

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0698063	<b>(X3) Date Survey Completed</b> 07/25/2024
<b>Name of Provider or Supplier</b> Baylor St Luke's Medical Group	<b>Street Address, City, State</b> 310 Gaslight Boulevard, Lufkin, TX	
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>	An onsite recertification survey conducted on 7/25/2024 found the laboratory out of compliance with 42 CFR Part 493, Requirements for Laboratories. The following condition not met was: D6063 - 42 C.F.R. 493.1421 Condition: Laboratories performing moderate complexity testing; testing personnel;
<b>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory test menu, laboratory documents, and confirmed in interview, the laboratory failed to perform a twice annual comparison of test results, to determine the relationship between two different chemistry analyzers (the Alfa Wasserman ACE Axcel and the iStat), for seven of seven analytes performed on both in 2023. The findings included: 1. Review of the laboratory test menu included the following seven chemistry analytes performed on the ACE Axcel and on the iSTAT Chem8+ cartridge: CO2 Glucose BUN Creatinine Sodium Chloride Potassium 2. Review of laboratory policy and laboratory documentation did not include instructions or documentation for a twice annual comparison to determine the relationship between the two analyzers performing the same chemistry test. Surveyor asked testing personnel (TP) 1 for documentation of a twice annual comparison of test results for 2023, and none was provided. 3. In an interview on 7/25/2024 at 14:00 hours, in the laboratory, confirmed that the laboratory did not perform a twice annual comparison of test results to determine the relationship between the ACE Axcel and the iSTAT for the seven analytes performed on both chemistry analyzers.</p>

**D6063**

**LABORATORY TESTING PERSONNEL**

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on review of the laboratory personnel form 209, personnel records, laboratory policy, and confirmed in interview, the laboratory failed to ensure two of two testing personnel hired in 2024 had documentation of training prior to testing patients, to qualify as a testing personnel which have earned a high school diploma or equivalent under 493.1423(b)(4)(ii). Refer to D6066.

**D6066**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(4)(ii)

Have documentation of training appropriate for the testing performed prior to analyzing patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the laboratory personnel form 209, personnel records, laboratory policy, and confirmed in interview, the laboratory failed to ensure testing personnel had documentation of training for each test method used in moderate complexity testing, prior to analyzing patient specimens, for two of two testing personnel hired in 2024. The findings included: 1. Review of the CMS209 personnel form included the following two new testing personnel, their hire dates, qualifications. TP3, hired 1/29/2024, earned a high school diploma or equivalent. TP4, hired 5/16/2024, earned a high school diploma or equivalent. 2. Review of the "Policy and Procedure Manual", section "Technical Consultant Responsibilities" included the following: "The Technical Consultant is responsible for ensuring the following: ... 12. Personnel have been appropriately trained and demonstrated competency prior to testing patient specimens." 3. Review of the moderate complexity testing performed included the following analyzers and the tests performed: Analyzer - Test Sysmex XP300 - CBC's Triage - D-Dimer Tosho AIA-360 - TSH Alfa Wasserman ACE Axcel - BMP, Lipid, Mg iStat - Chem 8+ Surveyor asked for training documentation for TP3 and TP4 to include the training requirements found in 493.1423(b)(4)(ii)(A) through (H) and none was provided. 4. In an interview on 7/25/2024 at 10:20 hours, in the office, TP1 confirmed the laboratory did not have documentation of training, for each test method used, prior to patient testing for TP3 and TP4.