

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521144	(X3) Date Survey Completed 08/12/2020
Name of Provider or Supplier St Mary's Health	Street Address, City, State 701 Lewiston St, Cottonwood, 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	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: Based on proficiency testing (PT) desk review, the laboratory failed to successfully participate in proficiency testing for the analyte Digoxin. Refer to D2118.
D2118	TOXICOLOGY CFR(s): 493.845(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 desk review and the laboratory ' s graded results from the American Proficiency Institute, the laboratory failed to achieve satisfactory performance in three consecutive testing events for Digoxin. This is a subsequent unsuccessful participation for the analyte Digoxin. Findings: Analyte Year Event Score Digoxin 2019 3 40% Digoxin 2020 1 0% Digoxin 2020 2 60%
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 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. This CONDITION is not met as evidenced by: Based on the deficiencies cited under the Laboratory Director's responsibilities at and continued unsuccessful performance in proficiency testing, the laboratory director failed to provide overall management and direction for the laboratory. See D6089.
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 and the laboratory's PT results from the American Proficiency Institute, the Laboratory Director failed to ensure that the laboratory maintained successful participation in proficiency testing for the analyte Digoxin. This constitutes a subsequent unsuccessful participation for the analyte Digoxin. Findings: Analyte Year Event Score Digoxin 2019 3 40% Digoxin 2020 1 0% Digoxin 2020 2 60%