Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0898867	01/08/2025
Name of Provider or Supplier	**Street Address, City, State**	
Christus St Michael	2600 St Michael Drive, Texarkana, TX	

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	An onsite validation survey conducted January 7, 2025 found the laboratory out of compliance with 42 CFR Part 493, Requirements for Laboratories for the following conditions : D6033 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; technical consultant.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) (a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based upon review of proficiency testing records, policies and procedures and interview of facility personnel, the laboratory failed to retain Arterial Blood Gas (ABG) proficiency testing records for at least two years to include three testing events in each year of 2023 and 2024 . The findings included: 1. Review of Proficiency testing records found the laboratory had no records available for review for three of three testing events of 2023. 2. Review of the policy ABG-PP-69 titled Record Retention (signed by the laboratory director on 12/13/2023) found on page 1 under the heading OBJECTIVE: "The objective of this policy is for the laboratory to be in compliance with record retention for (1) the CHRISTUS Management Directives and (2) The accrediting organization (AO). The laboratory will be retaining records for the longest required time based on the chart below which compares the AO with CHRISTUS years of retention. POLICY: Patient results: AO retention 2 years, CHRISTUS retention 5 years Log Books: AO retention 2 years, CHRISTUS retention 5 years Quality Control/IQCP records: AO retention 2 years, CHRISTUS retention 5 years Quality Management records : AO retention 2 years, CHRISTUS retention 5 years Proficiency Testing records: AO retention 2 years, CHRISTUS retention 5 years Instrument Maintenance records: AO retention 2 years, CHRISTUS retention 5 years" 2. During interview of testing person one conducted January 7, 2025 at 10:11 AM, she

	confirmed that all records from 2023 were discarded after the AO inspection completed in November 2024.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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: Review of the manufacturer's instructions for the Arterial Blood Sampling Kit, patient test records and interview of facility personnel found the laboratory failed to follow the manufacturer's instructions when using the sampling kit to collect 625 venous and mixed specimens for blood gasses between January 1, 2024 and September 30, 2024. The findings included: 1. Review of the Portex Dry Heparin Arterial Blood Gas Sampling kit for Gases and Electrolytes found on page 1 under the heading DESCRIPTION: "The Dry Heparin Arterial Blood Sampling Kit is a single-use, latex-free, in-vitro diagnostic device designed for the drawing of arterial blood. INDICATIONS: The arterial blood sampling syringe for Calcium Neutralized Dry Lithium Heparin Syringes is intended for sampling of arterial blood for the measurement of pO2, PCO2, pH, Co-Oximetry, electrolytes (Ca, Na, K, Cl and Mg)." 2. Review of patient test records for 2024 found the laboratory tested 625 venous and mixed samples as follows: January 2024 - 70 venous samples February 2024 - 62 venous samples March 2024 - 71 venous samples and 2 Mixed samples April 2024 - 42 venous samples May 2024 - 71 venous samples and 1 mixed sample June 2024 - 55 venous samples July 2024 - 84 venous samples and 1 mixed sample August 2024 - 77 venous samples and 1 mixed sample September 2024 - 87 venous samples and 1 mixed sample 3. During interview of testing person one conducted January 7, 2025 at 2:23 PM, she confirmed that the laboratory uses the arterial blood gas collection kit for collection of arterial venous and mixed samples.
D6033	TECHNICAL CONSULTANT-MODERATE COMPLEXITY 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 upon review of the CMS report 209 Laboratory Personnel Report, personnel records and interview of facility personnel, the laboratory failed to have a technical consultant that met the minimum education requirements for moderate complexity testing in Chemistry. (See D 6035)
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b)

The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; AND (b)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i)(A) Hold an earned doctoral or master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(3)(i)(B) Meet either requirements in 493.1405(b)(3)(i)(B) or (b)(4)(i)(B) or (C); AND (b)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(4)(i)(B) Meet 493.1405(b)(5)(i)(B); and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(5)(i) Have earned an associate degree in medical laboratory technology, medical laboratory science, or clinical laboratory science; and (b)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in nonwaived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. (b)(6) For blood gas analysis, the individual must- (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3) or (4) of this section; or (b)(6)(ii)(A) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (b)(6)(ii)(B) Have at least 2 years of laboratory training or experience, or both, in blood gas analysis; or (b)(7) Notwithstanding any other provision of this section, an individual is considered qualified as a technical consultant under this section if they were qualified and serving as a technical consultant for moderate complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024.

This STANDARD is not met as evidenced by:
Based on review of the CMS report 209 Laboratory Personnel Report, policies and procedures, personnel records and interview of facility personnel, the laboratory failed to have a technical consultant that met the the minimum education requirements for moderate complexity testing in Chemistry. The findings included: 1. Review of the CMS Report 209 found the laboratory defined one individual as the technical consultant. 2. Review of the policy ABG-PP-39 titled Responsibilities-Coordinator of ABG Lab (approved by the laboratory director 12/13/2023) found on page 1 under the heading PROCEDURE: "The ABG Lab Coordinator is responsible for selection of test methodology appropriate for the clinical use of the test results. Verification of the test procedures performed and the establishment of the laboratory test performance characteristics, including the precision and accuracy of each test and test system. Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered. 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. Resolving technical problems and ensuring that remedial actions are taken whenever test systems deviate from the laboratory's established performance specifications. Ensuring that patient test results are not reported until all corrective actions have been taken and the test system is functioning properly. Identifying training needs and assuring that each individual performing tests receives regular inservice training and education appropriate for the type and complexity of the laboratory services performed. Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently." 3. Review of education records for the individual defined as the technical consultant on the CMS Report 209 Laboratory Personnel Report found she had obtained a Bachelor degree in Applied Arts and Science. Transcripts were requested but not available for review. 4. During interview of testing person 7 conducted January 7, 2024 at 11:14 PM, she confirmed that she performed all the duties identified in the ABG Lab Coordinator procedure and her Bachelors degree was not in a chemical, physical, biological science or in medical technology.