Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0042038	05/23/2018
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
D0000	Based on an on-site recertification survey conducted on 5/23/18, condition level deficiencies were cited for Dahl Memorial Healthcare in Ekalaka, MT.
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 observation, record review, and interview, the laboratory failed to enroll in proficiency testing for 5 of 14 analytes performed by the laboratory for 2018. The findings include: 1. On 5/23/18 at 8:45 a.m., an i-STAT analyzer was observed on the laboratory counter. 2. On 5/23/18 at 8:45 a.m., staff member A stated troponin, prothrombin time (PT), blood gases (pH, pO2, pCO2, lactic acid), b-type natriuretic peptide (BNP), and waived chemistry tests were performed on the i-STAT analyzer. 3. A review on 5/23/18 at 9:30 a.m. of the American Proficiency Institute (API) binders for testing performed in 2017 and 2018 lacked documentation of enrollment for five tests on the i-STAT. a. PT. b. pO2. c. pH. d. pCO2. e. Lactic acid. 4. A review on 5/23/18 at 9:35 a.m. of the Dahl Memorial Healthcare Association, Inc. Laboratory Manual of Policies and Procedures listed PT, pH, pCO2, pO2, and lactic acid as performed on the i-STAT analyzer. Further, it stated the laboratory "participates in the API (American Proficiency Institute) proficiency-testing program. Specimens for all areas of the Laboratory are sent by API and analyzed by the properly trained

	personnel." 5. A review on 5/23/18 at 9:40 a.m. of staff member A's emails from September of 2017 included notification to the facility to pay for enrollment of these analytes. The emails did not indicate if enrollment was completed. 6. A review on 5/23 /18 at 9:40 a.m. of the API 2018 Order Confirmation form lacked enrollment for 2018 for PT, pH, pCO2, pO2, and lactic acid. 7. On 5/23/18 at 1:00 p.m., staff member B stated the laboratory began testing PT on the i-STAT in January of 2017 while troubleshooting discrepancies on waived analyzers. The laboratory began testing blood gases on the i-STAT on 9/21/17.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to sign and date approval of one of one Individualized Quality Control Plan (IQCP) from 8/1/17 through 5/23/18. The findings include: 1. A review on 5/23/18 at 11:50 a.m. of the Dahl Memorial Healthcare Association, Inc. i-STAT IQCP lacked the laboratory director's signature of approval. 2. A review on 5/23/18 at 11:50 a.m. of the quality control results for troponin, b-type natriuretic peptide (BNP), prothrombin time (PT), pH, pCO2, pO2, and lactic acid documented one level of external control performed every month from 8/1/17 through 5/23/18. 3. On 5/23/18 at 3:00p.m., staff member A stated the laboratory did not have a copy signed by the laboratory director.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on observation, record review and interview, the laboratory failed to perform multiple levels of external quality control with new lot numbers per the manufacturer instructions for 7 of 7 analytes performed on the i-STAT. The findings include: 1. On 5/23/18 at 8:45 a.m., an i-STAT analyzer was observed on the laboratory counter. 2. On 5/23/18 at 8:45 a.m., staff member A stated troponin, prothrombin time (PT), blood gases (pH, pO2, pCO2, lactic acid), b-type natriuretic peptide (BNP), and waived chemistry tests were performed on the i-STAT analyzer. 3. A review on 5/23 /18 at 9:35 a.m. of the Dahl Memorial Healthcare Association, Inc. Laboratory Manual of Policies and Procedures included "monthly quality control" instructions. The PT section included instructions for liquid quality control that stated to "run i-STAT PT Level 1 or Level 2 once a month and with each new shipment of cartridges (run QC per LOT received, not per box)." 4. A review on 5/23/18 at 11:50 a.m. of the quality control results for PT, troponin, BNP, pH, pO2, pCO2, and lactic acid documented one level of external control performed per month from 8/1/17 through 5 /23/18. 5. A review on 5/23/18 at 11:50 a.m. of the Dahl Memorial Healthcare Association Laboratory i-STAT Individualized Quality Control Plan (IQCP) included

	to run an unspecified number of external controls "with each new lot number of cartridge or monthly." 6. On 5/23/18 at 11:50 a.m., staff member A stated one level of control was run monthly for each cartridge type. 7. A review on 5/23/18 at 12:00 p.m. of the i-STAT instruction manual suggested "from each lot in each shipment of cartridges, analyze multiple levels of i-STAT controls using any verified analyzer." Controls for PT cartridges required the "i-STAT PT Control Level 1 (normal) and PT Control Level 2 (abnormal) are used to verify the integrity of newly received PT/INR cartridges." Controls for troponin and BNP cartridges documented the "i-STAT troponin, BNP, ... Control Levels 1, 2, and 3 are intended for use as an assayed quality control material which can be used to verify the integrity of newly received i-STAT troponin, BNP, ... cartridges."
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to document the room temperature from 4/8/16 to 5/23/18. The findings include: 1. A review on 5 /23/18 at 9:35 a.m. of the Dahl Memorial Healthcare Association, Inc. Laboratory Manual of Policies and Procedures included a room temperature limitation for the i-STAT analyzer of 16 to 30 degrees Celsius. Cartridges include instructions to allow to come to room temperature prior to testing. 2. On 5/23/18 at 1:20 p.m., a room temperature thermometer was not observed in the laboratory. 3. A review on 5/23/18 at 1:20 p.m. of the temperature charts lacked documentation of the room temperature. 4. On 5/23/18 at 1:20 p.m., staff member A stated the room temperature was not documented.
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, record review and interview, the laboratory failed to assess accuracy and precision for five of five new tests. The findings include: 1. On 5/23/18 at 8:45 a.m., an i-STAT analyzer was observed on the laboratory counter. 2. On 5/23 /18 at 8:45 a.m., staff member A stated troponin, prothrombin time (PT), blood gases

	(pH, pO2, pCO2, lactic acid), b-type natriuretic peptide (BNP), and waived chemistry tests were performed on the i-STAT analyzer. 3. A review on 5/23/18 at 12:30 p.m. of the verification data for PT and blood gases on the i-STAT analyzer was incomplete. a. PT accuracy data was accumulated without analysis of the data to assess accuracy. b. PT precision data was not documented. c. Blood gases precision data was accumulated without analysis of the data to assess precision. d. Review and approval by the laboratory director was not documented. 4. On 5/23/18 at 1:00 p.m., staff member B stated the laboratory began testing PT on the i-STAT in January of 2017 while troubleshooting discrepancies on waived analyzers. The laboratory began testing blood gases on the i-STAT on 9/21/17. 5. On 5/23/18 at 1:05 p.m., staff member A stated the statistics were not compiled.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to address testing personnel risks and failed to include the number of controls in the Individualized Quality Control Plan (IQCP) for seven of seven tests performed on the i-STAT analyzer from 8/1/17 to 5/23/18. The findings include: A. Missing Testing Personnel Risks 1. A review on 5/23/18 at 3:00 p.m. of the Dahl Memorial Healthcare Association Laboratory i-STAT IQCP risk assessment lacked the risks of unqualified testing personnel, incompetent testing personnel, and inadequate staffing. 2. On 5/23 /18 at 3:00 p.m., staff member A stated the risks were not in the risk assessment. B. Missing Number of External Controls 1. A review on 5/23/18 at 11:50 a.m. of the Dahl Memorial Healthcare Association Laboratory i-STAT IQCP quality control plan lacked the number of external controls to be performed by the laboratory. 2. On 5/23 /18 at 11:50 a.m., staff member A stated the number was not specified in the IQCP.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish in-house data supporting the i-STAT Individualized Quality Control Plan (IQCP) from 8/1/17 through 5/23/18. The findings include: 1. A review on 5/23/18 at 11:50 a.m. of the

	Dahl Memorial Healthcare Association i-STAT IQCP lacked utilization of in-house data to support the risk assessment decisions. 2. On 5/23/18 at 3:00p.m., staff member A stated the laboratory did not have data to support the risk assessment.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory director failed to provide overall management and direction from 4/8/16 through 5/23/18, failed to enroll in proficiency testing (see D2000 and D6015), failed to complete an Individual Quality Control Plan (IQCP) (see D5407, D5411, D5413, D5445, D5481), failed to complete validation of new tests (see D5421 and D63013), failed to prohibit unqualified testing personnel from performing testing (see D6028, D6063, and D6064), and failed to prevent a repeat deficiency for unperformed and incomplete competency assessments (see D6030 and D6046). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of the patient test results.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure verification procedures determine accuracy and precision for five of five new tests performed on the i-STAT analyzer. The findings include: 1. A review on 5/23/18 at 12:30 p.m. of the verification data for prothrombin time (PT) and blood gases (pH, pCO2, pO2, and lactic acid) on the i-STAT analyzer was incomplete. a. PT accuracy data was accumulated without analysis of the data to assess accuracy. b. PT precision data was not documented. c. Blood gases precision data was accumulated without analysis of the data to assess precision. 2. A review on 5/23/18 at 12:30 p.m. of the verification data for PT and blood gas cartridges on the i-STAT analyzer lacked documentation of the laboratory director's review and approval. 3. On 5/23/18 at 1:00 p.m., staff member B stated the laboratory began testing PT on the i-STAT in January of 2017 while troubleshooting discrepancies on waived analyzers. The laboratory began testing blood gases on the i-STAT on 9/21/17. 4. On 5/23/18 at 1:05 p.m., staff member A stated the statistics were not compiled for the verification data. 5. On 5/23

	/18 at 1:05 p.m., staff member A stated the laboratory director approved the policy and procedures for these analytes but documentation of the laboratory director reviewing the verification data could not be located.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory director failed to ensure the laboratory is enrolled in proficiency testing for 5 of 14 analytes performed by the laboratory. The findings include: 1. On 5/23/18 at 8:45 a.m., an i-STAT analyzer was observed on the laboratory counter. 2. On 5/23/18 at 8:45 a.m., staff member A stated troponin, prothrombin time (PT), blood gases (pH, pO2, pCO2, lactic acid), b-type natriuretic peptide (BNP), and waived chemistry tests were performed on the i-STAT analyzer. 3. A review on 5/23/18 at 9:30 a.m. of the American Proficiency Institute (API) binders for testing performed in 2017 and 2018 lacked documentation of enrollment for five tests on the i-STAT. a. PT. b. pO2. c. pH. d. pCO2. e. Lactic acid. 4. A review on 5/23/18 at 9:40 a.m. of staff member A's emails from September of 2017 included notification to the facility to pay for enrollment of these analytes. The emails did not indicate if enrollment was completed. 5. A review on 5/23/18 at 9:40 a.m. of the API 2018 Order Confirmation form lacked enrollment for 2018 for PT and blood gases. 6. On 5/23/18 at 1:00 p.m., staff member B stated the laboratory began testing PT on the i-STAT in January of 2017 while troubleshooting discrepancies on waived analyzers. The laboratory began testing blood gases on the i-STAT on 9/21/17.
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 record review and interview, the laboratory director employed unqualified testing personnel to perform moderate complexity testing from 4/8/16 to 5/23/18. The findings include: 1. A review on 5/23/18 at 8:45 a.m. of the CMS-209 form filled out by the laboratory included staff members B, E, and F listed as testing personnel. A review of the credentials lacked an applicable state license for staff members B, E,

and F. 2. A review on 5/23/18 9:35 a.m. of the Dahl Memorial Healthcare Association, Inc. Laboratory Manual of Policies and Procedures for the i-STAT included "staff who have been trained for the i-STAT 1 analyzer are authorized to use the i-STAT instrument." 3. A review on 5/23/18 at 11:30 a.m. of the 2016 Dahl Memorial Healthcare Association, Inc. competency evaluations included three unqualified testing personnel (staff members B, E, and F) evaluated as competent on the moderate complexity Sysmex PocH-100i hematology analyzer and i-STAT analyzer (troponin and BNP). The competency evaluation was signed off by the laboratory director. 4. A review on 5/23/18 at 2:00 p.m. of the Dahl Memorial Healthcare Association, Inc. quality control logs included a column titled "Test Run By." The column included the initials of the three unqualified testing personnel in every day of patient testing between 4/18/16 and 7/24/17. Each month was initialed as reviewed by the laboratory director. A. Unqualified staff member B performed testing on 4/18/16 (BNP and troponin), 4/21/16 (BNP), 4/22/16 (troponin), 4/25/16 (BNP and troponin), 4/26/16 (BNP), 4/28/16 (BNP), 5/4/16 (troponin), 5/6/16 (BNP), 5/13/16 (BNP), 5/31/16 (troponin), 6/3/16 (BNP), 6/9/16 (BNP), 6/10/16 (BNP), 6/13/16 (troponin), 6/18/16 (BNP), 6/19/16 (BNP), 6/20/16 (BNP), 7/7/16 (BNP), 7/25/16 (troponin), 8/5/16 (troponin), 8/6/16 (troponin), 8/17/16 (BNP), 8/20/16 (troponin), 8 /21/16 (troponin), 8/30/16 (BNP), 8/31/16 (BNP), 9/9/16 (BNP), 9/16/16 (BNP), 9/17 /16 (BNP), 9/18/16 (BNP), 9/22/16 (BNP), 9/28/16 (troponin), 10/4/16 (troponin), 10 /20/16 (BNP), 10/28/16 (BNP), 10/30/16 (BNP and troponin), 11/8/16 (BNP), 11/11 /16 (troponin), 11/12/16 (troponin), 12/9/16 (troponin), 12/10/16 (troponin), 12/25/16 (troponin), 12/31/16 (troponin), 1/1/17 (BNP and troponin), 1/5/17 (BNP), 1/6/17 (BNP), 1/19/17 (BNP and troponin), 1/20/17 (BNP), 1/26/17 (troponin), 1/27/17 (BNP), 2/1/17 (troponin), 2/2/17 (BNP), 2/16/17 (BNP), 2/27/17 (BNP), 2/28/17 (BNP), 3/3/17 (BNP), 3/9/17 (BNP), 3/10/17 (BNP), 3/12/17 (BNP), 3/16/17 (BNP), 3 /20/17 (BNP), 3/21/17 (troponin), 3/25/17 (troponin), 3/30/17 (BNP), 4/3/17 (BNP), 4 /7/17 (BNP), 4/21/17 (BNP), 4/23/17 (BNP), 4/27/17 (BNP), 5/4/17 (BNP), 5/5/17 (BNP), 5/6/17 (BNP), 5/7/17 (troponin), 5/11/17 (BNP), 5/13/17 (BNP), 5/14/17 (BNP), 5/25/17 (BNP and troponin), 5/26/17 (BNP and troponin), 5/27/17 (BNP), 5/29 /17 (BNP), 5/31/17 (BNP), 6/6/17 (BNP), 6/9/17 (BNP), 6/14/17 (BNP and troponin), 6/16/17 (BNP), 6/17/17 (BNP), 6/28/17 (BNP), 7/8/17 (BNP), 7/9/17 (troponin), 7/14 /17 (troponin), 7/16/17 (troponin), 7/20/17 (BNP), 7/21/17 (BNP), 7/22/17 (troponin), and 7/24/17 (BNP). B. Unqualified staff member E performed testing on 5/3/16 (BNP), 5/10/16 (BNP), 5/11/16 (BNP), 5/24/16 (BNP and troponin), 5/25/16 (BNP and troponin), 6/1/16 (BNP), 6/6/16 (BNP and troponin), 6/7/16 (BNP and troponin), 6 /15/16 (BNP), 6/21/16 (BNP and troponin), 6/28/16 (BNP and troponin), 7/12/16 (BNP), 7/20/16 (BNP), 7/26/16 (BNP), 7/27/16 (BNP), 8/1/16 (BNP), 8/9/16 (BNP), 8 /10/16 (BNP), 8/15/16 (BNP), 8/16/16 (BNP), 8/23/16 (BNP), 8/24/16 (BNP), 9/13/16 (troponin), 9/22/16 (troponin), 9/27/16 (BNP), 9/29/16 (BNP), 9/30/16 (BNP), 10/18 /16 (BNP), 10/24/16 (BNP), 10/26/16 (BNP), 11/9/16 (BNP), 11/22/16 (troponin), 11 /23/16 (BNP), 11/24/16 (troponin), 11/25/16 (BNP and troponin), 11/27/16 (troponin), 12/14/16 (troponin), 12/27/16 (troponin), 1/3/17 (BNP), 1/4/17 (troponin), 1/9/17 (BNP), 1/11/17 (BNP), 1/16/17 (BNP), 1/17/17 (BNP), 1/31/17 (BNP and troponin), 2 /7/17 (BNP), 2/20/17 (BNP), 2/22/17 (BNP and troponin), 3/8/17 (BNP), 3/13/17 (BNP), 3/14/17 (BNP), 3/22/17 (BNP), 3/23/17 (BNP), 3/24/17 (BNP), 3/25/16 (BNP), 3/27/17 (BNP), 3/28/17 (BNP), 4/10/17 (BNP), 4/17/17 (BNP and troponin), 4 /25/17 (troponin), 5/2/17 (BNP and troponin), 5/9/17 (BNP), 5/10/17 (BNP), 5/15/17 (BNP), 5/16/17 (BNP), 5/17/17 (BNP), 5/20/17 (BNP), 5/21/17 (BNP), 5/24/17 (BNP and troponin), 5/30/17 (troponin), 5/31/17 (troponin), 6/2/17 (BNP), 6/12/17 (BNP), 6 /13/17 (BNP), 6/26/17 (BNP), 6/27/17 (BNP), 7/11/17 (BNP), and 7/17/17 (BNP). C. Unqualified staff member F performed testing on 10/12/16 (BNP), 10/17/16 (troponin), 10/19/16 (troponin), 1/10/17 (BNP), 1/13/17 (BNP), 1/23/17 (BNP), 1/25

	/17 (BNP), 3/15/17 (BNP), 4/4/17 (BNP), 5/3/17 (BNP), 5/8/17 (BNP), 5/30/17 (BNP), 6/1/17 (BNP), 6/5/17 (BNP), 6/22/17 (troponin), 6/29/17 (BNP and troponin), and 7/13/17 (BNP). D. Initials from qualified testing personnel C and D in the "Test Run By" column were not documented on any of the quality control and patient result logs. 5. On 5/23/18 at 2:00 p.m., staff member A stated the initials on the logs belonged to staff members B, E, and F.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to assess the competency of two of two qualified testing personnel for 2017 and failed to assess five of six required aspects of competency for ten of ten new testing personnel in 2018. The findings include: A. 2017 Missing Evaluations 1. A review on 5/23/18 at 11:30 a.m. of the Dahl Memorial Healthcare Association, Inc. competency assessments lacked documentation of assessments for 2017 for testing personnel C and D. 2. On 5/23/18 at 11:30 a.m., staff member A stated the competency assessments were not done in 2017. 3. A review on 5/29/18 at 11:15 a.m. of the CMS-209 form filled out by the laboratory for the previous survey on 4/7/16 checked the laboratory director as the technical consultant. B. 2018 Incomplete Evaluations. 1. A review on 5/23/18 at 11:30 a.m. of the Dahl Memorial Healthcare Association, Inc. competency assessments for 2018 lacked documentation of assessing five of the six required aspects of competency for ten of ten new testing personnel (staff members A, G, H, I, J, K, L, M, N, O) on the Sysmex pocH-100i hematology analyzer and the i-STAT analyzer. a. No documentation of direct observations of routine patient test performance, including patient preparation, specimen handling, processing, and testing. b. No documentation of monitoring the recording and reporting of test results. c. No documentation of review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. No documentation of direct observation of performance of instrument maintenance and function checks. e. No documentation of assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. On 5/23/18 at 11:30 a.m., staff member A stated the competency assessments lacked documentation of competency. 3. A review on 5/29 /18 at 11:15 a.m. of the CMS-209 form filled out by the laboratory for the previous survey on 4/7/16 checked the laboratory director as the technical consultant.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)

	(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview, the technical consultant failed to assess the competency of two of two qualified testing personnel for 2017 and failed to assess five of six required aspects of competency for ten of ten new testing personnel in 2018. This is a repeat deficiency. The findings include: A. 2017 Missing Competency Evaluations 1. A review on 5/23/18 at 9:35 a.m. of the Dahl Memorial Healthcare Association, Inc. Laboratory Manual of Policies and Procedures for the i-STAT included "initial training, 6-month and annual competencies are required to maintain competency and testing privileges." 2. A review on 5/23/18 at 11:30 a.m. of the Dahl Memorial Healthcare Association, Inc. competency assessments lacked documentation of assessments for 2017 for qualified testing personnel C and D. 3. On 5/23/18 at 11:30 a.m., staff member A stated the competency assessments were not done in 2017. 4. A review on 5/29/18 at 11:15 a.m. of the CMS-209 form filled out by the laboratory for the previous survey on 4/7/16 checked the laboratory director as the technical consultant. B. 2018 Incomplete Evaluations. 1. A review on 5/23/18 at 11:30 a.m. of the Dahl Memorial Healthcare Association, Inc. competency assessments for 2018 lacked documentation of assessing five of the six required aspects of competency for ten of ten new testing personnel (staff members A, G, H, I, J, K, L, M, N, O) on the Sysmex pocH-100i hematology analyzer and the i-STAT analyzer. a. No documentation of direct observations of routine patient test performance, including patient preparation, specimen handling, processing, and testing. b. No documentation of monitoring the recording and reporting of test results. c. No documentation of review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d. No documentation of direct observation of performance of instrument maintenance and function checks. e. No documentation of assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. 2. On 5/23/18 at 11:30 a.m., staff member A stated the competency assessments lacked documentation of competency. 3. A review on 5/29/18 at 11:15 a.m. of the CMS-209 form filled out by the laboratory for the previous survey on 4/7/16 checked the laboratory director as the technical consultant.
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 and interview, the laboratory failed to ensure qualified testing personnel performed moderate complexity testing and unqualified testing personnel do not perform moderate complexity testing from 4/8/16 through 5/23/18 (see D6064). The cumulative effect of this systemic problem resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
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 and interview, the laboratory allowed unqualified testing personnel without an applicable state license to perform moderate complexity testing from 4/8/16 to 5/23/18. The findings include: 1. A review on 5/23/18 at 8:45 a.m. of the CMS-209 form filled out by the laboratory included staff members B, E, and F listed as testing personnel. A review of the credentials lacked an applicable state license for staff members B, E, and F. 2. A review on 5/23/18 9:35 a.m. of the Dahl Memorial Healthcare Association, Inc. Laboratory Manual of Policies and Procedures for the i-STAT included "staff who have been trained for the i-STAT 1 analyzer are authorized to use the i-STAT instrument." 3. A review on 5/23/18 at 11:30 a.m. of the 2016 Dahl Memorial Healthcare Association, Inc. competency evaluations included three unqualified testing personnel (staff members B, E, and F) evaluated as competent on the moderate complexity Sysmex PocH-100i hematology analyzer and i-STAT analyzer (troponin and BNP). The competency evaluation was signed off by the laboratory director. 4. A review on 5/23/18 at 2:00 p.m. of the Dahl Memorial Healthcare Association, Inc. quality control logs included a column titled "Test Run By." The column included the initials of the three unqualified testing personnel in every day of patient testing between 4/18/16 and 7/24/17. Each month was initialed as reviewed by the laboratory director. A. Unqualified staff member B performed testing on 4/18/16 (BNP and troponin), 4/21/16 (BNP), 4/22/16 (troponin), 4/25/16 (BNP and troponin), 4/26/16 (BNP), 4/28/16 (BNP), 5/4/16 (troponin), 5/6/16 (BNP), 5/13/16 (BNP), 5/31/16 (troponin), 6/3/16 (BNP), 6/9/16 (BNP), 6/10/16 (BNP), 6/13/16 (troponin), 6/18/16 (BNP), 6/19/16 (BNP), 6/20/16 (BNP), 7/7/16 (BNP), 7/25/16 (troponin), 8/5/16 (troponin), 8/6/16 (troponin), 8/17/16 (BNP), 8/20/16 (troponin), 8 /21/16 (troponin), 8/30/16 (BNP), 8/31/16 (BNP), 9/9/16 (BNP), 9/16/16 (BNP), 9/17 /16 (BNP), 9/18/16 (BNP), 9/22/16 (BNP), 9/28/16 (troponin), 10/4/16 (troponin), 10 /20/16 (BNP), 10/28/16 (BNP), 10/30/16 (BNP and troponin), 11/8/16 (BNP), 11/11 /16 (troponin), 11/12/16 (troponin), 12/9/16 (troponin), 12/10/16 (troponin), 12/25/16 (troponin), 12/31/16 (troponin), 1/1/17 (BNP and troponin), 1/5/17 (BNP), 1/6/17 (BNP), 1/19/17 (BNP and troponin), 1/20/17 (BNP), 1/26/17 (troponin), 1/27/17 (BNP), 2/1/17 (troponin), 2/2/17 (BNP), 2/16/17 (BNP), 2/27/17 (BNP), 2/28/17 (BNP), 3/3/17 (BNP), 3/9/17 (BNP), 3/10/17 (BNP), 3/12/17 (BNP), 3/16/17 (BNP), 3 /20/17 (BNP), 3/21/17 (troponin), 3/25/17 (troponin), 3/30/17 (BNP), 4/3/17 (BNP), 4 /7/17 (BNP), 4/21/17 (BNP), 4/23/17 (BNP), 4/27/17 (BNP), 5/4/17 (BNP), 5/5/17 (BNP), 5/6/17 (BNP), 5/7/17 (troponin), 5/11/17 (BNP), 5/13/17 (BNP), 5/14/17 (BNP), 5/25/17 (BNP and troponin), 5/26/17 (BNP and troponin), 5/27/17 (BNP), 5/29 /17 (BNP), 5/31/17 (BNP), 6/6/17 (BNP), 6/9/17 (BNP), 6/14/17 (BNP and troponin), 6/16/17 (BNP), 6/17/17 (BNP), 6/28/17 (BNP), 7/8/17 (BNP), 7/9/17 (troponin), 7/14 /17 (troponin), 7/16/17 (troponin), 7/20/17 (BNP), 7/21/17 (BNP), 7/22/17 (troponin), and 7/24/17 (BNP). B. Unqualified staff member E performed testing on 5/3/16 (BNP), 5/10/16 (BNP), 5/11/16 (BNP), 5/24/16 (BNP and troponin), 5/25/16 (BNP and troponin), 6/1/16 (BNP), 6/6/16 (BNP and troponin), 6/7/16 (BNP and troponin), 6 /15/16 (BNP), 6/21/16 (BNP and troponin), 6/28/16 (BNP and troponin), 7/12/16 (BNP), 7/20/16 (BNP), 7/26/16 (BNP), 7/27/16 (BNP), 8/1/16 (BNP), 8/9/16 (BNP), 8 /10/16 (BNP), 8/15/16 (BNP), 8/16/16 (BNP), 8/23/16 (BNP), 8/24/16 (BNP), 9/13/16 (troponin), 9/22/16 (troponin), 9/27/16 (BNP), 9/29/16 (BNP), 9/30/16 (BNP), 10/18 /16 (BNP), 10/24/16 (BNP), 10/26/16 (BNP), 11/9/16 (BNP), 11/22/16 (troponin), 11

	/23/16 (BNP), 11/24/16 (troponin), 11/25/16 (BNP and troponin), 11/27/16 (troponin), 12/14/16 (troponin), 12/27/16 (troponin), 1/3/17 (BNP), 1/4/17 (troponin), 1/9/17 (BNP), 1/11/17 (BNP), 1/16/17 (BNP), 1/17/17 (BNP), 1/31/17 (BNP and troponin), 2/7/17 (BNP), 2/20/17 (BNP), 2/22/17 (BNP and troponin), 3/8/17 (BNP), 3/13/17 (BNP), 3/14/17 (BNP), 3/22/17 (BNP), 3/23/17 (BNP), 3/24/17 (BNP), 3/25/16 (BNP), 3/27/17 (BNP), 3/28/17 (BNP), 4/10/17 (BNP), 4/17/17 (BNP and troponin), 4/25/17 (troponin), 5/2/17 (BNP and troponin), 5/9/17 (BNP), 5/10/17 (BNP), 5/15/17 (BNP), 5/16/17 (BNP), 5/17/17 (BNP), 5/20/17 (BNP), 5/21/17 (BNP), 5/24/17 (BNP and troponin), 5/30/17 (troponin), 5/31/17 (troponin), 6/2/17 (BNP), 6/12/17 (BNP), 6/13/17 (BNP), 6/26/17 (BNP), 6/27/17 (BNP), 7/11/17 (BNP), and 7/17/17 (BNP). C. Unqualified staff member F performed testing on 10/12/16 (BNP), 10/17/16 (troponin), 10/19/16 (troponin), 1/10/17 (BNP), 1/13/17 (BNP), 1/23/17 (BNP), 1/25/17 (BNP), 3/15/17 (BNP), 4/4/17 (BNP), 5/3/17 (BNP), 5/8/17 (BNP), 5/30/17 (BNP), 6/1/17 (BNP), 6/5/17 (BNP), 6/22/17 (troponin), 6/29/17 (BNP and troponin), and 7/13/17 (BNP). D. Initials from qualified testing personnel C and D in the "Test Run By" column were not documented on any of the quality control and patient logs. 5. On 5/23/18 at 2:00 p.m., staff member A stated the initials on the logs belonged to staff members B, E, and F.