Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0706467	10/25/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sovah Family Medicine Gretna	305 N Main St, Gretna, 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 Gretna on October 25, 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:
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 and interviews, the laboratory director and testing personnel (TP) failed to sign two (2) of the five (5) attestation statements reviewed. Findings include: 1. Review of the American Academy of Family Physicians (AAFP) hematology PT records for all three (3) events in 2017 and the first two (2) events in 2018 revealed lack of the laboratory director's and TP signature of the attestation statements for the following: 2017 Event A- no signature by the laboratory director, 2017 Event C- no signature by the TP. 2. Interview with the office manager and primary TP at approximately 12:30 PM confirmed the findings.
D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are

	reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and interviews, the laboratory director failed to document the review of the final PT results for three (3) of the five (5) PT events reviewed. Findings include: 1. Review of the American Academy of Family Physicians (AAFP) hematology PT records for all three (3) events in 2017 and the first two (2) events in 2018 revealed lack of the laboratory director's signature of review for the following: 2017 Event A, 2018 Event A and B. 2. Interview with the office manager and primary testing personnel at approximately 12:30 PM confirmed the findings.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on the review of the quality assurance (QA) policy, Laboratory Personnel Report Form (CLIA) (CMS-209 Form), testing personnel (TP) records, and interviews, the laboratory director failed to follow the written QA policy for performing and documenting initial competency assessment for one (1) of one (1) new TP reviewed. Findings include: 1. Review of the QA policy revealed the following statements: "Personnel Assessment policy- the lab director will use proficiency testing results, results of the quality control review, and director observation to perform an ongoing evaluation of all testing personnel in the laboratory to ensure competence in job performance. Procedure- 1. New testing personnel will be evaluated for competency in each laboratory test they will be responsible for before reporting any patient results. Training records will be maintained. 2. New testing personnel will be reevaluated in 6 months, the annually thereafter. 3. All testing personnel will be evaluated for competency on an annual basis." 2. Review of the CLIA CMS 209 form revealed 1 new TP in 2018 (See attached personnel code sheet). 3. Review of laboratory personnel files revealed lack of documentation of training and initial competency assessment by the laboratory director for the following testing personnel : -Testing Personnel A- Hired April 2018. 4. Interview with the office manager and primary testing personnel at approximately 12:30 PM confirmed the findings.