Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0672493	05/21/2025
Name of Provider or Supplier	**Street Address, City, State**	
Christus Central Louisiana Surgical Hospital	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was performed on May 20, 2025 through May 21, 2025 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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) 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. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policies, and interview with personnel, the laboratory failed to follow their policy for centrifugation of coagulation specimens for one (1) of one (1) centrifuges utilized for centrifugation of coagulation specimens. Findings: 1. Observation by surveyor during the laboratory tour on May 20, 2025 at 8:45 a.m. revealed the laboratory utilized the Hettich EBA 200 centrifuge for centrifugation of coagulation specimens. 2. In interview on May 20, 2025 at 9:10 a. m., the Laboratory Manager stated the laboratory spins samples for coagulation testing at a speed of 6000 RPM for two (2) minutes. 3. Review of the laboratory's policy "Testing Menu and Collection Requirements" revealed the following instructions for centrifugation of coagulation specimens: * Test: Protime/APTT - Specimen Requirements: Blue Top Citrated plasma (Spin at 4250 RPM/2520 G for 15 min) 4. In interview on May 20, 2025 at 4:23 p.m., the Laboratory Manager confirmed the laboratory did not follow their policy for centrifugation of coagulation specimens.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

	CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on observation, review of manufacturers' instructions and laboratory temperature records, as well as interview with personnel, the laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the frozen section room. Findings: 1. Observation by surveyor during the laboratory tour on May 21, 2025 at 9:53 a.m. revealed the laboratory stored supplies in the frozen section room at room temperature to include, but not limited to, the following: a) CDI's Tissue Marking Dyes Black - Manufacturer's storage requirements 15 to 30 degrees Celsius b) Epredia Cytoseal XYL - Manufacturer's storage requirements 15 to 30 degrees Celsius c) Epredia Eosin-Y - Manufacturer's storage requirements 15 to 30 degrees Celsius 2. Review of the laboratory's May 2025 room temperature records for the frozen room revealed the laboratory defined the acceptable room temperature limits as 18 - 35 degrees Celsius which exceeded the manufacturers' upper temperature limits. 3. In interview on May 21, 2025 at 10:00 a.m., the Laboratory Manager confirmed the laboratory's acceptable room temperature limits for the frozen room exceeded the manufacturers' limits as identified above. II. Based on observation, review of the manufacturers' storage requirements and laboratory temperature records, as well as interview with personnel, the laboratory failed to monitor the room temperature for two (2) of five (5) rooms where laboratory supplies are stored. Findings: 1. Observation by surveyor during the laboratory tour on May 21, 2025 at 9:53 a.m. revealed the following supplies stored in two (2) draw rooms: a) Pre-Admission Testing Draw Room * BD Vacutainer SST Blood Collection Tubes - Manufacturer's storage requirements 4 to 25 degrees Celsius * BD Vacutainer K2E - Manufacturer's storage requirements 4 to 25 degrees Celsius * BD Vacutainer Buffered Sodium Citrate - Manufacturer's storage requirements 4 to 25 degrees Celsius * BD Vacutainer Lithium Heparin - Manufacturer's storage requirements 4 to 25 degrees Celsius * Greiner bio-one vacuette K3E K3EDTA - Manufacturer's storage requirements 4 to 25 degrees Celsius b) Outpatient Lab Draw Room * BD Vacutainer SST Blood Collection Tubes - Manufacturer's storage requirements 4 to 25 degrees Celsius * BD Vacutainer K2E - Manufacturer's storage requirements 4 to 25 degrees Celsius * BD Vacutainer Buffered Sodium Citrate - Manufacturer's storage requirements 4 to 25 degrees Celsius * BD Vacutainer Lithium Heparin - Manufacturer's storage requirements 4 to 25 degrees Celsius * Greiner bio-one vacuette K3E K3EDTA - Manufacturer's storage requirements 4 to 25 degrees Celsius 2. Review of laboratory temperature records revealed no documentation of room temperature monitoring for the draw room. 3. In interview on May 23, 2025 at 9:55 a.m., the Laboratory Manager confirmed the laboratory did not monitor the room temperature of the draw rooms as identified above.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g)

	(f) Results of control materials must meet the laboratorys and, as applicable, the manufacturers test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and quality control (QC) records as well as interview with personnel, the laboratory failed to ensure quality control mean/range adjustments were documented for Endocrinology testing. Findings: 1. Review of the laboratory's policies revealed the laboratory had a quality control policy which included establishment of means/ranges, but did not include adjusting the established means/ranges to include, but not limited, criteria for adjustments and documentation. 2. Review of the laboratory's quality control form "New QC Ranges" revealed the laboratory established the following ranges for QC BioRad Lot 85380 for Prostate Specific Antigen (PSA), Thyroid Stimulating Hormone (TSH) and Testosterone: a) PSA: Level 1: 0.21 - 0.33 Level 3: 17.66 - 22.18 b) TSH: Level 1: 0.69 - 0.93 Level 3: 28.82 - 37.14 c) Testosterone: Level 1: 92.5 - 130.5 Level 3: 1031.3 - 1183.3 3. Further review of the QC lot establishment records for BioRad Lot 85380 revealed the laboratory put the above ranges into use on September 30, 2024. 4. Review of the laboratory's QC records from January 2025 revealed the following means/ranges for BioRad Lot 85380: a) PSA: Level 1: 0.19 - 0.31 Level 3: 16.94 - 22.46 b) TSH: Level 1: 0.68 - 0.92 Level 3: 30.30 - 38.62 c) Testosterone: Level 1: 85.3 - 123.3 Level 3: 1076 - 1228 5. Further review of the laboratory's January 2025 QC records revealed the ranges for BioRad Lot 85380 were different than the established ranges from September 2024, but the laboratory did not document the reason for the adjusted ranges. 6. In interview on May 21, 2025 at 11:15 a.m., the Laboratory Manager stated he calculates new means/ranges monthly utilizing the QC data points from the month and the laboratory's historical standard deviations (SD). He confirmed the laboratory did not have a policy that included adjustments to the laboratory's established quality control ranges.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D5401.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by:

	Based on record review and interview with personnel, the Laboratory Director failed to ensure that quality programs were in place to assure quality laboratory testing. Refer to D5481.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D5401.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultant failed to ensure the quality control program was maintained to assure the quality of laboratory testing. Refer to D5481.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (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, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the frozen section room. Refer to D5413 I. 2. The laboratory failed to monitor the room temperature for two (2) of five (5) rooms where laboratory supplies are stored. Refer to D5413 II.
D6144	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463 The general supervisor is responsible for day-to-day supervision or oversight of the laboratory operation and personnel performing testing and reporting test results.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the General Supervisors failed to provide day-to-day supervision to testing personnel to ensure accurate and reliable test performance of laboratory testing. Findings: 1. The laboratory failed to define acceptable room temperature limits within the manufacturers' required ranges for supplies stored in the frozen section room. Refer to D5413 I. 2. The laboratory failed to monitor the room temperature for two (2) of five (5) rooms where laboratory supplies are stored. Refer to D5413 II.