Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	35D0409270	07/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Mountrail County Medical Center	615 6th St Se, Stanley, ND	

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
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to verify the accuracy of results for 2 of 3 Chemistry Core events (Chemistry Core 3rd Event 2025, Chemistry Core 1st Event 2026) the American Proficiency Institute (API) assigned as not graded. The laboratory performed 10,456 total bilirubin patient tests in the past year. Findings include: 1. Reviewed at 9:24 a.m. on 07/16/26, the 3rd Event 2025 Chemistry Core proficiency testing showed Total Bilirubin samples CH-12 and CH-15 as not graded. The 1st Event 2026 Chemistry Core proficiency testing showed Total Bilirubin sample CH-05 as not graded. The laboratory failed to evaluate the not graded results. 2. During an interview the afternoon of 07/16/26, a Laboratory Manager (#1) confirmed the laboratory failed to evaluate the 3rd Event 2025 and 1st Event 2026 Total Bilirubin not graded results. 3. The laboratory failed to provide a policy regarding verification of accuracy of results for proficiency testing.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by:

	Based on record review and staff interview, the laboratory failed to verify the accuracy of results for 1 of 3 Hematology/Coagulation events (2nd Event 2025) the American Proficiency Institute (API) assigned as unacceptable. The laboratory performed 12,014 automated differential patient tests in the past year. Findings include: 1. Reviewed at 9:31 a.m. on 07/16/26, the 2nd Event 2025 Hematology /Coagulation proficiency testing records failed to show the laboratory documented verification of accuracy for sample DXH-06 Lymphocytes. 2. During an interview the afternoon of 07/16/26, a Laboratory Manager (#1) confirmed the laboratory failed to document review of the 2nd Event 2025 Lymphocytes unacceptable results. 3. The laboratory failed to provide a policy regarding verification of unacceptable proficiency testing.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on observation, policy and procedure manual review, record review, and staff interview, the laboratory failed to develop a written procedure for 1 of 2 new analyzers (Alcor miniiSED). The laboratory performed 630 erthryocyte sedimentation rate (ESR) tests the past year. Findings include: 1. Observation of the laboratory, beginning at 7:52 a.m. on 07/16/26, showed an Alcor miniiSED analyzer on the hematology counter. 2. Reviewed at 2:39 p.m. on 07/16/26, the April 2025 verification of performance specifications records for the Alcor miniiSED analyzer failed to include an updated procedure for personnel responsible for any aspect of the testing process. 3. During an interview in the afternoon of 07/16/26, the Laboratory Manager (#1) confirmed the laboratory failed to update the erythrocyte sedimentation rate (ESR) procedure. 4. Reviewed on 07/16/26, the laboratory's procedure manual failed to include a procedure for the Alcor miniiSED. Upon request, the laboratory failed to provide evidence of an updated procedure for the Alcor miniiSED procedure.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on observation, record review, staff interview, and package insert review, the laboratory failed to perform a positive and negative control each day of serum hCG (Human Chorionic Gonadotropin) proficiency and patient testing for 1 of 1 year (2025) reviewed. The laboratory performed 174 serum hCG patient tests the past year. Findings include: 1. Observation of the laboratory, beginning at 7:52 a.m. on 07/16 /26, showed a Sure-Vue serum/urine hCG kit in a cupboard above the urine analyzer. 2. During an interview at approximately 8:00 a.m. on 07/16/26, a Laboratory Manager (#1) confirmed the laboratory reported serum hCGs using the Sure-Vue serum/urine hCG kit. 3. Reviewed at 2:13 p.m. on 07/16/26, the 2025 serum hCG patient testing records indicated performance of patient testing on 01/01/25, 01/02/25, 01/09/25, 01

	/15/25, 01/16/25, 01/24/25, 01/25/25, 01/30/25, 02/07/25, 02/14/25, 02/28/25, 03/05 /25, 03/13/25, 03/14/25, 03/22/25, 03/26/25, 04/04/25, 04/08/25, 04/11/25, 04/16/25, 04/17/25, 04/20/25, 04/22/25, 04/23/25, 04/30/25, 05/02/25, 05/03/25, 05/06/25, 05/07 /25, 05/08/25, 05/12/25, 05/23/25, 06/06/25, 06/13/25, 06/15/25, 07/07/25, 07/29/25, 08/18/25, 08/21/25, 09/03/25, 09/04/25, 11/08/25, 11/24/25, 12/03/25, and 12/22/25. 4. Upon request on 07/16/26, the laboratory failed to provide evidence of serum hCG quality control in 2025. 5. During an interview at approximately 2:45 p.m. on 07/16 /26, a Laboratory Manager (#1) confirmed the laboratory did not perform serum hCG quality control in 2025. 6. Reviewed on 07/16/26, the "SURE-VUE Serum/Urine hCG " package insert, dated 01/15/18, stated, "It is recommended that a positive hCG control . . . and a negative hCG control . . . be evaluated to verify proper test performance. . . . For serum testing, federal, state, and local guidelines should be followed. . . ."
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) (e)(11) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory director failed to ensure 4 of 4 testing personnel (Testing Personnel #1, #2, #3, and #4) received appropriate training and demonstrated reliable testing performance before reporting patient results on a new erythrocyte sedimentation rate (ESR) analyzer (Alcor miniiSED) in April 2025. Findings include: 1. Reviewed at 8:46 a.m. on 07/16/26, the testing personnel records failed to include documentation of appropriate training and demonstration of reliable testing performance for Testing Personnel (#1, #2, #3, and #4) before reporting patient results on the Alcor miniiSED ESR analyzers. 2. Reviewed at 2:39 p. m. on 07/16/26, the April 2025 verification of performance specifications records for the Alcor miniiSED analyzer failed to include documentation of appropriate training and demonstration of reliable testing performance for Testing Personnel (#1, #2, #3, and #4). 3. Upon request on 07/16/26, the laboratory failed to provide evidence of training for Testing Personnel (#1, #2, #3, and #4) for the Alcor miniiSED analyzers. 4. During an interview in the afternoon of 07/16/26, the Laboratory Manager (#1) stated Testing Personnel (#1, #2, #3, and #4) had performed patient testing on the Alcor miniiSED and confirmed the laboratory failed to document training and demonstration of reliable testing performance for Testing Personnel (#1, #2, #3, and #4) on the Alcor miniiSED. 5. The laboratory failed to provide a policy regarding initial training of testing personnel.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on record review and staff interview, the technical consultant failed to evaluate and document the competency of 2 of 4 testing personnel (#2 and #3) requiring annual

	competency evaluations in 2024 and 2025. Findings include: 1. Reviewed at approximately 8:46 a.m. on 07/16/26, the competency evaluation records for testing personnel (#2) lacked evidence of hematology analyzer DxH 520 and portable blood analyzer iSTAT annual competency evaluations in 2025. 2. Reviewed at approximately 8:52 a.m. on 07/16/26, the competency evaluation records for testing personnel (#3) lacked evidence of hematology analyzer DxH520 annual competency evaluation in 2024 and 2025. 3. During an interview the afternoon of 07/16/26, a Laboratory Manager (#1) confirmed the laboratory failed to complete the annual DxH 520 and iSTAT competency evaluations for testing personnel #2 in 2025 and the annual DxH520 competency evaluations for testing personnel (#3) in 2024 and 2025. 4. The laboratory failed to provide a policy regarding annual competency evaluations.