

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0411099	(X3) Date Survey Completed 05/30/2018
Name of Provider or Supplier St Luke Community Healthcare	Street Address, City, State 107 6th Avenue Sw, Ronan, MT	
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
D0000	Based on an off-site proficiency testing desk review conducted on 5/30/18, deficiencies were cited for St Luke Community Healthcare in Ronan, MT.
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 routine desk audit of CMS-153 and 155 reports of proficiency testing performance and interview, the laboratory failed to achieve satisfactory performance for compatibility testing for two of three events (2017 event 2 and 2018 event 1), resulting in unsuccessful proficiency testing performance. See D2181.</p>
D2181	COMPATIBILITY TESTING

CFR(s): 493.863(e)

Failure to achieve an overall testing event score of satisfactory 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 review of proficiency testing scores and interview, the laboratory failed to achieve a score of 100 percent for compatibility testing in two of three events in 2017 and 2018, resulting in unsuccessful performance. The findings include: 1. During a review on 5/29/18 at 8:15 a.m. of the CMS-153 Unsuccessful Proficiency Testing Report included St Luke Community Healthcare with unsuccessful proficiency testing scores for compatibility testing. 2. During a review on 5/29/18 at 8:20 a.m. of the CMS-155 report, the American Proficiency Institute (API) compatibility testing score for event 2 of 2017 was 80%. 3. During a review on 5/29/18 at 8:20 a.m. of the CMS-155 report, the API compatibility testing score for event 1 of 2018 was 80%. 4. On 5/30/18 at 2:35 p.m., the laboratory manager stated the lab will investigate the failures.