Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0963697	10/13/2022
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 10/13/22 by the Virginia Department of Health's Office of Licensure and Certification. The surveyor performed a focused SARS-CoV-2 Test Reports survey on 10/13/22. 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: D3000 - 42 C.F.R. 493-1100 Condition: Reporting of SARS-CoV-2 Test Reports.
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100 Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on a tour of the facility, record review and interviews, the lab failed to report 146 SARS-CoV-2 (COVID-19) positive test results for 163 of 163 testing dates from 04/04/22 up to date of survey on 10/13/22. Findings include: 1. A tour of the facility and interview with the registered nurse (RN) coordinator on 10/13/22 at 11:30 AM revealed the facility had six Quidel Sofia readers that were utilized to perform to COVID-19 patient testing. During the same interview, the inspector requested to review a log sheet or mechanism in which the facility tracks COVID-19 testing and reporting positive results to the State agency. The RN coordinator stated "We do not

	have log sheets and we report results directly into our electronic medical records. We have not been reporting positive results." Patient testing data were retrieved from the six Sofia readers and the Athena electronic medical records. 2. 146 positive results were not reported as required during the period of review (163 testing dates). 3. The laboratory performed 1,108 COVID-19 tests during the period of review. 4. An exit interview with the RN coordinator on 10/13/22 at approximately 1330 confirmed the findings.
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 the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), manufacturer's instructions for use (IFU), tour of the lab, review of the policy and procedures (P&P), lack of documentation, and interviews, the laboratory failed to have a written policy for reporting positive patient SARS-CoV-2 (COVID-19) test results to the State agency from 04/04/22 and up to the date of survey on 10/13/22. Findings include: 1. Review of the CMS 116 application revealed the laboratory performs COVID-19 testing. 2. A tour of the facility and interview with the registered nurse (RN) coordinator on 10/13 /22 at 11:30 AM revealed the facility utilized six Quidel Sofia readers to perform to COVID-19 patient testing. During the same interview, the inspector requested to review a log sheet or mechanism in which the facility tracks COVID-19 testing and reporting positive results to the State agency. The RN coordinator stated "We do not have log sheets and we report results directly into our electronic medical records. We have not been reporting positive results." 3. Review of the manufacturer's IFU's revealed the following statements: Quidel Sofia SARS Antigen FIA (nasopharyngeal or nasal swab)- "Conditions of Authorization for the Laboratory", "Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 4. Review of the P&P revealed a lack of documentation of P&P for recording and reporting patient COVID-19 positive test results to the State agency. 5. An exit interview with the RN coordinator on 10/13/22 at approximately 1330 confirmed the findings.

D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of the hematology analyzer operator's guide, initial verification records, lack of documentation, and an interview, the laboratory failed to document and monitor the relative humidity percentage (RH%) from 04/29/21 and up to the date of survey on 10/13/22, 17 months reviewed. Findings include: 1. Review of the Sysmex XN-450 analyzer operator's guide revealed the following statement, ""Basic information- Installation Environment- Relative humidity should be within ranges of 20-85%." 2. Review of initial verification records revealed the Sysmex XN-450 analyzer installed and in use on 04/29/21. The inspector requested to review the monitoring and recording of the RH% from 04/29/21 up to the date of survey on 10/13 /22 (total of 17 months). The records were not available for review. 3. An exit interview with the registered nurse coordinator on 10/13/22 at approximately 1330 confirmed the findings.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on tour of the lab, review of policy and procedures (P&P), manufacturer package insert (PI) and interview, the lab failed to label three of three Sysmex XN-L Check hematology quality control (QC) vials with date placed in service and expiration date as described in the P&P at the date of survey on 10/13/22. Findings include: 1. Tour of the lab area on 10/13/22 at approximately 1230 revealed a small refrigerator that housed the Sysmex XN-L Check hematology QC materials. Three vials of the hematology QC were placed in a small cup (lot numbers 22381401, 22381402 and 22381403). The three vials lacked documentation of date placed in service and expiration date. 2. Review of the P&P revealed the following statement, "Quality Control", "III. Procedure- All control materials and reagents are labeled as to content, lot number, date of preparation where applicable, date placed into service and the expiration date." 3. Review of the Sysmex XN-L Check QC PI revealed the following statement, "Storage and shelf life after first opening- open vials and vials which have been sampled by cap piercing will retain stability for 15 days if stored after recapping." 4. During an exit interview at 1330 on 10/13/22, the registered nurse coordinator stated, "the three vials in the cup are the ones we are currently using and

	the dates are supposed to written on the vials. They were probably opened this morning."
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 policy and procedures (P&P), hematology quality control (QC) records, and interview, the laboratory director failed to follow the written policy for reviewing the QC records on at least a monthly basis for 16 of 16 months reviewed. Date of record review included 04/01/21 up to 09/30/22. Findings include: 1. Review of the P&P revealed the following statement, "Quality Control", "The Lab director or designee reviews all quality control charts, logs, and remedial actions on at least a monthly basis." 2. Review of the Sysmex XN-450 hematology QC records from 04/01/21 up to 09/30/22 revealed documentation of review by the laboratory director on 09/22/22. An interview with the registered nurse (RN) coordinator on 10 /13/22 at approximately 1235, the inspector inquired as the delay in the lab director's review of the QC records. They stated, "We have not had the lab director review documents on a monthly basis." 3. An exit interview with the RN coordinator on 10/13 /22 at approximately 1330 confirmed the findings.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), manufacturer's instructions for use (IFU), policy and procedures (P&P), lack of documentation, and interviews, the laboratory director failed to ensure the laboratory had a written policy for recording and reporting positive patient SARS-CoV-2 (COVID-19) test results to the State agency from 04/04/22 and up to the date of survey on 10/13/22. Refer to D5403.