Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0662186	08/27/2019
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
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: . Based on direct observation, reagent and manufacturer's instructions review, and interview with staff, the laboratory failed to record the open date expiration on test reagents removed from refrigerated storage to room temperature storage for iSTAT CD 4+ reagent cartridges for performing blood gas (arterial and cord blood) pH, partial pressure Carbon Dioxide, partial pressure Oxygen and lactic acid tests. The laboratory performed approximately 4 tests per week. Findings include: 1. Direct observation of two CD4+ test cartridges (lot number 191068 with an expiration date of 12/18/2019) at room temperature on 08/26/2019 at approximately 12:00 noon failed to include a revised expiration date for room temperature storage. 2. The i Stat reagent instructions included that room temperature storage altered the expiration date to 14 days after removal from refrigerated (2-8 degrees C) storage. The manufacturer's instructions also state the expiration date for CD4+ cartridges changed from the printed expiration date to 14 days at room temperature. 3. In an interview with testing personnel on 08/26/2019 at approximately 12:00 noon arterial blood gas testing personnel confirmed the test cartridges were not relabeled with the room temperature storage expiration dates. .
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: . Based on instrument manufacturer's preventive maintenance chart records review, lack of documentation, and interview with staff, the laboratory failed to document they performed daily and weekly maintenance at the frequency the manufacturer prescribed for two of two years reviewed for 5 of 7 instruments, (Dimension EXL, Sysmex xs1000i cell counter, CA 600 Coagulation, and Beckman Coulter Walk Away Microbiology instruments). Findings include: 1. Manufacturer's preventive maintenance records reviewed failed to include documentation the laboratory followed analyzer manufacturer's preventive maintenance instructions frequency for: A. Siemens EXL +LM chemistry analyser weekly preventive maintenance for the week of 06/05/2019 for patient #HSCMH01099142 tested on 06/05/2019; B. CA600 coagulation analyzer weekly preventive maintenance for 2 weeks (1 and 4) in February 2019 for patient HSCMH 01093447 on 02/08/2019 for prothrombin time and activated partial thrombin time tests and for the previous Stago instrument daily, weekly and monthly maintenance for 05/03/2017 for patient HSCMH01077879 for prothrombin time coagulation tests; C. Sysmex XS1000i blood cell counter weekly maintenance the week of 07/07/2019 for patient HSCMH01100535, daily and weekly preventive maintenance for patient HSCMH01093447 on 02/08/2019; and D. Beckmman coulter Walk Away Daily preventive maintenance was not performed on 01/23/2019 for ear culture HSCMH 01092679 and monthly preventive maintenance was not performed for June 2019 for patient # HSCMH01099282 wound culture collected on 06/08/2019 test reviewed. 2. In an interview with staff on 08/27/2019 at approximately 9:00 A.M. staff stated they had missed recording instrument maintenance in the past. .
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 patient test records review, lack of documentation, Individual Quality Control Plan review, and quality control records review, the laboratory failed to document they followed the Individual Quality Control Plan (IQCP) for 1 of 3 moderate complexity kits, serum pregnancy tests. The laboratory performed approximately 1 to 3 serum pregnancy tests per month. Findings include: 1. Patient test record review included documentation the laboratory performed a serum pregnancy test on 04/09/2018 for patient accession number 300336434 reporting a negative result for kit lot number hCG7030198. 2. The IQCP stated quality control for serum pregnancy tests included a positive and negative control is performed with each new test kit lot number. 3. Staff offered the quality control record log for documentation of quality control performance on 08/26/2019. 4. QC records review lacked documentation hCG serum quality control was performed since 0725/2017 for a different kit lot number and prior to or on 04/09/2018 for kit lot number hCG7030198. .

D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: . Based on patient test reports review, lack of documentation, and interview with staff, the laboratory failed to follow their procedure to immediately notify the individual requesting 1 of 2 critical value test reports reviewed. Findings include: 1. The laboratory reported a critical value of ".69 mg/L" (plus a "c" super script) for a D-Dimer assay for patient HSCMH01100761 on 07/11/2019 (normal range is 0.19 -0.59). 2. The laboratory report failed to include documentation the laboratory followed their policy to record the name of the individual they reported the result and date and time of the communication. 3. In an interview with staff on 08/27/2019 at approximately 8:15 A.M., staff stated the laboratory policy was to call critical values to the provider or unit were the patient was located and to document the report was communicated on the test report and the report did not include this information. .
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: . Based on proficiency testing records review, lack of documentation, and interview with staff, the blood gas technical consultant failed to ensure the laboratory enrolled in an approved proficiency testing program to ensure the laboratory received 2 of 6 blood gas proficiency testing events reviewed, the first testing events in 2018 and 2019. The laboratory tested approximately 4 specimens per month. Findings include: 1. Proficiency testing records review failed to include documentation the laboratory participated in the first College of American Pathologists (CAP) arterial blood gas proficiency testing program in 2018 and 2019 for blood pH, partial pressure carbon dioxide, partial pressure oxygen, and lactic acid. 2. In an interview with staff on 08/26 /2019 at approximately 12:30 P.M. staff stated the laboratory failed to enroll in the proficiency testing program in time to receive the first events of 2018 and 2019. .
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: . Based on competency evaluation reports review, lack of documentation, and interview with staff, the technical consultant failed to evaluate 1 of 1 new moderate

	complexity testing personnel semi-annually from 2017 to 2019 for arterial and cord blood gas testing. Findings include: 1. The laboratory lacked competency evaluations for test person F from August 2017 to August 2019 for blood gas testing (initial testing date was not determined). 2. In an interview on 08/26/2019 at approximately 12:45 P.M. the blood gas lab manager stated he was unaware of competency evaluations for August 2017 through August 2019. .
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with the general supervisor the technical consultant failed to evaluate one testing person performing arterial blood gas testing for two of two years of testing reviewed 2017 and 2018. Findings include: 1. The laboratory lacked documentation test person G was evaluated for arterial blood gas and cord blood venous pH and partial pressure test competency from August 2017 to August 2019. 2. In an interview with staff on 08/26/2019 at approximately 12:00 P. M. staff was asked for testing personnel competency evaluations. The competency evaluations were not produced by the survey exit at 9:45 A.M. on 08/27/2019. .
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: . Based on lack of documentation and interview with staff, 1 of 1 new testing person lacked documentation to qualify as a moderate complexity testing person for arterial and cord blood gas testing. (See D6065). .
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

	This STANDARD is not met as evidenced by: . Based on lack of documentation and interview with staff, 1 of 1 testing person lacked documentation to qualify as a moderate complexity testing person to perform arterial and cord blood gas testing. Findings include: 1. Testing person F lacked documentation to qualify as a moderate complexity testing personnel in meeting the educational benchmark of a minimum of an high school diploma or equivalent. 2. In an interview with staff on 08/26/2019 at approximately 11:30 A.M. staff stated testing persons F did not have a copy of their diplomas or transcripts to qualify as moderate complexity testing personnel. .
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: . Based on competency evaluations review, lack of documentation, and interview with staff, the technical supervisor failed to evaluate 1 of 1 high complexity testing personnel annually in 2018 for blood bank, microbiology, and hematology abnormal cell identification testing. Findings include: 1. The laboratory lacked competency evaluations for test person B from August 2017 to August 2018. 2. In an interview on 08/26/2019 at approximately 12:45 P.M. the laboratory technical supervisor stated he was unaware of competency evaluation performance from August 2017 through August 2018 for test person B. .
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: . Based on lack of documentation and interview with staff, 3 of 3 testing personnel lacked documentation to qualify as high complexity testing personnel for blood bank, microbiology, and hematology testing. (See D6171). .
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an

accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
. Based on lack of documentation, CMS 209 personnel form and interview with staff, 3 of 3 testing personnel lacked documentation to qualify as high complexity testing personnel to perform abnormal differentials, microbiology identification and susceptibility testing, and compatibility testing. Findings include: 1. Testing personnel C, D, and E lacked documentation to qualify as high complexity testing personnel in

	meeting the educational benchmarks of a minimum of an associates degree or equivalent in a laboratory science or medical laboratory technology. 2. In an interview with staff on 08/26/2019 at approximately 11:30 A.M. staff stated testing persons C, D, and E did not have a copy of their diplomas or transcripts to qualify as high complexity testing personnel. .