

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0704407	(X3) Date Survey Completed 08/05/2026
Name of Provider or Supplier Centra Danville Medical Center	Street Address, City, State 414 Park Avenue, Danville, 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 Centra Danville Medical Center on August 4 - 5, 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:
D2014	TESTING OF PROFICIENCY TESTING SAMPLES (b)(6) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to retain PT records to document their processing and testing/reporting of iSTAT PT results for two of five Core Chemistry PT modules during the 23 months of review (August 28, 2024 to August 5, 2026). Findings include: 1. Review of Core Chemistry PT records (2025 Events 1-3, 2026 Events 1-2) a total of five events, revealed that the laboratory utilized American Proficiency Institute (API) Core Chemistry module enrollment for their point of care moderate complexity iSTAT Chem8 patient testing. 2. Review of the laboratory's PT records for the module outlined above revealed that the records lacked the following: API 2025 Event 2 - iSTAT Chem8 results from analyzer; API 2025 Event 3 - copy of the proficiency testing program report forms, testing personnel and lab director (LD) attestation statements, iSTAT Chem8 results from analyzer, API scored report, nor review of PT results; API 2026 Event 2 - iSTAT Chem8 results from analyzer; The

	inspector requested to review the PT records outlined above, noting that the PT binder tab for API 2025 Event 3 was empty. The requested documentation was not available for review. The Point of Care Testing (POCT) supervisors stated on 8/4/26 at 3 PM, "We have looked and cannot locate those records. There have been staff changes and we cannot reach out to the previous laboratory lead to ask. We can print the results for the 2025 3rd event from API site and review retroactively." 3. An interview with the two POCT supervisors, Director of Urgent Care, and Lab Director on 8/4/26 at 5 PM, and the Practice Administrator on 8/5/26 at 2 PM confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on a review of procedures, analyzer maintenance records, lack of documentation, and interviews, the laboratory failed to document performance of required monthly iSTAT Electronic Simulator maintenance per protocol for 11 of 23 months reviewed (timeframe: September 2024 to August 5, 2026). Findings include: 1. Review of the laboratory's procedure manual revealed an iSTAT protocol (under heading: iSTAT Monthly Procedures) which stated, "The External Electronic Simulator will be run monthly and with software updates. Print the results and place in the iSTAT maintenance records." 2. Review of the laboratory's monthly iSTAT Daily/Monthly logs for September 2024 to the inspection date of 8/5/26 revealed the following months lacked the External Electronic Simulator check: September 2024; October 2024; November 2024; December 2024; May 2025; June 2025; August 2025; November 2025; March 2026; June 2026; July 2026; 11 of 23 months reviewed lacked External Electronic Simulator check documentation. The inspector requested to review documentation of the required iSTAT monthly maintenance checks outlined above. No additional records were available. 3. An interview with the two Point of Care Testing (POCT) supervisors, Director of Urgent Care, Lab Director (LD) on 8/4/26 at 5 PM, and the Practice Administrator on 8/5/26 at 2 PM confirmed the above findings. B. Based on a review of procedures, analyzer maintenance records, lack of documentation, and interviews, the laboratory failed to document every six month iSTAT Thermal Probe Check maintenance per protocol for three of four due dates during the 23 months reviewed (timeframe: September 2024 to August 5, 2026). Findings include: 1. Review of the laboratory's procedure manual revealed an iSTAT protocol (under heading: iSTAT Bi-Annual / Every Six Months Procedures) which stated, "The Thermal Probe Check is performed every six months on the iSTAT analyzer and should be documented on the maintenance log." 2. Review of the laboratory's iSTAT Daily/Monthly logs for September 2024 to the inspection date of 8/5/26 revealed that the Thermal Probe Check was documented as performed once in October 2025. The inspector requested to review additional documentation of the iSTAT Thermal Probe checks. The inspector inquired regarding the expected due timeframes of September 2024 to December 2024, any additional check in calendar year 2025, and January 2026 to the date of the inspection. No additional Thermal Probe records were available. 3. An interview with the two POCT supervisors, Director of Urgent Care, and LD on 8/4/26 at 5 PM, and the Practice Administrator on 8/5/26 at 2 PM confirmed the above findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT

CFR(s): 493.1289(a)(c)

(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.

This STANDARD is not met as evidenced by:

Based on a review of Centers of Medicaid and Medicare Services CLIA Survey Summary Report (CMS CASPER 0096D), tour, review of proficiency testing (PT) and patient result logs, quality control (QC) reports, lack of documentation, policies, and interviews, the laboratory failed to document monthly chemistry QC statistics and failed to identify the lapse in reviews during 6 of 23 months reviewed for their Vitros analyzer (timeframe: September 2024 to August 2025). Findings include: 1. During a pre-survey review, the CMS CASPER 0096D revealed enrollment with scores reported on Events 1-3 in calendar year 2025 for the following speciality of chemistry and regulated analytes: 0245 ROUTINE CHEMISTRY 0255 Alanine Aminotransferase (ALT) 0265 Albumin 0275 Alkaline Phosphatase (Alk Phos) 0285 Amylase 0295 Aspartate Aminotransferase (AST) 0305 Bilirubin, Total 0345 Calcium (Ca) 0351 Carbon Dioxide (CO₂) 0355 Chloride (CL) 0365 Cholesterol, Total 0375 Cholesterol, High Density (HDL) 0405 Creatinine 0415 Glucose 0455 Magnesium, (Mg) 0460 Phosphorus 0465 Potassium (K) 0475 Sodium (Na) 0485 Total Protein 0495 Triglyceride 0505 Blood Urea Nitrogen (BUN) 0515 Uric Acid 2. During a tour of the laboratory on 8/4/26 at 1 PM, the inspector noted a Vitros chemistry analyzer stored in the laboratory's record room not in use. The inspector inquired when the laboratory discontinued testing on the analyzer. The Point of Care Testing (POCT) Supervisors stated that they had moved the analyzer from the laboratory on 8/3/26 prior to the inspection. The POCT supervisor stated, "I am not sure what date that the laboratory discontinued testing on the Vitros but it was in early 2025. As of June 29, 2026 the only chemistry in use is the Abbott iSTAT per our hospital lab manager." 3. Review of the laboratory's American Proficiency Testing (API) Core Chemistry PT module records for 2025 Events 1-3 revealed: API Event 1 - the laboratory reported "Instrument Not in Use" for all analytes of speciality 0245 ROUTINE CHEMISTRY outlined on the CASPER report above- for Vitros analyzer; API Event 2 - the laboratory reported "Instrument Not in Use" for all analytes of speciality 0245 ROUTINE CHEMISTRY outlined on the CASPER report above- for Vitros analyzer; API Event 3 - The inspector noted that the records for API 2025 Event 3 were missing (**Cross Reference D2014). The inspector requested that the laboratory print out 2025 Event 3 from the API site. Review of the printed API scores revealed that the laboratory had reported Vitros results for the 21 analytes outlined on the CASPER report for 2025 3rd event and received score of 100%. 4. Review of patient data log for the Vitros analyzer with the IT Laboratory Information Systems Manager on 8/5/26 at 2 PM, revealed that the last date that patient results transmission was completed from the Vitros was 2/27/2025. 5. Review of the Vitros chemistry QC records for the 6 month timeframe of September 2024 to the last date of patient transmission on 2/27/25, the inspector noted no monthly Levey Jennings (LJ) statistical reports for the onboard analytes: Albumin, Alk Phos, ALT, Amylase, AST, Direct Bilirubin, Total Bilirubin, BUN, Ca, Cholesterol, HDL, CL, CO₂, Creatinine, Glucose, Mg, Phosphorus, K, Na, Total Protein, Triglyceride, Uric Acid. The inspector requested to review the LJ QC documentation for the Vitros analytes. The six months' QC records were not available for review. The inspector inquired regarding corrective action records for the lapses in monthly QC review for the Vitros analyzer from September 2024 to 2/27/25. No corrective documentation records were available. 6. The

	inspector inquired regarding the laboratory's quality assurance (QA) policy for chemistry QC review. The POCT Supervisor stated, on 8/5/26 at 1:00 PM, that "For hematology and chemistry analyzers the LJ reports are to be reviewed on a monthly basis in order to assess shifts/trends problems by either the TC or LD." 7. An interview with two POCT supervisors, Director of Urgent Care, and Lab Director on 8/4/26 at 5 PM, and the Practice Administrator on 8/5/26 at 2 PM confirmed the above findings.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on a tour, review of the laboratory's procedures, calibration verification records for the Abbott point of care chemistry analyzer, and interviews, a technical consultant (TC) failed to review and verify acceptability of calibration verification every six months for eight (8) of 8 iSTAT chemistry analytes during the 23 months of review (timeframe: September 2024 to August 5, 2026). Findings include: 1. During a tour of the urgent care side of the laboratory on 8/4/26 at 2 PM, the inspector observed a testing personnel running an iSTAT Chem8 panel and requested to review the iSTAT analyzer handheld onboard data for calibration verification for analytes Sodium (Na), Potassium (K), Chloride (Cl), TCO₂, Ionized Calcium (iCa), Glucose (Glu), Urea Nitrogen (BUN), and Creatinine (Creat). The review revealed data for the following dates: 10/5/24, 4/20/25, 10/23/25, 5/30/26, and 7/30/26. 2. Review of the laboratory's procedure manual revealed an Abbott iSTAT calibration verification protocol that stated, "Calibration Verification should be performed every 6 months and is used to verify the accuracy of results over the entire measurement range of each test. Initiate calibration verification tests from the iSTAT Quality Tests menu. Calibration throughout the reportable range of each analyte is verified if value falls within the corresponding range of the Controls Calibration Verification Set Value Assignment Sheet. Wait for all tests to complete, print, review, and document acceptable results. Maintain complete records with iSTAT maintenance logs." 3. Review of the iSTAT maintenance logs for September 2024 - 8/5/26, revealed that calibration verification forms had not been documented as evaluated/accepted by testing personnel, TC, nor laboratory director. The inspector requested to review documentation of that calibration verification runs for Na, K, Cl, TCO₂, iCa, Glu, BUN, and Creat had been evaluated for accuracy. The documentation was not available for review. The Point of Care Testing (POCT) Supervisor stated on 8/4/26 at 4 PM, "It appears that the previous supervisor did not follow the protocol for completing the Cal Ver report form every six months. I reprinted the results, reprinted value data sheets from Abbott site before you arrived and placed them on the forms." 4. An interview with the two POCT supervisors, Director of Urgent Care, and Lab Director on 8/4/26 at 5 PM, and the Practice Administrator on 8/5/26 at 2 PM confirmed the above findings.