

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2180876	(X3) Date Survey Completed 04/28/2021
Name of Provider or Supplier River Road Testing Laboratory	Street Address, City, State 6400 Perkins Road, Office L1016, Lab C2008, Baton Rouge, 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 April 27-28, 2021 at River Road Testing Laboratory, CLIA ID # 19D2180876. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5401	<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 record review and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's manual revealed the laboratory did not have written polices and procedures for the following: a) Temperature and humidity monitoring of the laboratory to include documentation of the monitoring system in place, process for alerting if out of range and acceptable ranges to meet all manufacturer instructions. b) Process for verifying each new lot number of reagents or quality control prior to patient testing. 2. In interview on April 27, 2021 at 10:53 am, the laboratory personnel confirmed the laboratory policy and procedure manual did not detail the current practices in place.</p>
D6031	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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 record review and interview with personnel, the Laboratory Director failed to ensure an approved policy and procedure manual was available to all personnel.

Refer to D5401