Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0042084	08/05/2021
Name of Provider or Supplier	**Street Address, City, State**	
Northern Montana Hospital	30 13th Street, Havre, 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
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 record review of American Proficiency Institute (API) proficiency testing scores and interview with the Technical Supervisor (TS) #1, the laboratory failed to achieve satisfactory performance for two out of three testing events in bacteriology and chemistry for years 2019 and 2020. (Refer to D2028, D2097)
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: . Based on record review of American Proficiency Institute (API) proficiency testing scores for bacteriology and interview with the Technical Supervisor (TS) #1, the laboratory failed to achieve satisfactory performance for Urine Colony Count for two out of three events in 2019 and 2020. Findings: 1. Review of American Proficiency Institute (API) proficiency testing scores for 2020 Microbiology under subspecialty bacteriology revealed unsuccessful proficiency testing for Urine Colony Count with a 0% score for 2019 Event 3 and 2020 Event 1. 2. Interview with the TS #1 on August 4, 2021 at 3:40 PM confirmed the laboratory failed to achieve satisfactory performance for Urine Colony Count for two out of three events in 2019 and 2020.
D2097	ROUTINE CHEMISTRY CFR(s): 493.841(g) 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: . Based on record review of American Proficiency Institute (API) proficiency testing scores for chemistry and interview with the Technical Supervisor (TS) #1, the laboratory failed to achieve satisfactory performance for NT-proBNP (CM) for two out of three events in 2019. Findings: 1. Review of American Proficiency Institute (API) proficiency testing scores for 2019 Chemistry Core revealed unsuccessful proficiency testing for NT-proBNP (CM) with a 40% score for 2019 Event 1 and 20% score for 2019 Event 3. 2. Interview with the TS #1 on August 4, 2021 at 3:40 PM confirmed the laboratory failed to achieve satisfactory performance for NT-proBNP (CM) for two out of three events in 2019.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: . Based on review of Immunohematology records, policy and procedures and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and of blood or blood products returned to the laboratory for years 2019 and 2020. Findings: 1. Review of Immunohematology records lacked documentation of temperatures of blood and blood products upon receipt of new shipments and of blood or blood products returned to the laboratory for years 2019 and 2020. 2. Review of Policy and Procedure Lab 3-05 lacks steps to ensure temperature documentation for receipt of new or returned blood or blood products. 3. Review of American Red Cross

	Hospital Partner Resource Guide revealed (page 17), "If products are received out of shipping temperature range or are packed incorrectly, notify Red Cross Customer Service. These products will be managed based on the non-conformance." 4. Interview with TS #1 on August 4, 2021 at 11:16 AM, confirmed the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and blood products and of blood or blood products returned to the laboratory for years 2019 and 2020.
D3043	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(7) The laboratory must retain cytology slide preparations for at least 5 years from the date of examination (see 493.1274(f) for proficiency testing exception). The laboratory must retain histopathology slides for at least 10 years from the date of examination. The laboratory must retain pathology specimen blocks for at least 2 years from the date of examination. The laboratory must preserve remnants of tissue for pathology examination until a diagnosis is made on the specimen. This STANDARD is not met as evidenced by: . Based on review of histology records, policy and procedures and interview with Technical Supervisor (TS) #1, the laboratory failed to retain histology slides for at least 10 years from the date of examination for 2020. Findings: 1. Review of histology patient #520-637, tissue stained with Giemsa stain performed on 6-5-2020 revealed the quality control slide could not be located. 2. Review of Policy and Procedure Lab 9-07 revealed "Stained slides are kept for 10 years.". 3. Interview with TS #1 confirmed the quality control slide for the histology patient #520-637 was not retained for at least 10 years from the date of examination of 6/5/2020.