Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0704407	08/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Centra Danville Medical Center	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 the Centra Danville Medical Center on 08/27/24 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The laboratory was not in compliance with the following 42 CFR part 493 CLIA Regulations: D2000 - 42 C.F.R. 493-801 Condition: Enrollment and Testing of Samples.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), CASPER Survey Summary (Report 0096D), tour of the laboratory testing room, proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to enroll in PT for 14 of 14 non-waived regulated chemistry analytes from 04/08/24 up to the date of survey on 08/27/24. Findings include, 1. Review of the CMS 116 form and a tour of the laboratory testing area on 08/27/24 at 09:45 AM revealed the laboratory uses the Ortho Vitros 350 (serial number J27004851) to perform patient testing in the specialty of chemistry. 2. An interview with the technical consultant and the Lab Manager on 08/27/24 at 10:00 AM revealed that the site ceased testing with the Ortho Vitros 350

	chemistry analyzer on 04/28/23 due to staff shortages. The laboratory implemented chemistry testing with the Abbott i-STAT Chem 8+ cartridges at that time for patient testing. The laboratory obtained full staff and re-implemented patient testing with the Ortho Virtros 350 chemistry analyzer on 04/08/24. 3. Review of the American Proficiency Institute (API) calendar for shipping dates for 2024 revealed that the second core chemistry modules was shipped on 05/13/24 and the third core chemistry modules was shipped on 08/19/24. 4. Review of the API PT records and the CASPER Report 0096D revealed lack of scores for the following 14 non-waived regulated analytes for the second event in 2024: Alanine Aminotransferase (ALT), Albumin, Alkaline phosphatase (ALK PHOS), Amylase, Asparate Trasferase (AST), total bilirubin, total calcium, total cholesterol, high density level (HDL) cholesterol, creatinine, magnesium (MG), total protein, triglycerides (TRIG), and uric acid. 5. In an interview with the Lab Manager on 08/27/24 at 11:45 AM, the surveyor requested to review proficiency testing records for the above-specified analytes performed on the Ortho Vitros 350 chemistry analyzer for the second event in 2024 or enrollment for the third event in 2024. They stated, "we are enrolled for the i-STAT but we haven't enrolled for the Vitros yet; I don't have the enrollment." 6. In an exit interview with the laboratory director, technical consultant, Lab Manager on 08/27/24 at 1445, the findings were confirmed.