Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410643	12/14/2021
Name of Provider or Supplier	**Street Address, City, State**	
Bozeman Clinic	1245 North 15th Avenue, Bozeman, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, and interview with the Technical Supervisor (TS)#1, the laboratory failed to retain patient test records for isolation and identification of bacteria and quality control (QC) records of microbiology reagents: catalase, indole, and PYR from January 2020 to November 2021. Findings: 1. No patient test records for isolation and identification of bacteria were available to review from January 2020 to November 2021. 2. Review of Bacteriology Log procedure revealed "On Day 1 this log will include: time and date a specimen was received in the lab, time a specimen was set up, media used for culture, and tech's initials. One Day 2 read and record the culture results and initial. When necessary record colony description, grams stain results, catalase, indole, oxidase, PYR reactions, media used for sub-culturing including ID tubes or sensitivities." 3. No QC documentation for microbiology reagent: catalase, indole, and PYR were available for review from January 2020 to November 2021. 4. Review of Bacteriology Log procedure revealed, "Quality Control must be performed and recorded on the Bacteriology log (Culture order) with each patient for gram stains, indole, oxidase, catalase, or PYR." 5. Interview on December 14, 2021 1:40 PM with (TS)#1 confirmed the patient test records for isolation and identification of bacteria and QC of microbiology reagents: catalase, indole and PYR were not retained from January 2020 to November 2021.
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 record review of the hematology and urinalysis, and interview with technical supervisor (TS) #1, the laboratory failed to include in their procedure manuals reference intervals (normal values) for manual differentials and microscopic urinalysis, and failed to have a step-by-step procedure for the preparation of blood smears. Findings: 1. No reference intervals (normal values) were available in the hematology procedure for manual differential. 2. No reference intervals (normal values) were available in the urinalysis procedure for microscopic urinalysis. 3. No step-by-step procedure for the preparation of blood smear were available for review. 4. Interview on December 14, 2021 at 11:00 AM with the TS #1, confirmed the laboratory failed to include normal values for manual differential and microscopic urinalysis, and failed to have a step-by-step procedure for the preparation of blood smears.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Supervisor (TS)#1, the laboratory failed to include the normal reference ranges and units in the patient results report for manual differential. Findings: 1. Review of Differential, Manual, Blood (#735512) patient results report lacked normal reference ranges and units. 2. Interview on December 14, 2021 10:00 AM with (TS)#1 confirmed the patient results report lacked normal reference ranges and units for manual differentials.