

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0520720	<b>(X3) Date Survey Completed</b>  10/31/2018
<b>Name of Provider or Supplier</b>  St Luke's Jerome Laboratory	<b>Street Address, City, State</b>  709 N Lincoln Ave, Jerome, ID	
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>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 proficiency testing (PT) review and the laboratory's PT results from the American Association of Bioanalysts (AAB), the laboratory repeatedly failed to successfully participate in proficiency testing for the analytes Lactate Dehydrogenase and Partial Thromboplastin Time. Refer to D2096 and 2130.</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</p>

	<p>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 a proficiency testing (PT) review and the laboratory's PT results from the American Association of Bioanalysts (AAB), the laboratory failed to achieve satisfactory performance for the analyte Lactate Dehydrogenase (LDH) and has sustained a subsequent occurrence of unsuccessful participation in PT. Findings: Analyte Year Event Score LDH 2017 3 0 LDH 2018 1 0 LDH 2018 2 0</p>
<p><b>D2130</b></p>	<p><b>HEMATOLOGY</b> CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) review and the laboratory's PT results from the American Association of Bioanalysts (AAB), the laboratory failed to achieve satisfactory performance for the analyte Partial Thromboplastin Time (PTT) and has sustained a subsequent occurrence of unsuccessful participation in PT. Findings: Analyte Year Event Score PTT 2017 2 60 PTT 2017 3 40 PTT 2018 1 0 PTT 2018 2 20</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on the deficiencies cited for subsequent unsuccessful performance in proficiency testing, the laboratory director failed to provide overall management and direction for the laboratory. Refer to D6089.</p>
<p><b>D6089</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) review and the laboratory's PT results from the American Association of Bioanalysts (AAB), the laboratory director failed to ensure that the laboratory maintained successful participation in proficiency testing for the analytes Lactate Dehydrogenase (LDH) and Partial Thromboplastin Time (PTT).</p>

Findings: Analyte Year Event Score LDH 2017 3 0 LDH 2018 1 0 LDH 2018 2 0  
Analyte Year Event Score PTT 2017 2 60 PTT 2017 3 40 PTT 2018 1 0 PTT 2018 2  
20