Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0672493	05/22/2019
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 conducted at Central Louisiana Surgical Hospital-CLIA ID # 19D0672493 on May 22, 2019 through May 23, 2019. The laboratory was found in compliance with 42 CFR 493 Requirement for Laboratories; however, standard deficiencies were cited.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on observation, record review and interview with personnel, the laboratory failed to follow the manufacturer's requirements for testing of samples in waived chemistry testing. Findings: 1. Observation by the surveyor on May 21, 2019 during the laboratory tour revealed the laboratory utilized the Abbott i-Stat analzer and the Abbott i-Stat G3+ cartridge for a Basic Metabolic Panel (BMP) testing to include the following tests: Calcium (CA), Blood Urea Nitrogen (BUN), Creatinine (CREA), Glucose (GLUC), Sodium (NA), Potassium (K), Chloride (CL), and Carbon Dioxide (CO2) 2. Review of the Abbott i-Stat operator's manual revealed under "Venous Specimens" to "Test Sample collected without anticoagulant immediately. Test sample for pH, pCO2, and ionized calcium within 10 minutes of sample draw. If not tested immediately, remix the sample before testing and discard the first two drops of blood from a syringe before testing. For other cartridge tests, test sample within 30 minutes of collection". 3. Review of patient records from February 10, 2019 through February 16, 2019 revealed the laboratory did not test patient samples for BMP testing within thirty (30) minutes as required by the manufacturer for the following thirteen (13) of fifty eight (58) patients reviewed: On February 11, 2019, Patient 310034 was collected at 11:00 am and resulted at 11:38 am (which is 8 minutes over the

	manufacturer's requirement of 30 minutes) On February 11, 2019, Patient 310764 was collected at 14:08 pm and resulted at 14:50 pm (which is 12 minutes over the manufacturer's requirement of 30 minutes) On February 11, 2019, Patient 310783 was collected at 15:14 pm and resulted at 15:52 pm (which is 8 minutes over the manufacturer's requirement of 30 minutes) On February 12, 2019, Patient 310401 was collected at 06:00 am and resulted at 06:52 am (which is 22 minutes over the manufacturer's requirement of 30 minutes) On February 12, 2019, Patient 310559 was collected at 05:45 am and resulted at 06:33 am (which is 18 minutes over the manufacturer's requirement of 30 minutes) On February 12, 2019, Patient 310068 was collected at 07:30 am and resulted at 08:11 am (which is 11 minutes over the manufacturer's requirement of 30 minutes) On February 12, 2019, Patient 310061 was collected at 11:00 am and resulted at 11:45 am (which is 15 minutes over the manufacturer's requirement of 30 minutes) On February 13, 2019, Patient 311059 was collected at 11:15 am and resulted at 11:50 am (which is 5 minutes over the manufacturer's requirement of 30 minutes) On February 13, 2019, Patient 311136 was collected at 15:36 pm and resulted at 16:18 pm (which is 12 minutes over the manufacturer's requirement of 30 minutes) On February 14, 2019, Patient 310465 was collected at 05:55 am and resulted at 06:40 am (which is 15 minutes over the manufacturer's requirement of 30 minutes) On February 14, 2019, Patient 311231 was collected at 10:56 am and resulted at 11:37 am (which is 11 minutes over the manufacturer's requirement of 30 minutes) On February 14, 2019, Patient 311305 was collected at 12:43 pm and resulted at 13:26 pm (which is 13 minutes over the manufacturer's requirement of 30 minutes) On February 15, 2019, Patient 310465 was collected at 06:20 am and resulted at 06:56 am (which is 6 minutes over the manufacturer's requirement of 30 minutes) 4. In interview on May 22, 2019 at 04:25 pm, the General Supervisor confirmed the laboratory did not test the above patients within the thirty (30) minutes according to the manufacturer.
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: Based on record review and interview with personnel, the laboratory failed to ensure written policies and procedures to address competency for Technical Consultant and General Supervisor were complete. Findings: 1. Review of the laboratory's CMS-209 form (Laboratory Personnel Report) revealed the following personnel positions: a) Personnel 2 serves as the Technical Consultant and General Supervisor b) Personnel 3 serves as the General Supervisor 2. Review of the laboratory's policy and procedure manual revealed the laboratory did not include competency assessment criteria or frequency for personnel serving as Technical Consultant and General Supervisor. 3. Review of personnel records for Personnel 2 revealed the laboratory did not perform a competency assessment for the duties of Technical Consultant and General Supervisor. 4. Review of personnel records for Personnel 3 revealed the laboratory did not perform a competency assessment for the duties of General Supervisor. 5. In interview on May 22, 2019 at 10:55 am, Personnel 2 confirmed the laboratory did not have a policy for competency assessment and did not perform competency assessments for the duties of Technical Consultant and General Supervisor.

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: I. Based on observation, record review and interview with personnel, the laboratory failed to ensure patient samples for Arterial Blood Gas testing are analyzed within ten (10) minutes according to the manufacturer for seven (7) of fifteen (15) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on May 21, 2019 revealed the laboratory was performing Arterial Blood Gas (ABG) testing on the Abbott i-Stat Clinical analyzer. 2. Review of the Abbott i-STAT operator's manual under "Arterial Specimens" revealed "Test sample collected without anticoagulant immediately. For pH, blood gases and ionized calcium, test within 10 minutes of collection". 3. Review of patient records from January 1, 2018 through May 22, 2019 revealed the laboratory did not perform patient samples for ABG testing within ten (10) minutes according to manufacturer for seven (7) of fifteen (15) patients reviewed: Patient 265100 - Collected January 18, 2018 at 11:38 am then resulted January 18, 2018 at 11:53 am - five (5) minutes over the manufacturer's requirement of ten (10) minutes Patient 276536 - Collected April 25, 2018 at 14:15 pm then resulted April 25, 2018 at 15:07 pm - forty two (42) minutes over the manufacturer's requirement of ten (10) minutes Patient 276536 - Collected April 25, 2018 at 14:55 pm then resulted April 25, 2018 at 15:14 pm - nine (9) minutes over the manufacturer's requirement of ten (10) minutes Patient 276536 - Collected April 25, 2018 at 14:40 pm then resulted April 25, 2018 at 15:10 pm - twenty (20) minutes over the manufacturer's requirement of ten (10) minutes Patient 276536 - Collected April 25, 2018 at 14:50 pm then resulted April 25, 2018 at 15:12 pm - twelve (12) minutes over the manufacturer's requirement of ten (10) minutes Patient 305474 - Collected December 31, 2018 at 16: 20 pm then resulted December 31, 2018 at 16:46 pm - sixteen (16) minutes over the manufacturer's requirement of ten (10) minutes Patient 307692 - Collected January 17, 2019 at 18:50 pm then resulted January 18, 2019 at 07:54 am - twelve (12) hours and fifty four (54) minutes over the manufacturer's requirement of ten (10) minutes 4. In interview on May 22, 2019, the General Supervisor confirmed the above patients were not analyzed within ten (10) minutes according to the manufacturer's requirements. 5. Review of the Task 1 & # form provided to surveyor revealed the laboratory performs four (4) ABG tests annually. II. Based on observation, record review, and interview with personnel, the laboratory failed to ensure donors for Mean Prothrombin Time studies met the laboratory's requirements of normal donors. Findings: 1. Observation by surveyor during laboratory tour on May 21, 2019 revealed the laboratory utilizes the Siemens Sysmex CA-600 analyzer for Prothrombin Time (PT) and International Normalized Ratio (INR) testing. 2. Review of the laboratory's donor questionnaires from February 13, 2018 through February 28, 2018 revealed the laboratory documented responses from twenty (20) donors for the following questions: a) Are you currently pregnant? b) Do you currently have any bruising as a result of recent trauma? c) Have you taken any of the following in the last 24 hours: (check all that apply) Coumadin/Warfarin Heparin or similar anticoagulant Plavix Aspirin or any medications containing aspirin Antibiotics Vitamin K d) Any diagnosed clotting disorder (Hemophilia, von Willebrand's, etc) or factor deficiency? 3. Review of the laboratory's donor questionnaires revealed the

	laboratory did not include the following criteria: a) Not on any oral contraceptives 4. Further review of the laboratory's donor questionnaires revealed the laboratory utilized the followng three (3) of twenty (20) donors taking aspirin/aspirin products and/or plavix: a) Sample ID 06 - Aspirin and plavix b) Sample ID 11 - Aspirin c) Sample ID 15 - Aspirin 5. In interview on May21, 2019 at 3:15 pm, the Laboratory Manager stated he was aware that three (3) donors were taking Aspirin, Aspirin products, and/or Plavix but since the donors results were within normal range, the donors were used for the study. The Laboratory Manager further stated he was unaware birth control for women should be added to the questionnaire. 6. In further interview on May 21, 2019, the Laboratory Director confirmed the laboratory utilized donors taking aspirin, aspirin products, and/or plavix for the study. 7. Review of the laboratory's Task 1 and 3 forms revealed the laboratory performs 719 PT/INR 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: Based on observation and interview with personnel, the laboratory failed to ensure blood collection supplies and calibration materials have not exceeded their expiration date. Findings: 1. Observation by surveyor during laboratory tour on May 21, 2019 revealed the following expired items: a) Located on a phlebotomy tray in the laboratory * BD Vacutainer Lithium Heparin 4.0 mL blood collection tubes, Lot #7130538, Expiration date: 2018-09-30, Quantity: four (4) tubes * BD Vacutainer SST 5.0 mL blood collection tubes, Lot #7285755, Expiration date: 2018-10-31, Quantity: five (5) tubes * BD Vacutainer SST 5.0 mL blood collection tubes, Lot #7164938, Expiration date: 2018-05-31, Quantity: one (1) tube * Greiner Bio-One Vacuette K3EDTA 3.0 mL blood collection tubes, Lot #B180134K, Expiration date: 2019-04-19, Quantity: two (2) b) Located in Kenmore Refrigerator * i-Stat Tri-Control 1-5 - Calibration Verification: Level 4, Lot 321100, Expiration date: 2019-04-30 * i-Stat Tri-Control 1-5 - Calibration Verification: Level 5, Lot 311100, Expiration date: 2019-04-30 2. In interview on May 21, 2019 at 10:55 am, the Laboratory Supervisor stated he was unaware of the expired supplies located on the phlebotomy tray which was used for the early morning lab draws. The Laboratory Supervisor further stated he was unaware the Calibration Verification supplies were expired. 3. In further interview on May 21, 2019, the Laboratory Supervisor confirmed the identified supplies were expired and in place for patient testing.
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, record review, and interview with personnel, the Laboratory Director failed to ensure laboratory personnel performed testing as required. Findings: 1. The laboratory failed to follow the manufacturer's requirements for testing of samples in waived chemistry testing. Refer to D1001. 2. The laboratory failed to ensure patient samples for Arterial Blood Gas testing are analyzed within ten (10) minutes according to the manufacturer for seven (7) of fifteen (15) patients reviewed. Refer to D5411 I. 3. The laboratory failed to ensure donors for Mean Prothrombin Time studies met the laboratory's requirements of normal donors. Refer to D5411 II. 4. The laboratory failed to ensure blood collection supplies and calibration materials have not exceeded their expiration date. Refer to D5417.
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 record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures were established for assessing personnel competency. Refer to D5209.
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, record review and interview with laboratory personnel, the Technical Consultant failed to provide technical and scientific oversight of the laboratory. Findings: 1. The laboratory failed to follow the manufacturer's requirements for testing of samples in waived chemistry testing. Refer to D1001. 2. The laboratory failed to ensure patient samples for Arterial Blood Gas testing are analyzed within ten (10) minutes according to the manufacturer for seven (7) of fifteen (15) patients reviewed. Refer to D5411 I. 3. The laboratory failed to ensure donors for Mean Prothrombin Time studies met the laboratory's requirements of normal donors. Refer to D5411 II. 4. The laboratory failed to ensure blood collection supplies and calibration materials have not exceeded their expiration date. Refer to D5417.