial action taken for unacceptable analyte scores on two of five hematology PT events during the review timeframe of July 25, 2024 to July 8, 2026. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology PT documentation (2024 Event 3, 2025 Events 1-3, 2026 Event 1) a total of five events, revealed no evidence of remedial action for the following unsatisfactory analyte scores: 2025 API 2nd Event - Blood Cell Identification BCI-07 reported as Monocyte with expected result Metamyelocyte, Eosinophil Count COU-09 reported as 8.0 with acceptable range 4.4-7.0; 2025 API 3rd Event - Red Blood Cell Distribution Width COU-15 reported as 15.2 with acceptable range 13.9-15.1. 2. Review of the laboratory's PT records revealed no corrective action documentation for the three unacceptable hematology analyte scores outlined above. 3. An exit interview with the testing

	personnel, General Supervisor, and Technical Supervisor at 2:30 PM on 7/8/26 confirmed the above findings
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 review of proficiency testing (PT) records, lack of documentation, procedures, and interviews, the laboratory failed to evaluate 17 hematology non-graded analyte challenges resulted on three of five events reviewed during timeframe of July 25, 2024 to July 8, 2026. Findings include: 1. Review of the laboratory's American Proficiency Institute (API) hematology PT results (2024 Event 3, 2025 Events 1-3, 2026 Event 1), a total of five events, revealed that API released non-graded analyte responses for the following 17 challenges: Nucleated Red Blood Cells due to variance on the following events: API 2025 Event 1 - Challenges COU-01, COU-02; API 2025 Event 3 - Challenge COU-12; Blood Cell Identification on the following event: API 2025 Event 2 - Challenge BCI-15, DIF-02, ECI-06, ECI-07, ECI-08, ECI-09, ECI-10; API 2025 Event 3 - Challenge BCI-15, DIF-03, ECI-11, ECI-12, ECI-13, ECI-14, ECI-15; 2. Review of the laboratory's PT documentation revealed no evaluation/verification recorded for the 17 non-graded challenge sample results outlined above. The inspector requested to review evaluations for the non-graded challenges. The documentation was not available. 3. Review of the laboratory's procedures revealed a policy (title: Proficiency Testing) that stated, "If the proficiency testing program cannot fully evaluate samples, the laboratory will verify the accuracy of tests. The Technical Supervisor or Laboratory Manager will document all corrective action. He/She will initial the summary report and submit to the Laboratory Director for review." 4. The inspector inquired regarding the lack of documentation outlined above for the non-graded analytes. The Technical Supervisor (TS) stated at 1 PM on 7/8/26, "For my other laboratories, we document review for all non-graded and educational challenges comparisons to the PT reported peer group and document the review on the evaluation form. PT results which are not graded due to lack of consensus, submitting results too late, failure to submit, are all reviewed with documentation of corrective action of any unacceptable result. I will meet with the lab director to make sure we do those same steps here." 5. An exit interview with the testing personnel, General Supervisor, and TS at 2:30 PM on 7/8/26 confirmed the above findings
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

	This STANDARD is not met as evidenced by: Based on a review of quality assessment (QA) records, lack of documentation, and interviews, the laboratory failed to document their laboratory director's (LD) onsite visits to conduct oversight during the twenty-four months of review (timeframe July 25, 2024 to July 8, 2026). Findings: 1. Review of the laboratory's QA records for the review timeframe of 7/25/24 - 7/8/26 revealed that the monthly QA reports were performed by the laboratory Technical Consultant (TC)/Technical Supervisor (TS). The inspector inquired regarding how often the LD was onsite to conduct oversight responsibility. The TC/TS stated on 7/8/26 at 2 PM, "Our director came over here once or twice last year in 2025." 2. The inspector requested documentation of the LD's onsite laboratory visits during the review timeframe outlined above. The records were not available for review. 3. An exit interview with the testing personnel, General Supervisor, and TC/TS at 2:30 PM on 7/8/26 confirmed the above findings.