Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0963697	09/21/2018
Name of Provider or Supplier	**Street Address, City, State**	
Sovah Pediatrics	201 South Main Street Suite 2100, 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 SOVAH Pediatrics on September 21, 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:
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 the review of proficiency testing (PT) records, hematology quality control (QC) records, instrument maintenance records, quality assessment (QA) policy, testing personnel (TP) records, and interviews, the laboratory director failed to (1) sign attestation statements (Refer to D6016); (2) review PT results (Refer to D6018); (3) follow written policy for hematology QC record review (Refer to D6020); and (4) perform and sign the competency assessments of TP (Refer to D6030).
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) 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)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;

	This STANDARD is not met as evidenced by: Based on the review of proficiency testing (PT) records and interviews, the laboratory director failed to review and sign the attestation statements for five (5) of the five (5) PT events reviewed. Findings include: 1. Review of the American Academy of Family Physicians (AAFP) hematology PT events, a total of 5 events, revealed a lack of the laboratory director's signature on the attestation statements for the following: 2016 Event C, 2017 Event A, B, and C, 2018 Event A. 2. Interviews with the office manager and primary testing personnel at approximately 12:00 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 five (5) of the five (5) PT events reviewed. Findings include: 1. Review of the American Academy of Family Physicians (AAFP) hematology PT events, a total of 5 events, revealed a lack of the laboratory director's signature of review for the following: 2016 Event C, 2017 Event A, B, and C, 2018 Event A. 2. Interviews with the office manager and primary testing personnel at approximately 12:00 PM confirmed the findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on the review of the quality control policy, hematology quality control (QC) records, instrument maintenance records for the Beckman Coulter AcT Diff 5 analyzer, and interviews, the laboratory director did not follow the written policy for reviewing hematology QC records for twenty-two (22) of the twenty-two (22) months reviewed. Findings include: 1. Review of the laboratory's quality control policy reveals the following statement (signed by laboratory director with no date): "The Lab director or designee reviews all quality control charts, logs, and remedial actions on at least a monthly basis." 2. Review of the hematology QC records and the manufacturer required instrument maintenance records for the Beckman Coulter AcT Diff 5

	analyzer from August 1, 2016 through June 30, 2018 (a total of 22 months) revealed no documentation of review by the laboratory director. 3. An interview with the office manager and primary testing personnel at approximately 12:00 confirmed that the findings for the above-listed timeframe. **This is a repeat deficiency.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; 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 competency assessments for seven (7) of seven (7) 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 7 TP. 3. Review of laboratory personnel files revealed that the 2017 and 2018 training and competency documentation lacked laboratory the director's signature for the following 7 testing personnel (See attached personnel code sheet): -Testing Personnel A- annual competency dated June 1, 2017 -Testing Personnel B- annual competency dated June 1, 2017 -Testing Personnel C- annual competency dated June 1, 2017 -Testing Personnel D- initial competency dated March 9, 2018 -Testing Personnel E- annual competency dated June 2, 2017 -Testing Personnel F- annual competency dated June 1, 2017 -Testing Personnel G- initial competency dated July 27, 2017 and semi-annual competency dated November 11, 2017. 4. Interviews with the office manager and primary testing personnel at approximately 12:00 PM confirmed the findings. **This is a repeat deficiency.