Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2066154	10/11/2023
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 CLIA Recertification survey was conducted at the SOVAH Internal Medicine (PIM) on October 10 & 11, 2023 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 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. D5400- 42 C.F. R. 493-1250 Condition: Analytic Systems.
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 a tour of the laboratory, the review of proficiency testing (PT) records, interview with the PT technical specialist and interviews with the primary testing personnel (TP), the laboratory failed to enroll in the correct chemistry PT module for the sodium (NA), potassium (K+), chloride (CL), carbon dioxide (CO2), urea nitrogen (BUN), creatinine (Creat), glucose (GLU), and ionized calcium (CA) analytes for the 2022 and 2023 calendar year events (a total of six events). Findings include: 1. Tour of the laboratory on 10/10/23 at 09:45 AM revealed an i-STAT portable hand-held analyzer. An interview with the primary TP during the tour revealed the lab uses the Abbott i-STAT Chem 8+ cartridge to perform chemistry testing on patients as needed.

	2. Review of the CASPER CLIA application and Survey Summary report 0096D revealed no results for the NA, K+, CL, CO2, BUN, Creat, GLU, and iCA analytes for 2022 and 2023 testing events (a total of six events). 3. A phone interview with the American Proficiency Institute (API) technical specialist on 10/10/23 at 10:30 AM and 11:30 AM revealed that the lab was enrolled in the waived module for the i-STAT Chem 8 profile. They stated, "this option allows for sites to test only two samples three times a year and it is for backup systems. Results are considered waived testing and not reported to CMS." The inspector reviewed the laboratory participation documents with the technical specialist and confirmed that the lab received and tested two samples per event for the calendar years of 2022 and 2023 and that the lab was currently enrolled in catalog #945 waived option for the specified analytes. 4. An interview with the lab director, office manager, market quality manager and primary TP on 10/10/23 at 1300 confirmed the findings.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of manufacturer's operator's manual, manufacturer's package insert, external quality control (QC) records, patient records, lack of documentation, and interviews, the lab failed to: 1. provide documentation of performing the thermal probe check every six months from 12/01/21 up to the date of survey on 10/10/23. Refer to D5429; 2. provide documentation of performing the calibration verification procedures every six months for the non-waived Abbott Chem 8+ analytes from 12/01 /21 up to the date of survey on 10/10/23. Refer to D5439; and 3. perform at least two levels of external QC materials each day of patient testing for the non-waived Abbott i-STAT Chem 8+ cartridge analytes from 12/01/21 up to the date of survey on 10/10 /23 while reporting 117 patients. Refer to D5447.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on the review of manufacturer's operator's manual, lack of documentation, and interviews, the lab failed to provide documentation of performing the thermal probe check every six months from 12/01/21 up to the date of survey on 10/10/23 (22 months reviewed). Findings include: 1. Review of the Abbott i-STAT operator's manual revealed recommendations of performing the thermal probe check be verified every six months. 2. Review of the monthly external quality control (QC) and the daily electronic simulator check logs from 12/01/21 up to the date of survey on 10/10

	/23 revealed lack of documentation of the performance of the thermal probe checks every six months. The inspector inquired about the thermal probe checks. In an interview with the primary testing personnel on 10/10/23 at 11:30 AM, they stated, "I think the point of care person performs that with the hospital." In an interview with the point of care manager on 10/10/23 at 12:30, they stated, "we do the CLEW software updates for the lab as a courtesy about every six months and I do the thermal probe checks at that time." The inspector requested to review documentation of the thermal probe checks for the Abbott i-STAT analyzer serial number S10461. The documentation was not available for review. 3. An interview with the lab director, office manager, market quality manager and primary TP on 10/10/23 at 1300 confirmed the findings. 4. An exit interview with the office manager and market quality manager on 10/11/23 at 11 AM confirmed the findings. B. Based on the review of the manufacturer operator's guide, lack of documentation, and interview, the lab failed to perform and document the monthly maintenance for the hematology analyzer for 22 of 22 months reviewed from 12/01/21 up to the date of survey on 10 /10/23. Findings include: 1. Review of the manufacturer operator's guide revealed instructions for performing monthly cleaning procedures utilizing the Boule Cleaning Kit (cleaning procedure and clot prevention) listed under "Section 8: Cleaning, Maintenance & Transport", "8.2 Monthly Cleaning". 2. Review of the available maintenance records for the Medonic M-series hematology analyzer revealed lack of documentation of the performance of the monthly maintenance for 22 of 22 months reviewed from 12/01/21 up to the date of survey on 10/10/23. The inspector requested to review aforementioned documents. The documents were not available for review. 3. An exit interview with the office manager and market quality manager on 10/11/23 at 11 AM confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on the review of manufacturer's package insert, lack of documentation, and interviews, the lab failed to provide documentation of performing the calibration

	verification procedures every six months for the non-waived Abbott Chem 8+ analytes from 12/01/21 up to the date of survey on 10/10/23 (22 months reviewed). Findings include: 1. Review of the non-waived Abbott i-STAT Chem 8+ reagent cartridge package insert revealed the following statement, "Calibration Verification procedure is intended to verify the accuracy of results over the entire measurement range of a test as may be required by regulatory or accreditation bodies." 2. Review of the monthly external quality control (QC) and the daily electronic simulator check logs from 12/01/21 up to the date of survey on 10/10/23 (22 months) revealed lack of documentation of the performance of calibration verification procedures every six months. The inspector inquired about the procedures. In an interview with the primary testing personnel on 10/10/23 at 11:30 AM, they stated, "I think the point of care person performs that with the hospital." In an interview with the point of care manager on 10/10/23 at 12:30, they stated, "we do the CLEW software updates for the lab as a courtesy about every six months, and I do the thermal probe checks and the calibration verifications at that time." The inspector requested to review documentation of the calibration verification records for the Abbott i-STAT analyzer serial number S10461. The documentation was not available for review. 3. An interview with the lab director, office manager, market quality manager and primary TP on 10/10/23 at 1300 confirmed the findings. 4. An exit interview with the office manager and market quality manager on 10/11/23 at 11 AM confirmed the findings.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of manufacturer operator's manual, external quality control (QC) records, patient records, and interviews, the lab failed to perform at least two levels of external QC materials each day of patient testing for the non-waived Abbott i-STAT Chem 8+ cartridge analytes from 12/01/21 up to the date of survey on 10/10/23 (22 months) while reporting 117 patients. Findings include: 1. Review of the Abbott i-STAT operator's manual revealed the following statement, "Quality Control 14, For each lot in each shipment of cartridges, analyze multiple levels of i-STAT controls using verified analyzer.* *This is not a manufacturer's system instructions; it is a suggestion to comply with regulatory requirements." 2. Review of the QC test logs for the non-waived Abbott i-STAT Chem 8+ cartridge analytes sodium (NA), potassium (K+), chloride (CL), carbon dioxide (CO2), urea nitrogen (BUN), creatinine (Create), glucose (GLU), ionized calcium (iCA) and hematocrit (HCT) revealed the lab performed external QC procedures each month and with each new lot number of cartridges received from 12/01/21 up to the date of survey on 10/10/23. 3. An interview with the primary testing personnel (TP) on 10/10/23 at 09:45 AM revealed the lab received their Abbott Chem 8+ cartridges from the affiliated hospital. They stated, "We receive our cartridges from the hospital, and I do the external QC each month and with new lot number. We thought these tests were waived." 4. Review of patient test records revealed 117 patients resulted from 12/01/21 up to the date of survey on 10/10/23. 5. An interview with the lab director, office manager, market quality manager and primary TP on 10/10/23 at 1300 confirmed the findings. 6. An

	exit interview with the office manager and market quality manager on 10/11/23 at 11 AM confirmed the findings.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on the review of manufacturer's operator's manual, manufacturer's package insert, external quality control (QC) records, patient records, lack of documentation, and interviews, the lab director failed to: 1) provide documentation of performing the thermal probe check every six months from 12/01/21 up to the date of survey on 10/10 /23. Refer to D5429; 2) provide documentation of performing the calibration verification procedures every six months for the non-waived Abbott Chem 8+ analytes from 12/01/21 up to the date of survey on 10/10/23. Refer to D5439; and 3) perform at least two levels of external QC materials each day of patient testing for the non-waived Abbott i-STAT Chem 8+ cartridge analytes from 12/01/21 up to the date of survey on 10/10/23 while reporting 117 patients. Refer to D5447. In an interview with the lab director, office manager, market quality manager and primary TP on 10/10 /23 at 1300, the lab director stated, "I didn't realize these cartridges were not CLIA waived."
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, the review of proficiency testing (PT) records, interview with the PT technical specialist and interviews with the primary testing personnel (TP), the laboratory director failed to ensure the enrollment of the correct chemistry PT module for the sodium (NA), potassium (K+), chloride (CL), carbon dioxide (CO2), urea nitrogen (BUN), creatinine, glucose (GLU), ionized calcium (CA) and hematocrit (HCT) analytes for the 2022 and 2023 calendar year events (a total of six events). Refer to D2000. In an interview with the lab director, office manager, market quality manager and primary TP on 10/10/23 at 1300, the lab director stated, "I didn't realize these cartridges were not CLIA waived."

D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (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. 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, the quality assurance (QA) policy and interview with the primary TP, the technical consultant failed to perform and document annual competency assessments for one of one TP in 2022. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of technical consultant and that there was one TP performing patient testing in 2022. 2. Review of TP #1's records revealed lack of documentation of an annual competency assessments for the calendar year 2022. The inspector requested the competency assessments for TP #1. The documentation was not available for review. 3. Review of the QA policy revealed the following statement: "5. 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 the individual's personnel file." 4. An interview with the lab director, office manager, market quality manager and primary TP on 10/10 /23 at 1300 confirmed the findings. 5. An exit interview with the office manager and market quality manager on 10/11/23 at 11 AM confirmed the findings.