

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D0698063	<b>(X3) Date Survey Completed</b> 03/19/2025
<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>	Based on a proficiency testing desk review survey performed March 19, 2025 the laboratory was found to be out of compliance based on the following condition level deficiencies: D2016 - 42 C.F.R. 493.803 Condition: Successful participation D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) records, the laboratory failed to achieve successful performance in two of two consecutive testing events in 2024 and 2025, resulting in unsuccessful performance</p>

for 17 of 17 regulated chemistry analytes (D2096), and the specialty of Routine Chemistry (D2097).

**D2096**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(f)

(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) testing records from 2024 and 2025, the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for two of two consecutive testing events for the 17 of 17 chemistry analytes. Two out of two overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. The findings included: 1. A review of the CASPER Report 155 listed the following scores for the following PT Program analytes: 2024 Event 3 2025 Event 1 ALT 60% 0% ALBUMIN 60% 0% ALK PHOS 60% 0% AST 60% 0% TBILI 60% 0% CA, TOTAL 60% 0% CL 60% 0% CHOL 60% 0% HDL 60% 0% CREA 60% 0% GLUCOSE 60% 0% MG 60% 0% K 60% 0% NA 60% 0% TP 60% 0% TRIGL 60% 0% BUN 60% 0% 2. A desk review of API proficiency testing records for 2024 and 2025 confirmed that the laboratory received the above scores. Key: ALT - Alanine Transaminase ALK PHOS - Alkaline Phosphatase AST - Aspartate Aminotransferase TBILI - Total Bilirubin CA, TOTAL - Total Calcium CL - Chloride CHOL - Cholesterol HDL - Cholesterol, High Density Lipoprotein CREA - Creatinine MG - Magnesium K - Potassium NA - Sodium TP - Total Protein TRIGL - triglycerides BUN - Blood Urea Nitrogen

**D2097**

**ROUTINE CHEMISTRY**

CFR(s): 493.841(g)

(g) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) records from 2024 and 2025, the laboratory failed to achieve an overall testing event score of satisfactory performance (80% or greater) for two of two consecutive testing events for the specialty of Routine Chemistry. Two out of two overall testing event scores of unsatisfactory performance results in unsuccessful PT performance. The findings included: 1. A review of the CASPER Report 155 listed the following scores for the PT specialty of Routine Chemistry: 2024 Event 3: 60% 2025 Event 1: 0% 2. A desk review of API proficiency testing records confirmed that the laboratory received the above scores for Routine Chemistry for 2024 Event 3 and 2025 Event 1.

**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 a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) records, the laboratory director failed to ensure successful participation in an HHS approved proficiency testing program for 17 of 17 chemistry analytes and the specialty of Routine Chemistry for two of two consecutive events reviewed in 2024 and 2025. Refer to D6016.

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on a desk review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 155 Individual Laboratory Profile, American Proficiency Institute (API) records, the laboratory director failed to ensure successful performance in two of two consecutive testing events in 2024 and 2025, resulting in unsuccessful performance for 17 of 17 regulated chemistry analytes (D2096), and the specialty of Routine Chemistry (D2097).