Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2066154	08/07/2025
Name of Provider or Supplier	**Street Address, City, State**	
Sovah Internal Medicine (Pim)	125 Executive Drive - Suite H, 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 CIA recertification survey was conducted at SOVAH Internal Medicine on August 7, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. SOVAH Internal Medicine was not in compliance with applicable Standards and Conditions with specific deficiencies cited as follows and include the Condition: D6000 - 42 CFR 493.1403 Condition: Laboratories performing moderate complexity testing- Laboratory Director.
D2127	HEMATOLOGY CFR(s): 493.851(d) (d) Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of the Center for Medicaid and Medicare Services CASPER 0155 report (CMS 0155), proficiency testing (PT) records, and interviews, the laboratory failed to submit hematology PT results receiving unsatisfactory scores for one (1) of five (5) PT events reviewed (survey timeframe: October 2023 to the date of inspection on August 7, 2025). Findings include: 1. A review of the laboratory's CMS 0155 revealed zero percent (0%) scores were reported on 2024 Event 3 for the following speciality and six (6) analytes: 0760 HEMATOLOGY 0765 CELL ID- Automated Diff 0775 RBC - Red Blood Cell Count 0785 HCT - Hematocrit 0795 HGB - Hemoglobin 0805 WBC -White Blood Cell Count 0815 PLT - Platelets 2. Review of the laboratory's American Proficiency Institute (API) PT hematology module reports (2023 Event 3, 2024 Events 1-3, 2025 Event 1), a total of 5 events, revealed unsatisfactory scores were reported for the following event: API 2024 Event 3: PT samples ABT 11, ABT 12, ABT 13, ABT 14, and ABT 15 received 0% scores for Cell Identification (Lymphocyte, Monocyte, Granulocyte), Red Blood Cell Count,

	White Blood Cell Count, Platelet Count, Hemoglobin, and Hematocrit. API reported "results not reported to API resulting in score of zero". 3. An exit interview with the lead testing personnel on 8/7/25 at 2:30 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: Based on a review of instrument maintenance logs, manufacturer's operations manual, 2023 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), lack of documentation, and interview, the laboratory failed to document required monthly hematology analyzer maintenance protocols for eleven (11) of twenty-two (22) months reviewed (survey timeframe: October 12, 2023 to August 7, 2025). ** REPEAT DEFICIENCY Findings include: 1. A review of the laboratory's Medonic hematology analyzer's maintenance logs (October 2023 to the date of the inspection on 8/7/25) revealed two required monthly tasks: CP Clean and CP- Clot Prevention. The inspector noted that the laboratory failed to document the above two maintenance protocols on the following monthly charts: Calendar year 2024: January, March, June, August, September, October, November; Calendar year 2025: January, April, May, July. A total of 11 months with no monthly maintenance recorded. 2. Review of the Medonic operations manual revealed manufacturer's maintenance instructions (on page 65) related to the monthly cleaning protocols outlined above: Monthly Cleaning: "The monthly cleaning procedure is to secure the correct function of the instrument and should be done on a monthly basis." Clot Prevention: "This process will decrease the risk of debris material building up in the instrument system. This should be performed at least once a month." 3. Review of the laboratory's policy and procedures revealed a CMS-2567 POC (LD signed/approved 10/20/23) that outlined a corrective action plan for monthly maintenance documentation that stated, "The laboratory primary testing personnel will utilize a log sheet to ensure the performance and documentation of the required monthly maintenance and cleaning of the Medonic M Series hematology analyzer." The inspector inquired regarding the lack of monthly maintenance documentation and to review corrective action. No documentation was available for review. 4. An exit interview with the lead testing personnel on 8/7/25 at 2:30 PM confirmed the above findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(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 (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(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 review of the Centers for Medicare and Medicaid Services CLIA Certification form (CMS 116), tour, review of procedures, hematology calibration records, lack of documentation, and interview, the laboratory failed to document calibration procedures every six (6) months for Complete Blood Count (CBC) testing according to policy resulting in a lapse for one of three required calibrations during the twenty-two (22) months of review (timeframe October 12, 2023 to August 7, 2025). Findings include: 1. During pre-survey preparation/review, the inspector noted the laboratory director indicated on the submitted CMS 116 form that patient CBC patient testing was performed by Medonic Series hematology analyzer during the 22 months of inspection review from 10/12/23 to 8/7/25. 2. During a tour of the laboratory on 8/7/25 at 11 AM revealed the Medonic Series hematology analyzer outlined above in use for CBC patient testing. 3. Review of the laboratory's procedure manual revealed a policy that outlined calibration frequency for CBC testing on the Medonic hematology analyzer (policy title "Hematology Quality Control"). The policy stated: "Analyzer is to be calibrated every six months with calibrators for the Medonic M Series". 4. Review of hematology instrument calibration documentation for the 22 months of review revealed calibrations were performed twice. The inspector noted the dates of calibration were 4/15/24 and 4/30/25 by a Cardwell Medical field service specialist during annual preventative maintenance procedures. The inspector requested to review additional calibration records performed at the 6 month interval in calendar year 2024. No additional calibration documentation was available. 5. The inspector inquired regarding corrective action documentation for the lapse in required calibration frequency in calendar year 2024. No records were available for review. 6. An exit interview with the lead testing personnel on 8/7/25 at 2:30 PM confirmed the above findings.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of Center for Medicaid and Medicare Services (CMS) CASPER 0155 report, tour, procedures, proficiency testing (PT) records, maintenance logs, 2023 CMS Statement of Deficiencies Plan of Correction form 2567, CMS CLIA Certification form 116, hematology calibration records, testing personnel (TP) records, lack of documentation, and interviews, the laboratory director (LD) failed to provide overall direction and management of the laboratory services. The LD failed to: 1. ensure that self grading was conducted after the laboratory failed to return hematology PT results to American Proficiency Institute for 2024 Event 3 - Refer to D6017; 2. to identify quality assessment failures as they occurred during the twenty-two (22) months reviewed (survey timeframe of October 12, 2023 to August 7, 2025) - Refer to D6020.
D6017	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(ii)

	(e)(4)(ii) Ensure that results are returned within the timeframes established by the proficiency testing program; This STANDARD is not met as evidenced by: Based on a review of Center for Medicaid and Medicare Services CASPER 0155 report, proficiency testing (PT) records, and interviews, the laboratory director failed to ensure that hematology PT results were returned to American Proficiency Institute (API) for the 2024 Event 3 resulting in unsatisfactory scores for one of five events reviewed (survey timeframe: October 2023 to the date of inspection on August 7, 2025). *Cross Reference D2127. Findings include: 1. A review of the laboratory's CMS 0155 report revealed zero percent (0%) scores on 2024 Event 3 for the speciality of Hematology and six (6) analytes (Cell ID Automated Diff, Red Blood Cell Count, Hematocrit, Hemoglobin, White Blood Cell Count, and Platelets). 2. Review of the laboratory's API PT hematology records (2023 Event 3, 2024 Events 1-3, 2025 Event 1), a total of 5 events, revealed unsatisfactory scores for API 2024 Event 3. API reported "results not reported to API resulting in score of zero". 3. The inspector inquired regarding corrective action for the event outlined above. The primary testing personnel stated on 8/7/25 at 1 PM, "We did not submit the scores before the deadline. We did run the samples but failed to get them submitted by the deadline". The inspector requested to review the self grading for the event. No documentation was available for review. 4. An exit interview with the lead testing personnel on 8/7/25 at 2:30 PM confirmed the above findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of Center for Medicaid and Medicare Services (CMS) CASPER 0155 report, tour, review of proficiency testing (PT) records, policies/procedures, maintenance logs, 2023 CMS Statement of Deficiencies Plan of Correction form 2567, CMS CLIA Certification form 116, hematology calibration records, CMS Laboratory Personnel Report form 209, testing personnel (TP) records, lack of documentation, and interviews, the laboratory director failed to identify the following quality assessment failures as they occurred during the twenty-two (22) month review (survey timeframe of October 12, 2023 to August 7, 2025): 1. lack of self grading when the laboratory failed to return hematology PT results to American Proficiency Institute for 2024 Event 3 resulting in unsatisfactory scores of zero percent - Cross Reference D6017; 2. lack of corrective action when hematology analyzer monthly maintenance was not documented for eleven (11) of the 22 months reviewed - Cross Reference D5429 -repeat deficiency; 3. lack of corrective action when a lapse in CBC calibration procedures occurred for one of three required calibrations during the 22 months reviewed - Cross Reference D5437; 4. lack of annual competency assessment documentation for one of two TP - Cross Reference D6046-repeat deficiency.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to-- This STANDARD is not met as evidenced by: Based on a review of Centers for Medicare and Medicaid Services Laboratory Personnel Report form (CMS 209), testing personnel (TP) files, lack of documentation, review of quality assurance (QA) policy, 2023 Centers for Medicare and Medicaid Services Statement of Deficiencies Plan of Correction (CMS-2567 POC), and interviews, the technical consultant (TC) failed to document annual competency assessments for one of two TP during the twenty-two (22) months reviewed (survey timeframe: October 12, 2023 - August 7, 2025). **REPEAT DEFICIENCY** Findings include: 1. Review of the CMS 209 personnel form revealed that the laboratory director (LD) performs duties of the TC and 2 TP as responsible for performing non-waived hematology Complete Blood Count (CBC) patient testing during the 22 months reviewed. 2. Review of personnel records revealed annual Medonic Series hematology competency assessments signed by the LD for TP A in October 2023 and in April 2025. The inspector requested to review TP A's annual CBC testing competency assessment completed in calendar year 2024. Documentation was not available for review. *See Personnel Code Sheet. 3. Review of the laboratory's QA policy revealed the following protocol statement, "Personnel Assessment -at least annually, the laboratory director will review the performance of each employee working in the laboratory to assure employee competency. The written result of the review will be filed in personnel file." 4. Review of the laboratory's policy and procedures revealed a 2023 CMS-2567 POC (LD signed/approved 10/20 /23) that outlined a corrective action plan for retention/documentation of competency assessments that stated "The laboratory director for Sovah Internal Medicine will perform annual competency assessments on all lab testing personnel. The lab competency assessments will be retained in the laboratory and a copy place in each laboratory testing personnel's file." 5. The inspector inquired regarding the laboratory's protocols for corrective action for missed competency assessments during an interview with the lead testing personnel on 8/7/23 at 11 AM. The lead testing personnel stated, "Our lab director completes the competency check lists annually. I am not sure why we have a missing competency assessment." 6. An exit interview with the lead testing personnel on 8/7/25 at 2:30 PM confirmed the above findings