Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D1061395	06/01/2023
Name of Provider or Supplier	**Street Address, City, State**	
Meeker Memorial Hospital & Clinics - Dassel	740 Parker Ave W, Dassel, MN	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director (LD) or designee failed to attest to the integration of proficiency testing (PT) samples into the routine patient workload on two of four occasions reviewed from 2022 and 2023. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the LD during a tour of the laboratory at 9:35 a.m. on June 1, 2023. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The LD or designee failed to sign the attestation statement for two of four Hematology/Coagulation API PT events reviewed in the January 2022 through June 2023 timeframe. See below. Event Specialty missing attestation 2022-1 Hematology /Coagulation 2023-1 Hematology/Coagulation 4. The Proficiency Testing policy, found in the Laboratory Procedure Manual, did not address the requirement of the LD (or designee) and testing personnel's signature on the Attestation Statement form. 5. In an interview at 10:42 a.m. on June 1, 2023, the LD confirmed the above findings stating that either the LD or the Technical Consultant can sign the Attestation Statement form. .
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:
. ITEM 1 Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure the procedure manual included quality control (QC) procedures and calibration verification procedures for one of three non-waived tests performed by the laboratory. Findings are as follows: 1. The laboratory performed Hematology testing as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 9:35 a.m. on June 1, 2023. 2. A Beckman Coulter DXH 520 hematology analyzer was observed as present and available for use during the tour of the laboratory. 3. The laboratory procedure, DXH 520, was approved by the LD 08/16 /2022. The procedure contained language from the manufacturer, Beckman Coulter, as follows: a. For QC performance: "Beckman Coulter recommends for QC and checks be performed using commercial controls at intervals established by your laboratory." b. For calibration verification performance: "Beckman Coulter recommends verifying the calibration on the instrument as dictated by your laboratory procedure" QC protocols and calibration verification procedures, established by the laboratory, including type, level, and frequency could not be found in the Laboratory Procedure Manual. 4. The laboratory was unable to provide written QC and calibration verification procedures, specific to the laboratory, upon request. 5. The laboratory performed approximately 3968 hematology tests annually as indicated on the Clinical Laboratory Improvement Amendments Application for Certification provided by the laboratory on 6/01/2023. 6. In an interview at 11:08 a.m. on June 1, 2023, the LD confirmed the above findings. . ITEM 2 Based on observation, record review, and interview with laboratory personnel, the laboratory failed to include step by step performance in one of three non-waived tests performed by the laboratory. Findings are as follows: 1. The laboratory performs manual microscopic urinalysis as confirmed by the Laboratory Director (LD) during a tour of the laboratory at 9:40 a.m. on June 1, 2023. 2. The microscope used to perform the manual microscopic urinalysis was observed as present and available for use during the tour of the laboratory. 3. Step-by-step instructions, how to perform the manual microscopic urinalysis test, were not included in the approved urinalysis procedure: Clinitek Status + Analyzer, signed by the LD 08/02/2020 4. In interviews between 11:08 and 11:20 a. m. on June 1, 2023, the LD and Testing Personnel 1 confirmed the step-by step procedure was missing from the procedure after inadvertently deleting it on May 31, 2023, the day before the survey. .