Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0963697	06/05/2023
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 unannounced CLIA complaint investigation (VA00058886) was conducted at SOVAH Pediatrics on 06/05/23 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: D5800 - 42 C.F. R. 493- 1290 Condition: Postanayltic Systems, D6000- 42 C.F.R. 493-1403 Condition: Moderate Complexity Laboratory Director.
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, review of the policy and procedures (P&P), lack of documentation, and interview, the laboratory failed to have procedures established for the staff to follow related to protection from physical, chemical, electrical hazards and biohazardous materials at the date of survey on 06/05/23. Findings include: 1. The inspector observed testing personnel (TP) #1 placing two patient complete blood count (CBC) sample tubes next to a jar of strawberry preserves and drink container on the counter at approximately 11:45 AM on 06/05/23. At approximately 1230, TP#1 was observed placing two "UTM-RT 3ml w/o beads" viral transport medium tubes, that included the patient swabs in the tubes, at the same counter next to the jar of strawberry preserves and drink container . 2. Review of the P&P revealed lack of documentation of safety procedures available for the staff. In an interview with the market quality manager on 06/05/23 at approximately 1240, the inspector requested to review safety procedures. They stated, "I know we had a policy but it's not in the manual today." 3. An exit interview with the market quality manager on 06/05/23 at

	1330 confirmed the laboratory did not have safety procedures established and available to the staff.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on the review of one patient final complete blood count (CBC) result, the policy and procedures (P&P), lack of documentation, and interview, the laboratory failed to have procedures established for staff related to the documentation and reporting of critical (panic) or alert values at the date of survey on 06/05/23. Findings include: 1. Review of patient #1 final CBC result (performed on 06/01/23) printout from the Sysmex XN-450 Hematology analyzer revealed a result of 18.5 10^3/uL for the White blood cell (WBC) count. The printed reference range for the WBC count on the Sysmex XN-450 result was 5.50-17.0 10^3/uL. 2. Review of the P&P revealed lack of documentation of a procedure available for staff for reporting CBC critical (panic) or alert values. The inspector requested to review a procedure for staff to follow for alert or critical values. The document was not available for review. In an interview with the market quality manager on 06/05/23 at approximately 1245, they stated that alert or critical values are manually entered into the Athena electronic medical record (EMR) and the ordering doctor performs review. Review of patient #1 final CBC results in the Athena EMR revealed the results reviewed by the ordering doctor on 06/01/23. The Athena EMR report for patient #1 lacked documentation of the WBC result as flagged critical or alert value. 3. An exit interview with the market quality manager on 06/05/23 at 1330 confirmed the findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by:

	Based on the review of one patient final complete blood count (CBC) result, the policy and procedures (P&P), lack of documentation, and interview, the laboratory director failed to review and approve critical (panic) or alert values in the subspecialty of hematology for the age-specific pediatric population at the date of survey on 06/05 /23. Findings include: 1. Review of patient #1 final CBC result (performed on 06/01 /23) printout from the Sysmex XN-450 Hematology analyzer and in the Athena electronic medical record (EMR) revealed the result for the White blood cell (WBC) count was 18.5 10^3/uL. The printed reference range for the WBC count on the Sysmex XN-450 result printout was 5.50-17.0 10^3/uL. The Sysmex XN-450 Hematology analzyer was installed on 04/21/21. The accuracy, precision and reportable range approved by the laboratory director on 04/21/21. 2. Review of the P&P revealed a stand-alone document titled "critical values" and noted a high critical value of >77. 0 t/cumm for the WBC count. The document was signed by a previous lab director on 12/16/1999. The document lacked review or revision by the current lab director, which assumed responsibility in December 2020. In an interview with the market quality manager on 06/05/23 at approximately 1235, the inspector asked if the stand-alone critical values document was specific to the pediatric population. They stated, "no it is not specific to our pediatric population." The inspector requested to review a current and approved critical (panic) or alert values document. The document was not available for review. 3. An exit interview with the market quality manager on 06/05/23 at 1330 confirmed the findings.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of policy and procedures (P&P), lack of documentation, 41 patient test results, and interview, the laboratory failed to provide an approved reference (normal) ranges for the age-specific pediatric population for the Complete Blood Count (CBC) results at the date of survey on 06/05/23. Refer to D5807.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the review of policy and procedures (P&P), lack of documentation, 41 patient test results, and interview, the laboratory failed to provide an approved reference (normal) ranges for the age-specific pediatric population for the Complete Blood Count (CBC) results at the date of survey on 06/05/23. Findings include: 1. Review of the P&P revealed lack of documentation of an approved reference (normal)

	ranges for the age-specific pediatric population for the CBC test results. The inspector requested to review the document in an interview with the market quality manager on 06/05/23 at 11:30 AM. They stated, "the pediatric doctors in the practice met and determined the reference (normal) ranges a long time ago." The inspector requested to review the documentation of the meeting and approved reference ranges. The document was not available for review. 2. Review of the Sysmex XN-450 Hematology analyzer result printouts and the Athena electronic medical record (EMR) for a total of 41 patients (age range of nine months to 17 years) revealed the following reference ranges: WBC 5.50-17.0 10^3/uL RBC 3.10-5.70 10^6/uL HGB 9.5-13.5 g /dL HCT 35.0-44.0 % MCV 76.0-92.0 fL MCH 23.0-31.0 pg MCHC 28.0-33.0 g/dL PLT 150-400 10^3/uL Neut 1.50-7.0 10^3/uL /35.0-47.0 % Lymph 2.00-5.00 10^3 /uL/ 40.0-45.0 % Mono 0.30-1.10 10^3/uL/ 3.0-11.0 % EO 0.20-2.00 10^3/uL/ 1.0-5.0 % Baso 0.00-0.30 10^3/uL/ 0.0-0.5 % IG 0.00-0.30 10^3/uL/ 0.0-2.0 % The reference range (normal) values for the CBC test results for both the analyzer printouts and the Athena EMR were the same for all ages of patients. 3. An exit interview with the market quality manager on 06/05/23 at 1330 confirmed the 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 the review of patient final complete blood count (CBC) results, policy and procedures (P&P), lack of documentation, and interview, the laboratory director failed to ensure the quality of laboratory procedures in the pre-analytic, analytic and post-analytic phases of testing in the subspecialty of hematology. Refer to D6007.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the review of patient final complete blood count (CBC) results, policy and procedures (P&P), lack of documentation, and interview, the laboratory director failed to 1) establish a P&P for the staff to follow related to protection from physical, chemical, electrical hazards and biohazardous materials; 2) review and approve critical (panic) or alert values for the CBC test results; 3) establish a P&P for staff to follow related to documenting and reporting critical (panic) or alert values for the CBC test results and 4) review and approve reference (normal) ranges for the age-

	specific pediatric population for the CBC test results the date of survey on 06/05/23. Refer to D3011, D5403, D5407 and D5807.