Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2053679	03/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sovah Family Medicine - Mt Hermon	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 the SOVAH Family Medicine- Mt Hermon on 03/28/23 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: The laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on the review of the Laboratory Personnel Report Form (CLIA) (CMS-209 Form), proficiency testing (PT) records, policy and procedures (P&P) and an interview with the office manager and testing personnel (TP), the lab failed to follow the established P&P for rotating the hematology PT events among all five TP in 2022. Findings include: 1. Review of the CMS-209 personnel form revealed five TP performing hematology procedures in the calendar year 2022. 2. Review of the American Academy of Family Physicians (AAFP) PT records revealed that the same TP personnel performed all three events in 2022 (TP-A). 3. Review of the P&P, "Proficiency Testing", revealed the following statement, "The testing of proficiency material is rotated among all staff members who normally perform the patient testing." 4. An exit interview with the office manager and TP on 03/28/23 at approximately 1300 confirmed the findings.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)

	The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, lack of documentation, and interview with the office manager and testing personnel (TP), the lab director failed to review and sign four of four PT attestation statements reviewed. Events of record review include all three PT events in 2022 and the first event in 2023. Findings include: 1. Review of the American Academy of Family Physicians (AAFP) PT 2022 records and the Wisconsin State Laboratory of Hygiene (WSLH) first PT event in 2023 records revealed the lack of documentation by the lab director for review and signature of the following: AAFP- 2022 Hematology 1-3 event attestation statements, and WSLH- 2023 Hematology 1st event attestation statement. 2. An exit interview with the office manager and TP on 03/28/23 at approximately 1300 confirmed the findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records, policy and procedures (P&P) and an interview with the office manager and testing personnel (TP), the lab failed to follow the established P&P for investigating the score of 60% for the White Blood Cell count (WBC) and the WBC Differential parameters for the 3rd event in 2022. Findings include: 1. Review of the American Academy of Family Physicians (AAFP) PT records for the 3rd event in 2022 revealed the lab received a score of 60% for the WBC and WBC Differential parameters (unsatisfactory performance). In addition, there was no documentation of investigation by the lab director or TP for the event. 2. Review of the P&P, "Proficiency Testing", revealed the following statements, "Results outside of the acceptable range require remediation as determined by the lab director or designee. Failures will be reviewed as an opportunity to correct problems, educate staff, and improve the quality of services. All failures will be investigated, even if remediation is not required." 3. An exit interview with the office manager and TP on 03/28/23 at approximately 1300 confirmed the findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as

	acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on the review of manufacturers operator's guide, hematology records, and an interview, the lab failed to perform the Medonic M-series calibration procedures every six months for the 22 months reviewed. Dates of record review include 05/21/21 up to date of survey on 03/28/23. Findings include: 1. Review of the manufacturers operator's guide for the Medonic M-series hematology analyzer, "Section 7: Calibration", revealed recommendations for performing calibration procedures every six months. 2. Review of hematology records, to include calibration documents, for the Medonic M-series hematology analyzer from 05/21/21 up to date of survey on 03 /28/23 revealed calibration procedures performed on 10/22/21 and 10/31/22. The inspector requested to review additional calibration procedures for the abovementioned time frame. The documents were not available for review. 3. An exit interview with the office manager and TP on 03/28/23 at approximately 1300 confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), hematology quality control (QC) records, lack of documentation, and an interview with the office manager and testing personnel (TP), the lab failed to follow the established P&P for verifying new lot numbers of hematology QC materials prior to use for seven lot numbers received and utilized from 01/01/22 up to date of survey on 03/28/23. Findings include: 1. Review of the P&P, "Quality Control", revealed the following statements, "Each new lot number of controls is validated before placing the lot number in service. This is accomplished by assaying new control in an analytical run that includes previously tested and validated control materials." 2. Review of hematology QC records for the Medonic M-series analyzer revealed the lab received and utilized the following seven lot numbers from 01/01/22 up to date of survey on 03/28/23: 22111, 22204, 22206, 22208, 22210, 22211 and 22212. In addition, the record review revealed lack of documentation of the lab staff verifying the new lot numbers of QC materials as specified by the abovementioned P&P. 3. An exit interview with the office manager and TP on 03/28/23 at approximately 1300 confirmed the findings.

D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on the review of Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, lack of documentation, and interview with the office manager and TP, the technical consultant (TC) failed to perform and document the semi-annual competency assessment for two of two TP in 2022. Findings include: 1. Review of the CMS-209 form revealed the lab director performs the duties of TC. 2. Review of the TP records revealed lack of documentation by the TC of performance and review of a semi-annual competency assessment for TP A and B. See attached TP code sheet. 3. An exit interview with the office manager and TP on 03/28/23 at approximately 1300 confirmed the findings.