

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2280805	(X3) Date Survey Completed 05/27/2025
Name of Provider or Supplier Sovah Family Medicine East	Street Address, City, State 404 Airport Drive, Suite A, 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 Sovah Family Medicine East on May 27, 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 deficiency cited is as follows and includes 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	<p>ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services CASPER 0096D CLIA Application and Survey Summary Report (CMS CASPER 0096D), CMS CLIA Laboratory Application for Certification form (CMS 116), proficiency testing (PT) records, lack of documentation, and interviews, the laboratory failed to enroll in a hematology PT program for Complete Blood Count (CBC) for four of twenty months reviewed (survey timeframe: 9/18/23 - 5/27/25, timeframe of non enrollment: 1/1/25-5/16/25). Findings include: 1. Review of the CASPER 0096D report during pre-survey preparation revealed a lack of hematology PT scores for the following speciality and analytes in calendar year 2025: 0760 HEMATOLOGY 0765 Cell Identification 0775 Red Blood Cell Count, RBC 0785 Hematocrit, HCT 0795</p>

Hemoglobin, HGB 0805 White Blood Cell Count, WBC 0815 Platelets, PLT 2. Review of the CMS 116 form revealed that the laboratory performed patient CBC testing in the speciality of hematology during the twenty month review timeframe of September 2023 to 5/27/25. 3. Review of the laboratory's PT records (2024 Events 1-3), a total of three events, revealed no PT records for calendar year to date 2025. The inspector inquired regarding the lack of PT documentation for Event 1 of 2025. The primary testing personnel stated on 5/27/25 at 1 PM, "I noticed that we did not have any 2025 records while preparing for this inspection. I asked our office manager to check on it. It was discovered that the 2025 enrollment deadline was missed." 4. The inspector inquired regarding an off schedule reinstatement PT module available for review. No documentation was available. The lead tech confirmed at 2:00 PM that "We cannot get the Event 1 at this time. Event 2 comes out in June. Payment was made to the PT company on May 16th." 5. An interview with the lead testing personnel and office manager on 5/27/25 at 2:30 PM confirmed the above findings.

D6015

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

(e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that--

This STANDARD is not met as evidenced by:
Based on a review of the Centers for Medicare and Medicaid Services CASPER 0096D CLIA Application and Survey Summary Report (CMS CASPER 0096D), CMS CLIA Laboratory Application for Certification form (CMS 116), proficiency testing (PT) records, lack of documentation, and interviews, the laboratory director (LD) failed to ensure that the laboratory enrolled in a PT program for six of six hematology analytes White Blood Cell Count (WBC), Red Blood Cell Count (RBC), Hemoglobin (HGB), Hematocrit (HCT), Platelet Count (PLT), and Cell Identification (Cell ID) from 1/1/25 up to 05/16/25. Cross Reference D2000. Findings include: 1. Review of the CMS CASPER 0096D report revealed a lack of PT scores for six of six hematology analytes: WBC, RBC, HGB, HCT, PLT, and Cell ID during calendar year 2025 to date 5/27/25. 2. Review of the CMS 116 form revealed that the LD indicated that the laboratory performed testing in the specialty of hematology: WBC, RBC, HGB, HCT, PLT, and Cell ID within the Complete Blood Count panel reported on the Sysmex XN-450 hematology analyzer during the review timeframe of September 2023 to 5/27/25. 3. Review of laboratory's Wisconsin State Laboratory of Hygiene (WSLH) hematology PT records, a total of three events (2024 Events 1-3), revealed no records of an expected 2025 Event 1 for the hematology speciality outlined above. The inspector requested to review Event 1 for calendar year 2025. The primary testing personnel stated on 5/27/25 at 1 PM, "The 2025 enrollment deadline was missed." 4. An interview with the lead testing personnel and office manager on 5/27/25 at 2:30 PM confirmed the above findings.