

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520720	(X3) Date Survey Completed 03/10/2022
Name of Provider or Supplier St Luke's Jerome Laboratory	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2016	<p>SUCCESSFUL PARTICIPATION 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) desk review of the Centers for Medicare and Medicaid (CMS) PT data report (Report 155D) and graded results from the College of American Pathologists (CAP), the laboratory failed to successfully participate and achieve an overall satisfactory score for two (2) of three (3) testing events in 2021 for the specialty of immunohematology. See D2162</p>
D2162	<p>ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f)</p>

Failure to achieve satisfactory performance for the same analyte 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 Proficiency Testing (PT) desk review of the Centers for Medicare and Medicaid (CMS) PT data report (Report 155D), graded PT results from the College of American Pathologists (CAP) and telephone interview with the laboratory manager on 3/10/2022, the laboratory failed to achieve a satisfactory score in two (2) of three (3) consecutive testing events in 2021 for the specialty of immunohematology. The findings include: 1. A PT desk review of Report 155D and graded PT results from CAP identified that the laboratory failed to achieve a satisfactory score of 100 percent for the analyte D (Rho) typing. Analyte Year Event Score D (Rho) 2021 2 80% D (Rho) 2021 3 80% 2. A telephone interview with the laboratory manager on 3/10/2022 at 1:48 pm confirmed the above findings.