

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0698063	<b>(X3) Date Survey Completed</b>  03/29/2019
<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>	The following deficiencies are a result of a desk review of proficiency testing scores obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, American Proficiency Institute (API). The facility was found to be out of compliance with the conditions of participation of the CLIA program. The following <b>CONDITION LEVEL DEFICIENCIES</b> were found to be out of compliance: 493.803 successful participation in a proficiency testing program 493.1403 laboratories performing moderate complexity testing; laboratory director 493.807 (a) Reinstatement after Failure D2017
<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 <b>CONDITION</b> is not met as evidenced by:</p>

Based on a desk review of proficiency testing records obtained from the CMS (Center for Medicare Services) national database and verified with the proficiency testing company, American Proficiency Institute (API), it was determined the laboratory had not successfully participated in a proficiency testing program approved by HHS, for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. The laboratory did not successfully participate in the specialty of chemistry for creatine and sodium. Refer to D2096.

**D2017**

**REINSTATEMENT OF NONWAIVED LABORATORIES**  
CFR(s): 493.807(a)(b)

(a) If a laboratory's certificate is suspended or limited or its Medicare or Medicaid approval is cancelled or its Medicare or Medicaid payments are suspended because it fails to participate successfully in proficiency testing for one or more specialties, subspecialties, analyte or test, or voluntarily withdraws its certification under CLIA for the failed specialty, subspecialty, or analyte, the laboratory must then demonstrate sustained satisfactory performance on two consecutive proficiency testing events, one of which may be on site, before CMS will consider it for reinstatement for certification and Medicare or Medicaid approval in that specialty, subspecialty, analyte or test. (b) The cancellation period for Medicare and Medicaid approval or period for suspension of Medicare or Medicaid payments or suspension or limitation of certification under CLIA for the failed specialty, subspecialty, or analyte or test is for a period of not less than six months from the date of cancellation, limitation or suspension of the CLIA certificate.

This CONDITION is not met as evidenced by:

Based on a desk review of proficiency testing scores from API found the laboratory failed to participate successfully for the analytes creatine and sodium. Findings include: 1. The laboratory received the following failing scores (passing = >80%) for the analyte creatine: Second testing event 2018 40% Third testing event 2018 40% First testing event 2019 0% 2. The laboratory received the following failing scores (passing = >80%) for the analyte sodium: Second testing event 2018 60% Third testing event 2018 60% First testing event 2019 40% 3. These three consecutive failures result in a second unsuccessful performance for the analytes creatine and sodium. 4. The laboratory must demonstrate sustained satisfactory performance (>80%) on two consecutive testing events for reinstatement.

**D2087**

**ROUTINE CHEMISTRY**  
CFR(s): 493.841(a)

Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on a proficiency testing desk review of CMS form 155 and American Proficiency Institute API records found that the laboratory failed to attain a satisfactory score of at least 80% for the following chemistry analytes. Findings include: 1. API 2018 - 2nd testing event the laboratory received the following unsatisfactory scores: Creatine 40% Sodium 60% 2. API 2018 - 3rd testing event the laboratory received the following unsatisfactory scores: Creatine 40% Sodium 60% 3. API 2019 - 1st event the laboratory received the following unsatisfactory scores:

	<p>Alanine aminotransferase (ALT/SGPT) 20% Albumin 20% Alkaline Phos 20% Aspartate aminotransferase (AST/SGPT) 40% Total Bilirubin 40% Calcium 20% Cholesterol 0% Cholesterol HDL 40% Creatine 0% Glucose 0% Magnesium 20% Potassium 40% Sodium 40% Total Protein 20% Triglycerides 60% Blood Urea Nitrogen 0%</p>
<b>D2088</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(b)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Review of the CMS report 155 and API proficiency testing records found that the laboratory failed to achieve a satisfactory score of at least 80% for the overall chemistry testing event score. Findings: 1. API 2019 - 1st event reported an event chemistry score of 28%.</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on desk review of proficiency testing records, it was determined the laboratory failed to achieve satisfactory performance (80% or greater) for the same analyte in two consecutive testing events or two out of three consecutive testing events in the specialty of Chemistry for the analytes creatine and sodium. Two out of three unsatisfactory scores results in unsuccessful PT performance. 1. The laboratory received the following failing scores (passing = &gt;80%) for the analyte creatine: Second testing event 2018 40% Third testing event 2018 40% First testing event 2019 0% 2. The laboratory received the following failing scores (passing = &gt;80%) for the analyte sodium: Second testing event 2018 60% Third testing event 2018 60% First testing event 2019 40% 3. These three consecutive failures result in a second unsuccessful performance for the analytes creatine and sodium.</p>
<b>D6000</b>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a desk review of laboratory proficiency testing performance it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6016</p>

**D6016**

**LABORATORY DIRECTOR RESPONSIBILITIES**

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

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)(4)(i) Ensure that 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 proficiency testing results it was revealed that the laboratory director failed to ensure the overall quality of the laboratory services provided. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program. Refer to D2096