Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2066154	03/13/2018
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 Initial survey was conducted at the SOVAH Internal Medicine (PIM) on March 13, 2018 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:
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of quality assurance (QA) policy, quality control (QC) records, and interviews, the laboratory failed to follow the written QA policy for the review of their analytic test system from October 17, 2017 to March 13, 2018. Findings include: 1. Review of the QA policy revealed the following statements: "Each month, one of the following systems in our laboratory will be evaluated to be sure that it meets our quality goals. If a problem is identified, we will design and implement a solution that is approved by the laboratory director. 1. Patient test management 2. Quality control and instrumentation 3. Proficiency testing 4. Relationship of patient information to patient results 5. Personnel assessment 6. Communication 7. Laboratory Errors 8. Complaints 9. Quality Assurance review 10. Quality Assurance records." 2. Review of QC records for the hematology analytic testing system and available QA documentation revealed that there was no documentation of the QA review according the to written policy from October 17, 2017 to March 13, 2018. 3. An interview with the primary testing personnel and lab director at approximately 4:00 PM confirmed that the staff had not performed the QA reviews as described within the written policy from October 17, 2017 to March 13, 2018.

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, the quality assurance (QA) policy, and interviews, the technical consultant failed to perform and document annual competency assessments for two (2) of two (2) TP in 2017. Findings include: 1. Review of the CMS-209 form revealed that the lab director also performs the duties of technical consultant and that there were 2 TP performing patient testing in 2017. (See attached personnel code list.) 2. Review of the 2 TP records revealed no documentation of competency assessments performed by the lab director in 2017. The inspector requested the competency assessments for the 2 TP. 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 primary testing personnel and technical consultant at approximately 4:00 PM confirmed that the technical consultant failed to perform the competency assessments in 2017.