Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0672493	11/16/2021
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 Certification Survey was performed at Christus Central La Surgical Hospital - CLIA # 19D0672493 on November 15, 2021 through November 16, 2021. Christus Central La Surgical Hospital was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR 493.1409 CONDITION: Laboratories Performing Moderate Complexity Testing; Technical Consultant
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: ***Repeat deficiency from survey on May 21, 2019*** I. Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to ensure the personnel competency policy included the frequency of performance for the Technical Consultant and General Supervisor. Findings: 1. Review of the laboratory's policy "Competency" revealed the laboratory did not include the frequency of performance for assessment of duties for the Technical Consultant and General Supervisor. 2. In interview on November 15, 2021 at 1:29 pm, General Supervisor 1 confirmed the policy did not include the frequency of assessment for the Technical Consultant and General Supervisor. II. Based on review of the laboratory's policy and procedure manual, CMS 209 form, Employee Competency Assessment form, and personnel records as well as interview with personnel, the laboratory failed to follow their established competency assessment policy for one (1) of five (5) testing personnel reviewed. Findings: 1. Review of the laboratory's "Competency" policy revealed "Employee competency will be assessed at

	initial hire, at 6 months of employment, 1 year of employment, and annually thereafter". 2. Review of the laboratory's CMS 209 form (Laboratory Personnel Report) revealed that Personnel 2 serves as Technical Consultant, General Supervisor and Testing Personnel. 3. Review of the laboratory's Employee Competency Assessment form for Personnel 2 from 2019, 2020, and 2021 revealed the laboratory did not perform a competency assessment for the duties of Testing Personnel. 4. In interview on November 15, 2021 at 1:29 pm, General Supervisor 1 stated that he was unsure who should perform the testing personnel competency assessment since he also serves as General Supervisor and Technical Consultant. General Supervisor confirmed that a competency assessment for his duties of testing personnel was not performed for the identified years.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of laboratory records, and interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to ensure the policy and procedure manual contained complete policies and procedures. Refer to D5403. 2. The laboratory failed to ensure patient samples for Arterial Blood Gas testing are analyzed within fifteen (15) minutes according to the manufacturer for one (1) of thirteen (13) patient reviewed from August 2020 through October 2021. Refer to D5411. 3. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 4. The laboratory failed to take corrective action when Quality Control (QC) values were unacceptable for Coagulation testing as required by laboratory policy. Refer to D5783. 5. The laboratory's quality assessment monitors failed to correct issues identified within the analytic system. Refer to D5793.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) 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. This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual and interview with personnel, the laboratory failed to have a complete Quality Control procedure. Findings: 1. Review of the laboratory's policy and procedure revealed the laboratory did not include detailed, written instructions to include, but not limited to: a) Actions for testing personnel to take when quality control results are unacceptable and do not meet the laboratory's criteria for acceptability 2. In interview on November 16, 2021 at 11:00 am, General Supervisor confirmed the laboratory did include the above identified policy.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: *** Repeat Deficiency from survey on May 22, 2019*** Based on observation by surveyor , review of manufacturer's operator manual, patient records and interview with personnel, the laboratory failed to ensure patient samples for Arterial Blood Gas testing are analyzed within fifteen (15) minutes according to the manufacturer for one (1) of thirteen (13) patient reviewed from August 2020 through October 2021. Findings: 1. Observation by surveyor during the laboratory tour on November 15, 2021 at 11:45 am revealed the laboratory performs Arterial Blood Gas (ABG) testing on the Nova Biomedical Stat Profile Prime Plus analyzer. 2. Review of the Nova Biomedical Stat Profile Prime Plus operator's manual under "Handling Requirements" revealed "Nova Biomedical recommends that you analyze the sample within 15 minutes for blood gases". 3. Review of patient records from August 2020 through October 2021 revealed the laboratory did not perform patient samples for ABG testing within the fifteen (15) minutes recommended by the manufacturer for one (1) of thirteen (13) patients reviewed: a) Patient ID 00127712: collected May 6, 2021 at 8:28 am then resulted May 6, 2021 at 9:22 am - thirty-nine (39) minutes over the manufacturer's recommendation of fifteen (15) minutes 4. In interview on November 16, 2021 at 2:42 pm, General Supervisor 1 confirmed the above patient was not analyzed within the recommended fifteen (15) minutes per manufacturer. 5. Review of the task 1&3 form provided to surveyor revealed the laboratory performs thirteen (13) ABG tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: ***Repeat deficiency from survey on November 15, 2021*** Based on direct observation by surveyor, laboratory's policy and procedure, and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration date. Findings: 1. Direct observation by surveyor during the laboratory tour on November 15, 2021 at 11:51 am revealed the following expired supplies located on a red phlebotomy tray: a) Lithium Heparin microtube, Lot PO72711, Expiration 07/21, Quantity: one (1) b) BD Vacutainer K2 EDTA tube, Lot 9220483, Expiration 01/31 /21, Quantity: one (1) c) BD Vacutainer K2 EDTA tube, Lot 0100284, Expiration 09 /30/21, Quantity: one (1) 2. Review of the laboratory's policy "Inventory Control and Management" revealed "Materials and reagents with defined expiration dates will not be utilized beyond the specified expiration date. Stock should be rotated to minimize the loss of materials and reagents due to expiration. Expired reagents and materials will be disposed". 3. In interview on November 15, 2021 at 11:51 am, General Supervisor 1 confirmed the identified supplies were expired.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory's policy and procedures and quality control records as well as interview with personnel, the laboratory failed to take corrective action when Quality Control (QC) values were unacceptable for Coagulation testing as required by laboratory policy. Findings: 1. Observation by surveyor during the laboratory tour on November 15, 2021 at 10:45 am revealed the laboratory utilizes the Siemens Sysmex CA-620 analyzer along with the Citrol I and III quality control materials for the following Coagulation testing: a) Prothrombin Time (PT) b) Activated Partial Thromboplastin Time (APTT) 2. Review of the laboratory policy "Troubleshooting QC" under "Coagulation" revealed the following: a) Coagulation controls Ci-TROL 1 and Ci-TROL 3 are run at the start of each day of operation and every 8 hours of patient testing b) Values obtained for Citrol levels I and III should be evaluated and meet defined criteria in CL-003 Quality Control policy prior to accepting patient results. c) If the controls are deemed unacceptable for patient testing, perform the following: * Rerun controls * Make up new control and/or reagents * Open new bottles of reagents * Check or change distilled water to fresh * Call Siemens Technical Service 1-800-242-3233 * Document out of control and corrective actions taken using form CL-076 Out of Control Log 3. Review of quality control (QC) records for the Sysmex CA-620 Coagulation analyzer revealed the laboratory did not take corrective action when QC results were unacceptable for the following three (3) of four (4) months reviewed in 2020 and 2021: a) September 10, 2020 at 13:48 pm: APTT Ci-TROL I QC reported as 27.9 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 500406262: reported APTT on September

	10, 2020 at 14:13 pm * Patient ID 500406276: reported APTT on September 10, 2020 at 15:51 pm b) September 11, 2020 at 6:07 am: APTT Ci-TROL I QC reported as 28.0 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 600406384: reported APTT on September 11, 2020 at 11:58 am c) September 15, 2020 at 13:54 pm: APTT Ci-TROL III QC reported as 60.6 seconds (acceptable range noted as 54.0 sec - 60.4 sec) * Patient ID 3004066790: reported APTT on September 15, 2020 at 11: 23 am d) September 17, 2020 at 6:08 am: APTT Ci-TROL I QC reported as 28.2 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 500407258: reported APTT on September 17, 2020 at 13:03 pm e) September 21, 2020 at 13:55 pm: APTT Ci-TROL I QC reported as 27.9 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 200407695: reported APTT on September 21, 2020 at 15: 18 pm f) September 22, 2020 at 13:38 pm: APTT Ci-TROL I QC reported as 27.9 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 300407862: reported APTT on September 22, 2020 at 15:35 pm g) September 23, 2020 at 5:56 am: APTT Ci-TROL I QC reported as 28.0 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 400407979: reported APTT on September 23, 2020 at 11: 41 am * Patient ID 400407994: reported APTT on September 23, 2020 at 12:20 pm * Patient ID 400408004: reported APTT on September 23, 2020 at 13:37 pm h) September 23, 2020 at 13:52 pm: APTT Ci-TROL III QC reported as 60.6 seconds (acceptable range noted as 54.0 sec - 60.4 sec) i) October 1, 2020 at 6:11 am: APTT Ci-TROL I QC reported as 28.1 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 500409025: reported APTT on October 1, 2020 at 10:25 am * Patient ID 500409038: reported APTT on October 1, 2020 at 11:08 am j) October 1, 2020 at 13:31 pm: APTT Ci-TROL I QC reported as 28.0 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 500409076: reported APTT on October 1, 2020 at 16:28 pm k) October 7, 2020 at 13:39 pm: APTT Ci-TROL I QC reported as 28.0 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 400409711: reported APTT on OCtober 7, 2020 at 13:52 pm l) October 7, 2020 at 13:41 pm: APTT Ci-TROL III QC reported as 61.0 seconds (acceptable range noted as 54.0 sec - 60.4 sec) * Patient ID 400409711: reported APTT on OCtober 7, 2020 at 13:52 pm m) October 8, 2020 at 13:31 pm: APTT Ci-TROL I QC reported as 28.3 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 500409937: reported APTT on October 8, 2020 at 14:07 pm * Patient ID 500409946: reported APTT on October 8, 2020 at 15:02 pm n) October 9, 2020 at 6:08 am: APTT Ci-TROL I QC reported as 28.1 seconds (acceptable range noted as 25.8 sec - 27.8 sec) * Patient ID 600410026: reported APTT on October 9, 2020 at 6:21 am o) September 22, 2021 at 13:46 pm: PT Ci-TROL I QC reported as 10.7 seconds (acceptable range noted as 9.8 sec - 10.6 sec) * Patient ID 400453116: reported PT on September 22, 2021 at 15:07 pm * Patient ID 400453108: reported PT on September 22, 2021 at 15:09 pm * Patient ID 400453131: reported PT on September 22, 2021 at 16:47 pm p) September 30, 2021 at 13:49 pm: PT Ci-TROL I QC reported as 10.7 seconds (acceptable range noted as 9.8 sec - 10.6 sec) * Patient ID 500454190: reported PT on September 30, 2021 4. In interview on November 16, 2021 at 11:00 am, General Supervisor 1 stated that the acceptable range for QC should fall within +/- 2SD. General Supervisor 1 further stated that if QC results are unacceptable then testing personnel should repeat the QC and follow the troubleshooting policy. 5. In further interview on November 16, 2021 at 11:00 am, General Supervisor 1 confirmed the above identified QC was not within 2SD and that no troubleshooting actions had been performed. 6. Review of the task 1 and 3 form provided to surveyor revealed the laboratory performs 902 PT tests annually and 739 APTT tests annually.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)

	(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory records and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified within the analytic system. Findings: 1. The laboratory failed to ensure patient samples for Arterial Blood Gas testing are analyzed within fifteen (15) minutes according to the manufacturer for one (1) of thirteen (13) patient reviewed from August 2020 through October 2021. Refer to D5411. 2. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 3. The laboratory failed to take corrective action when Quality Control (QC) values were unacceptable for Coagulation testing as required by laboratory policy. Refer to D5783.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of laboratory records, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure laboratory personnel performed testing as required. Refer to D6014. 2. The Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D6021. 3. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 4. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6030. 5. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(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)(3) Ensure that-- (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 by surveyor, review of laboratory records, and interview with

	personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to ensure patient samples for Arterial Blood Gas testing are analyzed within fifteen (15) minutes according to the manufacturer for one (1) of thirteen (13) patient reviewed from August 2020 through October 2021. Refer to D5411. 2. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory's records, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D5783.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Findings: 1. The laboratory failed to ensure the personnel competency policy included the frequency of performance for the Technical Consultant and General Supervisor. Refer to D5209 I. 2. The laboratory failed to follow their established competency assessment policy for one (1) of five (5) testing personnel reviewed. Refer to D5209 II.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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 review of laboratory records and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyor, review of laboratory records, and interview with personnel, the Technical Consultant failed to provide technical oversight of the laboratory for moderate complexity testing. Findings: 1. The Technical Consultant failed to provide technical and scientific oversight to the laboratory. Refer to D6036. 2. The Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D6044.
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 observation by surveyor, review of laboratory records and interview with personnel, the Technical Consultant failed to provide technical and scientific

	oversight to the laboratory. Findings: 1. The laboratory failed to ensure patient samples for Arterial Blood Gas testing are analyzed within fifteen (15) minutes according to the manufacturer for one (1) of thirteen (13) patient reviewed from August 2020 through October 2021. Refer to D5411. 2. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417.
D6044	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(6) (b) The technical consultant is responsible for-- (b)(6) Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly; This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with personnel, the Technical Consultant failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.