Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0863834	08/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Rva Peds - Southside	14400 Sommerville Court, Midlothian, 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 RVA Peds Southside on August 16, 2021 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 is performing COVID-19 testing and in compliance with the applicable COVID-19 reporting requirements.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: A. 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), lack of documentation, and interviews, the laboratory failed to provide documentation of required training for the use and interpretation of results for the Quidel Sofia SARs Antigen FIA test kits for twelve (12) of 12 months reviewed. Findings include: 1. Review of the CMS 116 form revealed the laboratory performs COVID-19 testing. An interview with the laboratory supervisor on 08/16/21 at approximately 1:30 PM revealed the lab began patient testing with the Quidel Sofia SARs Antigen FIA kits on 07/10/20. 2. Review of the manufacturer's IFU's revealed the following statement: Quidel Sofia SARs Antigen FIA (nasopharyngeal or nasal swab) - "Conditions of Authorization for Laboratory and Patient Care Setting", "All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling." 3. On 08/16/21 at approximately 2:25 PM, the inspector requested to review

	documentation of the training for the Quidel Sofia SARs Antigen FIA test kit on or before 07/10/20 up to 07/10/21 (12 months). The documentation was not available for review. 4. An exit interview with the laboratory supervisor on 08/16/21 at approximately 4:00 PM confirmed the above findings. B. 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), lack of documentation, and interviews, the laboratory failed to provide documentation of required training for the use and interpretation of results for the Abbott ID Now COVID-19 test kits for ten (10) of 10 months reviewed. Findings include: 1. Review of the CMS 116 form revealed the laboratory performs COVID-19 testing. An interview with the laboratory supervisor on 08/16/21 at approximately 1:30 PM revealed the lab began patient testing with the Abbott ID Now COVID-19 kits on 10 /08/20. 2. Review of the manufacturer's IFU's revealed the following statement: Abbott ID Now COVID-19 (Antigen nasopharyngeal or nasal swab) - "Conditions of Authorization for Laboratory and Patient Care Setting", "All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling." 3. On 08/16/21 at approximately 2:25 PM, the inspector requested to review documentation of the training for the Abbott ID Now COVID-19 test kit on or before 10/08/20 up to 08/10 /21 (10 months). The documentation was not available for review. 4. An exit interview with the laboratory supervisor on 08/16/21 at approximately 4:00 PM confirmed the above 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), policy and procedures (P&P), lack of documentation, and interviews, the laboratory failed to have a written policy for reporting patient SARS-CoV-2 (COVID-19) positive and negative results to the State agency from 07/10/20 and up to the date of survey on 08/16/21. Findings include: 1. Review of the CMS 116

	application revealed the laboratory performs COVID-19 testing. An interview with the laboratory supervisor on 08/16/21 at approximately 1:30 PM revealed the lab began patient testing with the Quidel Sofia SARs Antigen FIA kits on 07/10/20 and the Abbott ID Now COVID-19 kits on 10/08/21. 2. Review of the manufacturer's IFU's revealed the following statements: Abbott ID Now COVID-19 (Antigen nasopharyngeal or nasal swab) - "Conditions of Authorization for Laboratory and Patient Care Setting", "Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate." 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." 3. Review of the P&P revealed lack of documentation of policy or procedure for reporting patient COVID- 19 positive and negative test results to the local health department. 4. An exit interview with the laboratory supervisor on 08/16/21 at approximately 4:00 PM, the document was not available for review and findings confirmed.