

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D1079564	<b>(X3) Date Survey Completed</b>  02/16/2022
<b>Name of Provider or Supplier</b>  Red Stick Pediatrics	<b>Street Address, City, State</b>  888 Tara Blvd, Baton Rouge, LA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Recertification survey was performed on February 15, 2022 at Red Stick Pediatrics, CLIA ID # 19D1079564. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of manufacturer's instructions, test menu, and interview with personnel, the laboratory failed to include "Fact Sheets" to patients for Emergency Use Authorization (EUA) SARS COV-2 testing. Findings: 1. Observation by surveyor during laboratory tour on February 16, 2022 at 9:16 am revealed the laboratory utilizes the Quidel Sofia 2 SARS Ag and the Quidel Sofia 2 Flu + SARS Ag test systems for SARS CoV-2 patient testing. 2. Review of the manufacturer's instructions for use under the "Conditions of Authorization for the Laboratory" section revealed "Authorized laboratories using your product must include with test result reports, all authorized Fact Sheets. Under extingent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." 3. In interview on February 16, 2022 at 11:30 am, Personnel 2 stated that she was unaware that a fact sheet must be provided to patients with waived testing. Personnel 2 confirmed the laboratory does not include fact sheets upon patient testing.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p>

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures and interview with personnel, the laboratory failed to have a complete policy and procedure manual.

Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not include a policy stating written, detailed instructions for the reporting of SARS CoV-2 test results to the state public health agency, to include but not limited to who is responsible for reporting test results and the frequency at which reporting is performed. 2. In interview on February 16, 2022 at 11:30 am, Personnel 2 stated she was unaware the laboratory needed a policy for SARS CoV-2 reporting of test results to state agency. Personnel 2 confirmed the laboratory did not have the above identified policy.

**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 review of laboratory policy and procedure manual and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401.