

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0450763	(X3) Date Survey Completed 05/06/2020
Name of Provider or Supplier St Luke Hospital & Living Center	Street Address, City, State 535 S Freeborn, Marion, KS	
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	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. This CONDITION is not met as evidenced by: A proficiency testing record review on May 5, 2020 revealed the laboratory failed to successfully participate in proficiency testing from American Proficiency Institute (API) for the regulated analyte Bacteriology. Findings include: 1. Second event 2019 revealed a score of 50% for Bacteriology. 2. First event 2020 revealed a score of 50% for Bacteriology. The laboratory failed to achieve an acceptable score of 80% or higher for two of three consecutive events which resulted in unsatisfactory performance for the regulated analyte Bacteriology. (refer to D2028)
D2028	BACTERIOLOGY

CFR(s): 493.823(e)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

A proficiency testing record review on May 5, 2020 revealed the laboratory failed to successfully participate in proficiency testing from American Proficiency Institute (API) for the regulated analyte Bacteriology. Findings include: 1. Second event 2019 revealed a score of 50% for Bacteriology. 2. First event 2020 revealed a score of 50% for Bacteriology. The laboratory failed to achieve an acceptable score of 80% or higher for two of three consecutive events which resulted in unsatisfactory performance for the regulated analyte Bacteriology.