

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2053679	(X3) Date Survey Completed 01/30/2025
Name of Provider or Supplier Sovah Family Medicine - Mt Hermon	Street Address, City, State 2767 Franklin Turnpike, 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 - Mt Herman on January 30, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows and includes the Condition under 42 CFR part 493 CLIA Regulation: D6063 -42 CFR. 493.1421 Condition Testing Personnel.
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) records, lack of documentation, and interview, the laboratory failed to document review/evaluation for one (1) of six (6) hematology PT modules reviewed (timeframe March 2023 to January 30, 2025). Findings include: 1. Review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) hematology PT records, a total of 6 events (2023 Events 1-3, 2024 Events 1-3), revealed no retained scored results or documentation of review /evaluation for 2024 WSLH Hematology Module Complete Blood Count and Auto Differential Event 1. 2. The inspector requested to review the WSLH scored results and evaluation documentation for the hematology module event outlined above. No documentation of review/evaluation was available. 3. An interview with the office manager at 2 PM on 1/20/25 confirmed the above findings.</p>
D6063	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the</p>

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, lack of documentation, and interview, the laboratory failed to retain documentation of education qualifications for one new testing personnel during the review timeframe of 3/29/23 to the date of the inspection on January 30, 2025. 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), personnel records, lack of documentation, and an interview, the laboratory failed to retain documentation of education qualifications for one (1) of seven (7) testing personnel (TP) reviewed during the review timeframe of March 29, 2023 to the date of the inspection on January 30, 2025. Findings include: 1. Review of the CMS 209 form revealed that the laboratory director identified 7 TP qualified to perform patient hematology Completed Blood Count testing during the twenty-two months of review. 2. Review of the laboratory personnel records revealed a new personnel (TP A) completed initial laboratory training on 3/5/24 with semi-annual competency assessment documented on 9/20/24. The inspector noted that TP A's personnel file lacked documentation of required education qualification. (SEE PERSONNEL CODE SHEET.) 3. The inspector requested to review an official transcript or diploma as documentation of TP A's education qualifications. Neither record was available for review. 4. An interview with the office manager at 2 PM on 1/30/25 confirmed the above findings.