

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  19D0672493	<b>(X3) Date Survey Completed</b>  07/26/2023
<b>Name of Provider or Supplier</b>  Christus Central Louisiana Surgical Hospital	<b>Street Address, City, State</b>  651 North Bolton Avenue, Alexandria, 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 July 25, 2023 through July 26, 2023 at Central Louisiana Surgical Hospital, CLIA ID # 19D0672493. 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 the laboratory's proficiency testing records and interview with personnel, the laboratory failed to ensure the Laboratory Director signed the attestation forms for one (1) of four (4) proficiency testing events reviewed. Findings: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the laboratory director did not sign the following document for one (1) of four (4) proficiency testing events reviewed in 2022 and 2023: a. 2022 Immunology/Immunohematology 2nd event: Laboratory Director/designee no signature on attestation 3. In interview on July 25, 2023 at 12:55 pm, General Supervisor 1 confirmed the identified attestation statement was not signed by the laboratory director.</p>

**D5429**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(1)

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.

This STANDARD is not met as evidenced by:

I. Based on observation by surveyor, review of maintenance records and interview with personnel, the laboratory failed to ensure the weekly maintenance on the Sysmex CA-600 analyzer was performed as required by the manufacturer for two (2) of eighty (80) weeks reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 25, 2023 at 11:07 am revealed the laboratory utilizes a Sysmex CA-600 analyzer for coagulation testing. 2. Review of the laboratory's CA 620 maintenance records for 2022 and 2023 revealed the laboratory performs the following weekly tasks: a) Clean CA620 Interior/Exterior 3. Further review of the CA 620 maintenance records revealed the laboratory did not perform weekly maintenance for the following two (2) of eighty (80) weeks reviewed: a) June 10, 2022 b) June 2, 2023 4. In interview on July 26, 2023 at 1:15 pm, General Supervisor 1 confirmed the weekly maintenance identified was not performed. II. Based on observation by surveyor, review of maintenance records and interview with personnel, the laboratory failed to ensure the semi-annual maintenance on the TOSOH AIA 360 analyzer was performed as required by the manufacturer for 2022 and 2023. Findings: 1. Observation by surveyor during the laboratory tour on July 25, 2023 at 11:07 am revealed the laboratory utilizes the TOSOH AIA 360 analyzer for the following tests: Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH), Testosterone (TEST), Intact Parathyroid Hormone 2. Review of the laboratory's TOSOH AIA 360 maintenance records revealed the laboratory performs the following semi-annual maintenance: a) Decontaminate diluent wash tubing lines b) Replace filter diluent and wash bottle 3. Further review of the TOSOH maintenance records from 2022 and 2023 revealed the laboratory did not perform the following maintenance semi-annually: a) April 2022 b) March 2023 4. In interview on July 26, 2023 at 1:15pm, General Supervisor stated that service representatives perform the semi-annual maintenance when they are onsite for preventive maintenance (PM) but he could not find the documentation that states from the manufacturer. General Supervisor 1 confirmed the above identified maintenance was not performed.

**D6018**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(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)(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;

This STANDARD is not met as evidenced by:

Based on review of the laboratory's proficiency testing records and interview with personnel, the Laboratory Director failed to ensure proficiency testing evaluations

were maintained and signed by the Laboratory Director. Findings: 1. The laboratory failed to ensure the Laboratory Director signed the attestation forms for one (1) of four (4) proficiency testing events reviewed. Refer to D2015.

**D6023**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on review of laboratory policy and records as well as interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to ensure the weekly maintenance on the Sysmex CA-600 analyzer was performed as required by the manufacturer for two (2) of eighty (80) weeks reviewed. Refer to D5429 I. 2. The laboratory failed to ensure the semi-annual maintenance on the TOSOH AIA 360 analyzer was performed as required by the manufacturer for 2022 and 2023. Refer to D5429 II.