

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D0464339	(X3) Date Survey Completed 01/14/2022
Name of Provider or Supplier Steven Unkel Md	Street Address, City, State 811 James Ave, Farmerville, LA	
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	A Recertification survey was performed on January 14, 2022 at Steven Unkel, MD, CLIA ID # 19D0464339. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D1001	<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 January 14, 2022 at 9:10 am revealed the laboratory utilizes the Quidel Sofia SARS-CoV-2 test system 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 January 14, 2022 at 10:23 am, Personnel 1 stated that she was unaware that a fact sheet must be provided to patients with waived testing. Personnel 1 confirmed the laboratory does not include fact sheets upon patient testing.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the</p>

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 January 14, 2022 at 10:23 am, Personnel 1 stated she was unaware the laboratory needed a policy for SARS CoV-2 reporting of test results to state agency. Personnel 1 confirmed the laboratory did not have the above identified policy.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
Based on direct observation by surveyor, review of laboratory policy and procedure and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration date. Findings: 1. Direct observation by surveyor during the laboratory tour on January 14, 2022 at 9:10 am revealed the following expired supplies located on a phlebotomy tray: a) BD vacutainer SST 8.5 mL tubes: Lot 0301417, Expiration 10/31/2021, Quantity: nine (9) 2. Review of the laboratory's policy "Expired Lab Supplies" revealed "When and if any supplies expire we have made a box to put it in and give to the schools that are in need of supplies". 3. In interview on January 14, 2022 at 9:53 am, Personnel 1 stated that she was unaware some of the tubes on the phlebotomy tray were expired. Personnel 1 confirmed the above identified supplies were expired.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on observation during laboratory tour, review of laboratory records and

interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417.

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.