

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0520720	(X3) Date Survey Completed 01/05/2021
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 in PT for the analyte free thyroxine (freeT4) for two (2) of three (3) consecutive testing events. The findings include: 1. A PT desk review revealed the laboratory had unsatisfactory scores for the 2nd event of 2020 and the 3rd event of 2020 for free T4. See D2107.</p>
D2107	ENDOCRINOLOGY

CFR(s): 493.843(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 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 achieve satisfactory performance for the analyte free thyroxine (freeT4) in two (2) consecutive testing events. The findings include: 1. A PT desk review of report 155D and CAP graded results revealed that the laboratory failed to achieve satisfactory performance for the analyte free T4 in two (2) consecutive testing events. Subspecialty Year Event Score free T4 2020 2 0% free T4 2020 3 0% 2. The laboratory reports performing 320 free T4 test annually.

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

The laboratory director must ensure 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 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 director failed to ensure the proficiency testing samples are tested as required under subpart H of this part. The finding include: 1. A PT desk review of report 155D and CAP graded results revealed that the laboratory failed to achieve satisfactory performance for the analyte free T4 in two (2) consecutive testing events. See D2016, D2107 2. The laboratory reports performing 320 free T4 test annually.