Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0666047	04/28/2026
Name of Provider or Supplier	**Street Address, City, State**	
Billings Clinic - Cody	201 Yellowstone Ave, Cody, WY	

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	Validation survey A validation survey was performed on April 28,2026, with the following standard level deficiencies cited.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedures, textbook reference, direct observation, and interview with Laboratory Director, the laboratory failed to have textbook references in their procedure while performing microscopic urines for the last year as evidenced by: 1. In review of laboratory's policy and procedures Titled, "Test Name Urinalysis using Clinitek Status +", the laboratory had a combine procedure with microscopic urines. Step 13 and 14 stated the following, "Pour 3 mls of specimen into a clean, labeled centrifuge tube, Centrifuge for 3 minutes at 3,000 revolutions per minute (RPM)'s." The laboratory did not have any references in the procedure to addressing centrifuge speed and time. 2. In review of the laboratory's textbook procedure provided to the surveyor, Urinalysis and Body Fluids by Strasinger pg. 89 stated, "A standard amount of urine, usually between 10 and 15 mls, is centrifuged in a conical tube... Centrifugation for 5 minutes at a relative centrifugal force (RCF) of 400 will produce an optimum amount of sediment with the least chance of damaging elements." 3. In direct observation at 0935, the Bench top horizon 6 Flex #CNT251 was set at 3000 RPM for 3 minutes with a relative centrifugal force of 1100 (Xg). 4. In an interview with the Laboratory Director at 0941 confirmed that

	she didn't have a reference in a procedure and was not sure where the specifications came from. 5. The laboratory had an annual volume (2025) of 1447 microscopic urines per year.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 review of the laboratory's coagulation procedure, and interview with the Laboratory Director, the laboratory failed to have a step-by-step procedure on how to perform the Mean of the normal patient range (MNPT) study when the laboratory changes thromboplastin in the last two years for the Siemens CA-620 as evidenced by: 1. The laboratory could not provide to the surveyor a step by step procedure on how to perform the MNPT study for the Siemens CA-620 coagulation analyzer. 2. In interview with the Laboratory Director at 1056 confirmed that they did not have a procedure on how to perform the MNPT study each time the thromboplastin lot is changed once per year, to ensure all patients were "normal".
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 direct observation, manufacturer's instructions, and interview with

	Laboratory Director, the laboratory failed to monitor room temperature where supplies were stored in the room for the last two years as evidenced by: 1. In review of the manufacturer's instructions for Griener Bio-one tubes (Lithium heparin and Sodium Citrate) stated, "Store at 4-25 degrees C." 2. In review of the manufacturer instuctions for the Becton Dickinson (BD) BBL swabs stated, "store at 5-25 degrees C." 3. During a tour of the laboratory at 0843 the following supplies were stored in the draw room without temperature monitoring: a. 50 - Griener Lithium Heparin Lot# B260135F expiration date: 5-03-2027. b. 50- Griner Lithium Heparin Lot#B2602346 expiration date: 6-28-2026. c. 50- 2ml Sodium Citrate lot#B25124K d. 3- BBL Culture Swabs collection transport system lot# 250455100 expiration date: 6-28-2026 4. The laboratory could not provide a temperature chart documenting the room temperature for the draw room. 5. In interview with the Laboratory Director at 0845 it was confirmed that the laboratory did not monitor room temperature per the manufacturer's instructions.