Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0662186	10/30/2025
Name of Provider or Supplier	**Street Address, City, State**	
Hot Springs County Memorial Hospital Laboratory	150 E Arapahoe St, Thermopolis, 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	A recertification survey was conducted at Hot Springs Health on 10/29/25 through 10 /30/25. The laboratory was surveyed under 42 CFR part 493 CLIA requirements. The laboratory was found out of compliance with the following condition: 42 CFR 493.1441, Laboratory Director; High Complexity
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of patient test reports, review of the VITROS XT 5600 analyzer manufacturer's instructions for use, review of the ImmunoCard STAT Crypto/Giardia Rapid Assay manufacturer's instructions, and staff interview, the laboratory failed to follow the manufacturer's instructions to include the prostate specific antigen (PSA) test assay method on 1 of 1 PSA patient test reports (patient #1) reviewed. In addition, the laboratory failed to follow the manufacturer's instructions to not use the Crypto /Giardia kit beyond the expiration date for 1 of 4 patient tests (patient #2) reviewed. The laboratory performed 484 PSA and 24 Crypto/Giardia patient tests annually. The findings were: 1. Review of the VITROS XT 5600 analyzer manufacturer's instructions stated "Different test methods cannot be used interchangeably. PSA results in a given patient sample determined with different tests and from different manufacturers can vary due to differences in test methods and reagent specificity. A change to a different method during serial monitoring of a patient should be accompanied by additional sequential testing to confirm baseline values. The results reported by the laboratory to the physician must include the identity of the PSA test used." Review of the VITROS XT 5600 new instrument verification study showed it

	was approved by the laboratory director on 11/8/23. The following concerns were identified: a. Review of the test report for patient #1, dated 2/24/25, failed to include the PSA test methodology. b. Interview with the general supervisor on 10/30/25 at 3: 30 PM revealed she was unaware of the requirement. 2. Review of the ImmunoCardSTAT Crypto/Giardia Rapid Assay manufacturer's instructions showed under "Warnings and Precautions...2. Do not use kit beyond the printed expiration date." The following concerns were identified. a. Review of the laboratory's testing logs showed lot #08241412 had an expiration date of 8/31/25. Further review of the patient testing logs showed a Crypto/Giardia test was performed on patient #2 on 9/5 /25 using lot #08241412. b. Interview with the general supervisor on 10/30/25 at 9:15 AM confirmed the patient test was performed using an expired kit.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) (d)(3)(v) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient testing logs, review of quality control (QC) records, lack of documentation, review of the laboratory's individualized quality control plan (IQCP), review of quality assurance documentation, and staff interview, the laboratory failed to perform two levels of control every 30 days for 1 of 9 test systems reviewed (Alethia Clostridium difficile DNA Amplification Assay test system) from 1 /1/25 through 9/30/25. The failure affected 4 patient tests performed between 7/15/25 and 7/21/25. The laboratory performed approximately 85 C. difficile patient tests per year. The findings were: 1. Review of the patient testing log and QC records for the Alethia C. difficile DNA Amplification Assay test system showed the following concerns: a. QC was performed on lot #480050T032 on 6/12/25 and not again until 7 /25/25. b. Patient testing was performed on 7/15/25, 7/16/25, 7/18/25, and 7/21/25. c. Review of the laboratory's C. difficile IQCP, last reviewed by the laboratory director on 4/23/25, showed QC was to be performed every 30 days, with a new lot number, or with a new shipment. 2. Interview with the general supervisor on 10/30/25 at 9:13 AM confirmed QC had not been completed within the 30-day timeframe as outlined in the IQCP. THIS IS A REPEAT DEFICIENCY, last cited on 7/21/21 and 6/27/23.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of quality control (QC) records, the patient testing log, and the individualized quality control plan (IQCP), lack of documentation, review of quality

	assurance documentation, and staff interview, the laboratory failed to have a system in place to correct identified problems related to control procedures. The findings were: 1. Review of the patient testing log and QC records for the Alethia C. difficile DNA Amplification Assay test system showed the following concerns: a. QC was performed on lot #480050T032 on 6/12/25 and not again until 7/25/25. b. Patient testing was performed on 7/15/25, 7/16/25, 7/18/25, and 7/21/25. c. Review of the laboratory's C. difficile IQCP, last reviewed by the laboratory director on 4/23/25, showed QC was to be performed every 30 days, with a new lot number, or with a new shipment. d. Review of the laboratory's quality assurance documentation showed a pre-analytic, analytic, and post-analytic random audit of patient testing was performed on a monthly basis; however, the documentation failed to show an ongoing audit was performed to ensure QC was performed as directed by the laboratory's IQCPs. e. Review of the CMS-2567 form the previous recertification surveys showed the laboratory was cited for failing to perform two levels of control every 30 days as directed by the IQCP on 7/21/21 and 6/27/23. 2. Interview with the general supervisor on 10/30/25 at 9:13 AM confirmed QC had not been completed within the 30-day timeframe as outlined in the IQCP.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of quality control records, the patient testing log, and the individualized quality control plan, lack of documentation, review of quality assurance documentation, and staff interview, the laboratory director failed to ensure an effective quality control program was maintained to assure the quality of laboratory services provided. Refer to D5445 and D5791. THIS IS A REPEAT DEFICIENCY, last cited on 7/21/21 and 6/27/23.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on review of quality control records, the patient testing log, and the individualized quality control plan, lack of documentation, and staff interview, the laboratory director failed to ensure a quality control and quality assessment program was established to assure the quality of laboratory services provided. Refer to D5445 and D5791. THIS IS A REPEAT DEFICIENCY, last cited on 7/21/21 and 6/27/23.