Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0701400	07/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Minidoka Memorial Hospital	1224 8th St, Rupert, 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 review of the Centers for Medicare and Medicaid (CMS) proficiency testing (PT) data report (Report 155D), graded results from the American Proficiency Institute (API) and an interview with the laboratory manager, the laboratory failed to successfully participate and achieve an overall satisfactory score for two (2) of three (3) testing events in 2021 and 2022 for the specialty of hematology. See D2127, D2130
D2127	HEMATOLOGY CFR(s): 493.851(d)

	Failure to return proficiency testing results to the proficiency testing program within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) Proficiency Testing (PT) data report (Report 155D), graded PT results from the American Proficiency Institute (API) and an interview with the laboratory manager on 7/28 /2022, the laboratory failed to return PT results within the specified time frame for the analyte prothrombin time resulting in a score of zero. The findings include: 1. A review of Report 155D and graded PT results from API identified that the laboratory failed to return PT results within the specified time frame for the specialty of hematology for the analyte prothrombin time resulting in a score of zero for 2022 event one. 2. An interview with the laboratory manager on 7/28/2022 at 3:00 pm confirmed that the laboratory failed to return prothrombin time PT results within the required timeframe. 3. The laboratory reports performing 946 prothrombin time tests annually.
D2130	HEMATOLOGY CFR(s): 493.851(f) Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid (CMS) Proficiency Testing (PT) data report (Report 155D), graded PT results from the American Proficiency Institute (API) and an interview with the laboratory manager on 7/28 /2022, the laboratory failed to achieve satisfactory performance for two (2) consecutive PT events for the analyte prothrombin time. The findings include: 1. A review of Report 155D and graded PT results from API identified that the laboratory failed to achieve satisfactory performance for events three (3) in 2021 and one (1) in 2022 for the specialty of hematology for the analyte prothrombin time. Analyte Year Event Score Prothrombin time 2021 3 60% Prothrombin time 2022 1 0% 2. An interview with the laboratory manager on 7/28/2022 at 3:00 pm confirmed the above findings. 3. The laboratory reports performing 946 prothrombin time tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the Cepheid GeneXpert maintenance logs and an interview with the laboratory manager on 7/28/2022, the laboratory failed to perform monthly maintenance as required by the manufacturer. The findings include: 1. A review of Cepheid GeneXpert maintenance logs identified that the laboratory failed to perform

	disinfection of the cartridge bay interior and the plunger rod monthly in June 2021, July 2021, October 2021, November 2021, May 2022 and June 2022 as required by the manufacturer. 2. An interview with the laboratory manager on 7/28/2022 at 3:05 pm confirmed that monthly disinfection of the Cepheid GeneXpert was not performed for six (6) of 15 months since the last inspection. 3. The laboratory performs SARS Covid-19, Influenza A/B, respiratory syncytial virus, group A Streptococcus, Clostridium difficile, Methicillin-resistant Staphylococcus aureus, Chlamydia trachomatis and Neisseria gonorrhoeae testing on the Cepheid GeneXpert. 4. The laboratory reports performing 2096 tests annually on the Cepheid.