

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D2187966	<b>(X3) Date Survey Completed</b>  07/21/2021
<b>Name of Provider or Supplier</b>  Lsu School Of Vet Med, La Animal Disease Diag Lab	<b>Street Address, City, State</b>  River Road Room 1043, 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>	An initial certification survey was performed on July 21, 2021 at LSU School of Vet Med, dba LA Animal Disease Diag Laboratory, CLIA ID # 19D2189766. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</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 complete policies for performance</p>

	<p>specifications, calibration and specimen stability. Findings: 1. Review of the laboratory's policies revealed the laboratory did not contain detailed instructions for the following: a) Frequency of calibration, acceptability criteria and who is responsible b) Complete precision for performance specifications prior to patient testing, acceptable criteria and responsible party c) Specimen acceptability and rejection to include consistency throughout all policies 2. In interview on July 21, 2021 at 11:56 am, laboratory personnel confirmed the laboratory policies did not specifically address the above practices within the laboratory.</p>
<p><b>D5421</b></p>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p> <p>This STANDARD is not met as evidenced by: Based on observation, review of verification studies, and interview with laboratory personnel, the laboratory failed to verify complete precision on Quant Studio 5 for SARS-CoV-2. Findings: 1. Observation by surveyor during laboratory tour on July 21, 2021 at 10:00 am revealed the laboratory utilizes one (1) Quant Studio 5 analyzer for SARS-CoV-2 testing in on site. 2. Review of the laboratory's performance verification studies revealed the laboratory performed simple precision but did not include day to day, run to run, within run or operator variance. 3. In interview on July 21, 2021 at 10:15am, the testing personnel stated the laboratory utilized the CMS CLIA brochure for performance specifications and understood that for qualitative testing, only simple precision to be required. The laboratory personnel confirmed the verification of performance specifications did not include complete precision.</p>
<p><b>D6013</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(ii)</p> <p>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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method;</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to verify complete precision on Quant Studio 5 for SARS-CoV-2. Refer to D5421.</p>
<p><b>D6031</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(13)</p>

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 record review and interview with personnel, the Laboratory Director failed to ensure a complete policy and procedure manual was available to all personnel. Refer to D5403.