Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 13D0521144	(X3) Date Survey Completed 10/17/2022
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 a Proficiency Testing (PT) desk review of the Centers for Medicare and Medicaid (CMS) PT data report (Report 155D) and graded results from the American Proficiency Institute (API), the laboratory failed to successfully participate and achieve an overall satisfactory score for two (2) of three (3) testing events in 2022 for the specialty of immunohematology. See D2162
D2162	ABO GROUP AND D(RHO) TYPING CFR(s): 493.859(f)

	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 theAmerican Proficiency Institute (API) and telephone interview with the laboratory manager on 10 /13/2022, the laboratory failed to achieve a satisfactory score in two (2) of three (3) consecutive testing events in 2022 for the specialty of immunohematology. The findings include: 1. A PT desk review of Report 155D and graded PT results from API identified that the laboratory failed to achieve a satisfactory score of 100 percent for the analyte ABO group typing. Analyte Year Event Score ABO Group 2022 1 80% ABO Group 2022 2 0% 2. A telephone interview with the laboratory manager on 10/13/2022 at 1:01 pm confirmed the above findings. 3. The laboratory reports performing 145 ABO group typing tests annually