Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0042038	01/24/2024
Name of Provider or Supplier	**Street Address, City, State**	
Dahl Memorial Healthcare Assn, Inc	106 E Park St, Ekalaka, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a record review and interview with testing personnel (TP) #2, the laboratory failed to enroll in an HHS-approved proficiency testing program for alcohol performed on the Siemens Dimension EXL 200 chemistry analyzer from October 21, 2022, to January 24, 2024. Findings: 1. A review Siemens Dimension EXL 200 chemistry analyzer verification documents approved on October 21, 2022, included alcohol (ETOH) as an analyte available for testing. 2. A review of 2023 American Proficiency Institute (API) proficiency testing records lacked documentation for ETOH. 3. An interview with TP #1 on January 24, 2024, at 2:25 PM confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for ETOH performed on the Siemens Dimension EXL 200 chemistry analyzer from October 21, 2022, to January 24, 2024.
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 a a review of American Proficiency Institute (API) records and an interview with testing personnel (TP) #2, the laboratory failed to review and document corrective actions for unsatisfactory or not graded scores for two out of three chemistry core events and one out of three immunology events for the year 2023. 1. Review of API proficiency testing records for 2023 Immunology/Immunohematology 1st Event revealed a score of 50% for C-Reactive protein, which lacked performance review and corrective action by the laboratory director or designee. 2. A review of API proficiency testing records for the 2023 Chemistry Core 1st Event revealed a score of "Not Graded" for ALT/SGPT, which lacked corrective action by the laboratory director or designee for the laboratory's reported result of 20 U/L being outside API's expected result range (12-19 U/L). 3. A review of API proficiency testing records for the 2023 Chemistry Core 3rd Event revealed a score of 80% for partial pressure of carbon dioxide (pCO2), pH, and partial pressure of oxygen (pO2), which lacked corrective action for the unacceptable samples by the laboratory director or designee. 4. No procedure for addressing the corrective action plan for unsatisfactory, not graded or educational proficiency testing scores was available for review. 5. An interview with TP #2 on January 24, 2024, at 1:50 PM confirmed the laboratory failed to review and provide corrective action for unsatisfactory or not graded proficiency scores for the 2023 Immunology/Immunohematology 1st Event, Chemistry Core 1st Event, and 3rd Event.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: REPEAT DEFICIENCY CITE Based on record review, patient results reports, procedures, and interview with testing personnel (TP) #2, the laboratory lacked verification studies for precision, accuracy, and reference ranges for the analytes tested on the Siemens Dimension EXL chemistry analyzer (Refer to D5421); failed to perform at least a three-point (a minimal, mid-point, and maximum) calibration verification every six months for analytes sodium, potassium, chloride, and d-dimer (Refer to D5439, REPEAT DEFICIENCY CITE); failed to perform comparison studies twice a year and define the relationship between the test results (Refer to D5775); the laboratory director failed have procedures for calibration verification and to ensure hematology procedures and testing personnel refer uncommon, atypical, or immature cells to a qualified high complexity testing person for interpretation and identification (Refer toD5403, D6028, and D6069).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling,

	storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a record review of policies and an interview with testing personnel (TP) #2, the laboratory's procedures lacked instructions for calibration verification for chemistry and lacked instructions to refer abnormal manual differential blood counts to a high complexity laboratory from January 24, 2022, to January 24, 2024. Findings: 1. No calibration verification procedure for analytes performed on the Siemens Dimension EXL 200 chemistry analyzer to include a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results every six months was available for review. 2. A review of hematology's "Smear Review and Manual Differential" procedures failed to have instructions to refer uncommon, atypical, or immature cells to a qualified high complexity testing person for interpretation and identification. 3. An interview with TP #2 on January 24, 2024, at 11:30 AM confirmed the laboratory failed to provide instruction for calibration verification for chemistry and lacked instruction to refer abnormal manual differentials to a high complexity laboratory in their procedures from January 24, 2022, to January 24, 2024.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation, review of the Siemens Dimension EXL chemistry analyzer verification records, patient results report, and an interview with testing personnel (TP #2), the laboratory lacked precision studies to assess day-to-day variation over time, lacked patient samples as part of the comparison studies for accuracy, and lacked patient population studies to verify the reference ranges are appropriate for the laboratory's patient population prior to patient testing from October 21, 2022, to

	January 24, 2024. Findings: 1. Observed on January 24, 2024, at 10:00 AM, one of one Siemens Dimension EXL chemistry analyzer in use. 2. A review of the Siemens Dimension EXL verification records revealed the laboratory failed to have more than two days of data to assess the repeatability of day-to-day variance and failed to include patient samples to verify accuracy prior to the laboratory director's approval dates of October 21, 2022, and December 1, 2023. 3. No patient population studies to verify reference intervals (normal values) were available for review to support the reference ranges listed in the laboratory's patient results reports. 4. No procedure for the verification of performance of new assays, instruments or methods was available for review 5. An interview with TP #2 on January 24, 2024, at 10:50 AM confirmed the lack of verification studies for precision, accuracy, and reference range for the analytes tested on the Siemens Dimension EXL chemistry analyzer from October 21, 2022, to January 24, 2024
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: REPEAT DEFICIENCY CITE Based on review of the calibration records, manufacturer's instructions, and interview with testing personnel (TP) #2, the laboratory failed to perform at least three-point (a minimal, mid-point, and maximum) calibration verification every six months for chemistry electrolytes and hematology D-Dimer from January 24, 2022, to January 24, 2024. Findings: 1. A review of the Siemens Dimension EXL 200 chemistry analyzer calibration records for electrolyte analytes: sodium, potassium, and chloride lacked one of two calibration verification records for year 2023. 2. A review of calibration records for the Sysmex CA-600 for analyte D-Dimer lacked one of two calibration verification records for years 2022 and 2023. 3. An interview with the TP #2 on January 24, 2024, at 11:30 AM, confirmed the laboratory failed to perform calibration verifications every six months for D-dimer performed on the Sysmex CA-600 and the electrolytes performed on the Siemens Dimension EXL 200 chemistry analyzer from January 24, 2022, to January 24, 2024.

D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review, procedures, and an interview with testing personnel (TP) #2, the laboratory failed to perform comparison studies twice a year and define the relationship between the test results using two different chemistry analyzers and two different coagulation analyzers from January 24, 2022, to January 24, 2024. Findings: 1. No comparison studies between the Siemens Dimension EXL 200 and Abbott i-STAT for the analytes sodium, potassium, chloride, ionized calcium, total CO (2), glucose, blood urea nitrogen (BUN), and creatinine were available for review. 2. No comparison studies between the Sysmex CA-600 and Abbott i-STAT for prothrombin time testing with INR calculations were available for review. 3. No procedures for comparison studies to include a written criteria for acceptable differences in test values for chemistry and coagulation were available for review. 4. An interview with TP #2 on January 24, 2024, at 4:30 PM confirmed the laboratory failed to perform comparison studies twice a year and define the relationship between the test results between two chemistry analyzers (Siemens Dimension EXL 200 and Abbott i-STAT) and the two coagulation analyzers (Sysmex CA-600 and Abbott i-STAT) from January 24, 2022, to January 24, 2024.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on a record review, the CMS-209 Laboratory Personnel Report (CLIA) form, patient results reports, and an interview with testing personnel (TP) #2, the laboratory director failed to ensure testing personnel had an applicable state license, education, and training to perform moderate diagnostic testing on the Abbott i-STAT and Siemens Dimension EXL 200 and failed to ensure hematology procedures and testing personnel refer uncommon, atypical, or immature cells identified by manual differential blood count to a qualified high complexity testing person for interpretation and identification from January 24, 2022, to January 24, 2024. Findings: 1. A review of patient results reports (Accession #2308180018) and (Accession #2309080010) revealed individual A (not listed on the CMS-209 form) verified moderate diagnostic tests for venous blood gas performed on the Abbott i-STAT and for triglycerides,

	magnesium, and PSA screening performed on the Siemens Dimension EXL 200. 2. A review of patient results reports (Accession #2312070004) for manual differential blood counts and hematology's "Smear Review and Manual Differential" procedure failed to refer uncommon, atypical, or immature cells identified by manual differential blood count to a qualified high complexity testing person for interpretation and identification. 3. Interview with TP #2 on January 24, 2024, at 4:05 PM confirmed the laboratory director failed to ensure moderate tests were performed by qualified testing personnel and failed to refer uncommon, atypical, or immature cells identified by manual differential blood count to a qualified high complexity testing person for interpretation and identification from January 24, 2022, to January 24, 2024..
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on record review, patient results reports, procedures, and interview with testing personnel (TP) #2, the laboratory failed to ensure testing personnel had an applicable Montana state license (Refer to D6064); failed to ensure testing personnel had the appropriate educational background and training (Refer to D6065); and failed to refer uncommon, atypical, or immature cells to a qualified high complexity testing person for interpretation and identification (Refer to D6069).
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on record review, the CMS-209 Laboratory Personnel Report (CLIA) form, patient results reports, and interview with testing personnel (TP) #2, the laboratory failed to ensure testing personnel had an applicable state license to perform patient testing on the Abbott i-STAT and Siemens Dimension EXL 200 from January 24, 2022, to January 24, 2024. Findings: 1. A review of patient results reports (Accession #2308180018) revealed that individual A (not listed on the CMS-209 form) verified the results on 08/18/2023 for venous blood gas performed on the Abbott i-STAT. 2. A review of patient results reports (Accession #2309080010) revealed individual A (not listed on the CMS-209 form) verified results on 09/08/2023 for triglycerides, magnesium, and PSA screening performed on the Siemens Dimension EXL 200. 3. No document of applicable state licensure was available for individual A at the time of the survey. 4. An interview with TP #2 on January 24, 2024, at 4:00 PM confirmed individual A did not have an applicable Montana licensure to perform moderate-level diagnostic tests from January 24, 2022, to January 24, 2024.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

	(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on record review, the CMS- 209 Laboratory Personnel Report (CLIA) form, patient results reports and interview with testing personnel (TP) #2, the laboratory failed to ensure testing personnel had the appropriate educational background and training prior to performing moderate-level diagnostic tests from January 24, 2022, to January 24, 2024. Findings: 1. A review of patient results reports (Accession #2308180018) revealed that individual A (not listed on the CMS-209 form) verified the results on 08/18/2023 for venous blood gas performed on the Abbott i-STAT. 2. A review of patient results reports (Accession #2309080010) revealed individual A (not listed on the CMS-209 form) verified results on 09/08/2023 for triglycerides, magnesium, and PSA screening performed on the Siemens Dimension EXL 200. 3. No proof of the required minimal educational documents for individual A (not listed on the CMS-209 form) were available to review at the time of the survey. 4. Interview with TP #2 on January 24, 2024, at 4:00 P.M., confirmed the lack of educational records for individual A's (not listed on the CMS-209 form) from January 24, 2022, to January 24, 2024.
D6069	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(a) Each individual performs only those moderate complexity tests that are authorized by the laboratory director and require a degree of skill commensurate with the individual's education, training or experience, and technical abilities. This STANDARD is not met as evidenced by: Based on a record review, patient results report, procedure, and interview with testing personnel (TP) #2, the laboratory failed to ensure testing personnel refer uncommon, atypical, or immature cells identified by manual differential blood count to a qualified high complexity testing person for interpretation and identification from January 24, 2022, to January 24, 2024. Findings: 1. A review of patient results reports (Accession #2312070004) revealed the results for manual differential blood counts include specific abnormal morphology (nucleated red blood cells) and lacked specimen referral to a qualified high complexity testing person for interpretation and identification. 2. Testing personnel failed to refer manual differential blood count results of uncommon, atypical, or immature cells to a qualified high complexity testing person for interpretation and identification. 3. A review of hematology's "Smear Review and Manual Differential" procedures failed to have instructions to refer uncommon, atypical, or immature cells to a qualified high complexity testing person for interpretation and identification. 4. Interview with TP #2 on January 24,

	2024, at 4:00 PM confirmed testing personnel failed to refer uncommon, atypical, or immature cells identified by manual differential blood count to a qualified high complexity facility for interpretation and identification from January 24, 2022, to January 24, 2024.