

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0710641	<b>(X3) Date Survey Completed</b>  10/31/2022
<b>Name of Provider or Supplier</b>  Albert G Kerr Md	<b>Street Address, City, State</b>  121 Christian Drive, Rayville, 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 October 31, 2022 at Albert Kerr MD, CLIA ID # 19D0710641. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <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.</p> <p>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 October 31, 2022 at 03:00 pm, the Laboratory Director confirmed the laboratory did not include the above identified policy.</p>
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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</p>

use.

This STANDARD is not met as evidenced by:

Based on observation by surveyor, review of manufacturer instructions, and interview with personnel, the laboratory failed to label hematology controls with updated expiration dates after opening. Findings: 1. Observation by surveyor during the laboratory tour on October 31, 2022 at 1:20 pm revealed the laboratory stored open Coulter 4C-ES Cell Control for Hematology testing (Lot Number: Low 068800, Normal 078800, High 088800; Expiration date 01/02/2023) in a refrigerator without labeling with the "open" and updated "expiration" dates. 2. Review of the Coulter 4C-ES Cell Control manufacturer's instructions under the "Storage, Stability, and Disposal" section revealed "For opened vial stability, refer to the Table of Expected Results for your system. Open vial stability 35 days". 3. In interview on October 31, 2022 at 2:40 pm, the Laboratory Director confirmed the laboratory did not label the in-use hematology control vials with "open" and "expiration" dates.

**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 by surveyor, review of manufacturer's instructions, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5415.

**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. Refer to D5401.