

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0464339	<b>(X3) Date Survey Completed</b>  12/27/2023
<b>Name of Provider or Supplier</b>  Steven Unkel Md	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Certification survey was performed on December 27, 2023 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.
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory proficiency testing records and interview with personnel, the laboratory failed to ensure the appropriate personnel signed the attestation forms for four (4) of six (6) proficiency testing events reviewed. Findings: 1. Review of the laboratory's American Association of Bioanalysts (AAB) proficiency testing records revealed the laboratory director and testing personnel did not sign the attestation statement for the following four (4) of six (6) proficiency testing events reviewed in 2022 and 2023: a) NonChemistry Q1 2022 - Testing Personnel signature on attestation statement b) NonChemistry Q2 2022 - Laboratory Director and Testing Personnel signature on attestation statement c) NonChemistry M1 2023 - Laboratory Director signature on attestation statement d) NonChemistry M2 2023 - Laboratory Director and Testing Personnel signature on attestation statement 2. In interview on</p>

	<p>December 27, 2023 at 11:21 am, Personnel 1 confirmed the attestation statement was not signed for the identified proficiency testing events.</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by: Based on observation by surveyor, review of maintenance records and interview with personnel, the laboratory failed to ensure the monthly maintenance on the Sysmex XP-300 analyzer was performed as required by the manufacturer. Findings: 1. Observation by surveyor during the laboratory tour on December 27, 2023 at 10:30 am revealed the laboratory utilizes a Sysmex XP-300 analyzer for Complete Blood Count (CBC) testing in the specialty of Hematology. 2. Review of the laboratory's Sysmex XP-300 maintenance log revealed the laboratory performs the following monthly maintenance: a) Clean RBC and WBC Transducer b) Clean Waste Chamber 3. Further review of the maintenance logs from May 2022 through December 2023 revealed the laboratory did not perform the monthly maintenance for the following four (4) of twenty (20) months reviewed: a) May 2022 b) June 2022 c) January 2023 d) June 2023 4. In interview on December 27, 2023 at 11:21 am, Testing Personnel 1 confirmed the monthly maintenance was not performed for the identified months above.</p>
<p><b>D6014</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(iii)</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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory maintenance records and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5429.</p>
<p><b>D6018</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(iii)</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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;</p>

This STANDARD is not met as evidenced by:  
Based on review of laboratory proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency testing attestation statements were signed by the appropriate personnel. Refer to D2015.

**D6036**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory.

This STANDARD is not met as evidenced by:  
Based on review of laboratory maintenance records and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5429.