Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0662186	06/27/2023
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
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 review of proficiency testing records, lack of documentation, and staff interview, the laboratory director failed to attest to the routine integration of the American Proficiency Institute (API) and the College of American Pathologists (CAP) proficiency tests into the patient workload for 9 of 23 proficiency testing events reviewed from August 2021 through June 2023. The findings were: 1. Review of the API and CAP proficiency testing records failed to include an attestation statement signed by the laboratory director for the following events: a. 2021 API microbiology event #2 b. 2021 API microbiology event #3 c. 2021 API miscellaneous chemistry event #2 d. 2022 API hematology/coagulation event #3 e. 2022 API immunohematology/immunology event #3 f. 2022 API microbiology event #3 g. 2022 API miscellaneous chemistry event #2 h. 2022 CAP blood gas event C i. 2023 CAP blood gas event A 2. Interview with the general supervisor and the technical supervisor on 6/27/23 at 8:35 AM confirmed the attestations statements for the proficiency testing events had not been signed by the laboratory director. THIS IS A REPEAT DEFICIENCY, last cited on 7/21/21
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 lack of documentation and staff interview, the laboratory failed to have a written procedure for the Meridian ImmunoCard STAT test system for Shiga Toxin 1 and Shiga Toxin 2. The laboratory performed 8 patient tests for Shiga Toxin 1 and Shiga Toxin 2 from 1/1/23 through 5/31/23. The findings were: 1. Review of the laboratory's procedure manuals showed no evidence the laboratory had developed a policy and procedure for the Meridian ImmunoCard STAT test system for the detection of Shiga Toxin 1 and Shiga Toxin 2. 2. Interview with the general supervisor on 6/27/23 at 12:38 PM confirmed the laboratory did not have a written procedure for the Meridian ImmunoCard STAT test system for the detection of Shiga Toxin 1 and 2.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) 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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (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), and staff interview, the laboratory failed to perform two levels of control every 30 days for 2 of 4 test systems reviewed (AmniSure ROM used for detecting fetal membrane rupture, Bio-Rad Tox/See test system used for urine drugs of abuse screening). The failure affected 29 AmniSure patient tests and 18 Bio-Rad Tox/See patient urine drug screens. The findings were: 1. Review of the patient testing log and QC records for the AmniSure ROM test system showed the following concerns: a. QC was performed on lot #57901769 on 4/2/22 and on lot #57204165 on 4/2/23. b. 29 patient tests had been performed between 4/2/22 and 4/2/23. c. Review of the laboratory's AmniSure ROM IQCP, effective 8/2017 and last reviewed 6/27/23, showed QC was to be performed every 30 days or with the start of a new lot number. 2. Review of the patient testing log and QC records for the Bio-Rad Tox/See test system showed the following concerns: a. QC was performed on lot #0000625470 on 2/5/23 and on lot #0000634313 on 3/29/23. b. 18 patient tests had been performed between 3/5/23 and 3/29/23. c. Review of the laboratory's Bio-Rad Tox/See IQCP, effective 8/2017 and last reviewed on 6/21/23, showed QC was to be performed every 30 days or with the start of a new lot number. 3. Interview with the general supervisor and the technical supervisor on 6/27/23 at 1:48 PM confirmed QC had not been performed as required. THIS IS A REPEAT DEFICIENCY, last cited on 7/21/21.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)

	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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the quality control (QC) records and the patient testing log, and staff interview, the laboratory failed to perform two levels of QC each day of patient testing from 12/6/22 to 6/27/23 for 3 of 3 microbiology test kits reviewed (Meridian ImmunoCard STAT for Campylobacter, Meridian ImmunoCard STAT for Cryptosporidium and Giardia antigens, Meridian ImmunoCard STAT for Shiga Toxin 1 and Shiga Toxin 2). This failure affected 47 patient samples. The findings were: 1. Review of the QC and patient testing records for the Campylobacter test kit showed 18 patient tests were performed between 12/6/22 and 6/27/23 without QC being performed. 2. Review of the QC and patient testing records for the Cryptosporidium /Giardia test kit showed 21 patient tests were performed between 12/6/22 and 6/27/23 without QC being performed 3. Review of the QC and patient testing records for the Shiga Toxin 1 and 2 test system showed 8 patient tests were performed between 12/28 /22 and 6/27/23 without QC being performed. 4. Interview with the general supervisor and the technical supervisor on 6/27/23 at 1:48 PM confirmed QC had not been performed as required. THIS IS A REPEAT DEFICIENCY, last cited on 7/21/21 and 10/20/21.
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 proficiency testing records, quality control records, the patient testing log, the individualized quality control plan, lack of documentation, and staff interview, the laboratory director failed to sign and date the American Proficiency Institute and the College of American Pathology proficiency testing attestation statements (D6089); and failed to ensure a quality control program was established to assure the quality of laboratory services provided (D6093). THIS IS A REPEAT DEFICIENCY, last cited on 7/21/21 and 10/20/21.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing records, lack of documentation, and staff interview, the laboratory director failed to attest to the routine integration of American Proficiency Institute and the College of American Pathologists proficiency tests into

	the patient workload for 9 of 23 proficiency testing events reviewed from August 2021 through June 2023. Refer to D2009. THIS IS A REPEAT DEFICIENCY, last cited on 7/21/21
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 program was established to assure the quality of laboratory services provided. Refer to D5445 and D5449. THIS IS A REPEAT DEFICIENCY, last cited on 10/20/21.