Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0042038	01/13/2021
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
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 review of CMS-155 Individual Laboratory Profile report, record review of American Proficiency Institute (API), proficiency tests and interview with hospital administrator (not listed on the Laboratory Personnel Report (CMS-209) form), the Laboratory Director failed to provide sufficient oversight of the proficiency program for years 2019 and 2020. See D6018 Findings include: 1. Review of laboratory manual, Policy #LAB-030 states Remedial Action for Failures; Proficiency Tests: If failure occurs with the second set of samples, testing personnel will review results with the Laboratory Director for appropriate education and analysis. 2. Review of CMS-155 Individual Laboratory Profile report showed the laboratory recieved 0%

	score for Routine Chemistry (0245), PH Blood Gas (0315), PO2 Blood Gas (0325) and PCO2 Blood Gas (0335) for 2019 Event 1 and 2020 Event 1. 3. Review of the American Proficiency Institute (API), confirmed the Laboratory Director failed to ensure Chemistry- Core proficiency testing results were submitted in a timely manner for 2019 Event 1 and 2020 Event 1 resulting in 0% score for Routine Chemistry (0245), PH Blood Gas (0315), PO2 Blood Gas (0325) and PCO2 Blood Gas (0335). 4. Review of American Proficiency Institute (API) proficiency results, the Laboratory Director failed to review and document corrective action for unsuccessful analytes for 2019 Hematology/Coagulation 2nd Event and 3rd Event, 2019 Chemistry-Core 3rd Event, 2020 Chemistry-Core 1st Event and 2nd Event. 5. Exit interview on 1/13/2021 at 1:15pm with hospital administrator verified lack of review.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel files, laboratory policies and procedures, and communication with the technical consultant (TC1), the laboratory failed to perform annual competency for years 2019 and 2020. Findings include: 1. Policy #LAB-030 states: Education is provided, and competency testing is performed upon hire and at 6 months for new staff and annually thereafter for all testing personnel. 2. Review of Personnel Records revealed the laboratory failed to perform annual competency for testing personnel for the years 2019 and 2020. 3. Note from Technical Consultant (TC1) on 1/13/21 at 9:43 am, confirmed competency assessments were not performed for years 2019 and 2020.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of Quality Control Logs, laboratory policies and procedures and interview with hospital administrator (not listed on the Laboratory Personnel Report (CMS-209) form, the laboratory failed to review quality assessment for 2019 and 2020. Findings include: 1. Policies and Procedures review form states; Reviews shall be conducted at least once a year performed by the Administrator, Physician Assistant, Physician and one member for the community. 2. The laboratory failed to review policies and procedures for 2019 and 2020. 3. Laboratory was unable to provide proof of Review of Quality Control Logs for Urine Dipstick for 2019 and 2020. 4. Interview on 1/13/2021 at 1:15pm with hospital administrator verified lack of quality assessment review.

D6018	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii) 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)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action; This STANDARD is not met as evidenced by: Based on review of laboratory policies and procdedure, CMS-155 Individual Laboratory Profile report, American Proficiency Institute (API) proficiency results, and interview with hospital administrator (not listed on the Laboratory Personnel Report (CMS-209) form), the laboratory director failed to provided oversite of the laboratory's performance of proficiency results for 2019 and 2020. Findings include: 1. Review of laboratory manual, Policy #LAB-030 states Remedial Action for Failures; Proficiency Tests: If failure occurs with the second set of samples, testing personnel will review results with the Laboratory Director for appropriate education and analysis. 2. Review of CMS-155 Individual Laboratory Profile report showed the laboratory recieved 0% score for Routine Chemistry (0245), PH Blood Gas (0315), PO2 Blood Gas (0325) and PCO2 Blood Gas (0335) for 2019 Event 1 and 2020 Event 1. 3. Review of the American Proficiency Institute (API), confirmed the Laboratory Director failed to ensure Chemistry- Core proficiency testing results were submitted in a timely manner for 2019 Event 1 and 2020 Event 1 resulting in 0% score for Routine Chemistry (0245), PH Blood Gas (0315), PO2 Blood Gas (0325) and PCO2 Blood Gas (0335). 4. Review of American Proficiency Institute (API) proficiency results, the Laboratory Director failed to review and document corrective action for unsuccessful analytes for 2019 Hematology/Coagulation 2nd Event and 3rd Event, 2019 Chemistry-Core 3rd Event, 2020 Chemistry-Core 1st Event and 2nd Event. 5. Exit interview on 1/13/2021 at 1:15pm with hospital administrator verified lack of review