Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0405291	03/22/2019
Name of Provider or Supplier	**Street Address, City, State**	
Pipestone County Medical Center Laboratory	916 4th Ave Sw, Pipestone, 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
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 observation, document review and interview with laboratory personnel, the laboratory failed to include accurate Chemistry and Hematology reference intervals in the procedure manual. Findings are as follows: The laboratory performed Chemistry and Hematology testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 03/21/19 at 8:10 a.m. A. Chemistry 1. A Radiometer ABL80 blood gas analyzer was observed as present and available for use during the tour. 2. The Ionized Calcium reference intervals found in the Ionized Calcium procedure were discrepant with that indicated on patient test report (Date performed = 12/21/2017,

	Sex / age = Female / 78 years) reviewed on date of survey. See below. Test Procedure Test Report Ionized Calcium 15 - 1.29 1.15 - 1.29 3. In an interview on 03/22/19 at 8: 45 a.m., the GS confirmed the above findings. B. Hematology 1. A Streck Auto Plus Erythrocyte Sedimentation Rate (ESR) analyzer was observed as present and available for use during the tour. 2. ESR reference intervals were not included in the ESR Auto Plus procedure versus that indicated on patient test report (Date performed = 5/17 /2018, Sex / age = Female / 51 years) reviewed on date of survey. See below. Test Procedure Test Report ESR Not found 0 - 22 3. In an interview on 03/22/19 at 8:45 a. m., the GS confirmed the above findings. .
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: . Based on observation, document review and interview with laboratory personnel, the laboratory failed to perform and document functional checks of a biological safety cabinet for 2017 and 2018. Findings are as follows: 1. During a tour of the laboratory conducted on 03/21/19 at 8:10 a.m., a LabConco Class II Safety Cabinet was observed as present and available for use. 2. A requirement for functional checks of the biological safety cabinet by an outside vendor was established in the Laboratory: Maintenance Records procedure located in the Maintenance Records manual. 3. Documentation of the required functional checks for 2017 and 2018 were not found during review of laboratory records. The laboratory was unable to provide these documents upon request. 4. In an interview on 03/21/19 at 11:50 a.m., the GS confirmed the above findings. .