Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	53D0519856	08/31/2022
Name of Provider or Supplier	**Street Address, City, State**	
Cody Regional Health Dba/West Park Co Hospital	707 Sheridan 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
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 individual testing the proficiency testing samples and the laboratory director failed to attest to the routine integration of the American Proficiency Institute (API) proficiency tests into the patient workload for 1 of 26 proficiency testing events reviewed from September 2020 through August 2022. The findings were: 1. Review of the 2022 API Immunology/Immunohematology Event #1 showed the attestation statement was not signed by the laboratory director. In addition the testing personnel performing the Immunohematology testing failed to sign the attestation statement. 2. Interview with the laboratory manager on 8/30/22 at 12:07 PM confirmed the attestation statements had not been signed.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of personnel files, review of the CMS (Centers for Medicare and Medicaid Services) 209 Laboratory Personnel Report, lack of documentation, and

	staff interview, the laboratory failed to retain documentation of competency assessments for 3 of 20 testing personnel reviewed (TP #1, TP #2, TP #3). The findings were: 1. Review of the personnel file or TP #1 showed he was hired on 11/30 /20 in the cardiopulmonary department and had an annual competency assessment in 2022; however there was no evidence the initial and 6 month competency assessment had been retained. 2. Review of the personnel file for TP #2 showed she was hired on 11/16/20 in the cardiopulmonary department and had an annual competency assessment in 2021 and 2022; however there was no evidence the initial and 6 month competency assessment had been retained. 3. Review of the personnel file for TP #3 showed she worked in the cardiopulmonary department and had a competency assessment in 2020 and 2022; however there was no evidence the 2021 competency assessment had been retained. 4. Interview with the cardiopulmonary department manager and lead respiratory therapist on 8/30/22 at 2:10 PM confirmed the documentation could not be located.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in 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 failed to review and evaluate proficiency testing results for 5 of 26 proficiency testing events reviewed from September 2020 to August 2022. The findings were: 1. Review of the American Proficiency Institute (API) proficiency testing (PT) report failed to include documentation the laboratory had evaluated test scores of less than 100%. The following concerns were identified: a. Review of the 2021 API Chemistry Core Event #3 results showed the laboratory scored an 80% on carbon dioxide and an 80% on neonatal bilirubin. There was no documentation the laboratory had evaluated the test results. b. Review of the 2021 API Microbiology Event #2 results showed the laboratory scored an 80% on norovirus detection. There was no documentation the laboratory had evaluated the test results. c. Review of the 2021 API Microbiology Event #3 showed the laboratory scored an 80% on adenovirus and rhinovirus/enterovirus detection. There was no documentation the laboratory had evaluated the test results. d. Review of the 2022 API Chemistry Core Event #1 showed the laboratory scored an 80% on sodium, phosphorus, and troponin. There was no documentation the laboratory had evaluated the test results. e. Review of the 2022 API Microbiology Event #1 showed the laboratory scored an 80% on gram stain morphology. There was no documentation the laboratory had evaluated the test results. 2. Interview with the laboratory manager on 8/30/22 at 12:07 PM confirmed the PT scores of less than 100% had not been investigated.
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 review of the CMS (Centers for Medicare and Medicaid Services) 116 form, lack of documentation, and staff interview, the laboratory failed to have a written procedure for reporting SARS-CoV-2 test results to the appropriate agencies. The findings were: 1. Review of the CMS-116 form showed the laboratory performed SARS-CoV-2 testing using the Abbott ID NOW and BD Max test systems. 2. Review of the laboratory's procedure manuals showed no evidence the laboratory had developed a policy and procedure for reporting SARS-CoV-2 test results to the appropriate agencies. 2. Interview with the laboratory manager on 8/31/22 at 11 AM confirmed the laboratory did not have a written procedure for reporting SARS-CoV-2 patient test results.
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 procedure manual review, lack of documentation, and staff interview, the laboratory failed to ensure the procedure manual contained all the required elements for 2 of 4 procedure manuals reviewed (Abbott iSTAT, Radiometer ABL80 FLEX). The findings were: 1. Review of the Radiometer ABL80 FLEX procedure manual, used for testing blood gases, showed the laboratory was using the operator's manual as the procedure manual. The operator's manual failed to include the laboratory's system for entering results in the patient record, the laboratory's quality control plan, reference intervals, or alert values. 2. Review of the Abbott iSTAT policy, effective 5 /1/2017, failed to include a procedure for calibration verification. 3. Interview with the lead respiratory therapist and cardiopulmonary department manager on 8/30/22 at 5: 04 PM confirmed the laboratory's procedure manuals were incomplete.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 observation, review of the laboratory's temperature monitoring log sheets, lack of documentation, review of the BD Affirm VP manufacturer's instructions, and staff interview, the laboratory failed to follow the BD Affirm VP manufacturer's instructions to verify the temperature of the heat block to ensure the incubator was within the 85 degrees plus or minus 5 degree range. The laboratory performed approximately 260 Candida/Trichomonas/Gardnerella panels per year. The findings were: 1. Observation of the laboratory on 8/30/22 at 10 AM showed the laboratory was performing Candida/Trichomonas/Gardnerella panels on the BD Affirm analyzer. 2. Review of the laboratory's temperature monitoring log sheets show no evidence the temperature of the heat block had been verified prior to patient testing. 3. Review of the BD Affirm VP manufacturer's instructions showed the laboratory must verify the BD Micro Probe Lysis Block was at 85 degrees plus or minus 5 degrees. 4. Interview with the laboratory manager on 8/30/22 at 3:44 PM confirmed the temperature of the heat block had not been documented.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on lack of documentation, review of the Abbott iSTAT manufacturer's instructions, and staff interview, the laboratory failed to verify the reportable range at least every 6 months using testing materials with values at the zero or minimal level, the mid-level, and the upper-level of the reportable range for the CG4+ test cartridge (pH, partial pressure of oxygen, partial pressure of carbon dioxide) analyzed on the Abbott iSTAT instrument for 2 of 2 years of testing (2021, 2022) reviewed. The findings were: 1. Review of the laboratory's records showed a calibration verification had been performed on 6/24/20, 4/5/21, and 6/29/22. There was no further documentation to show the calibration verification study had been completed every 6

	months as required. 2. Review of the Abbott iSTAT manufacturer's instructions showed "...Calibration Verification is a procedure intended to verify the accuracy of results over the entire measurement range of a test. The performance of this procedure at defined intervals may be required by regulatory accreditation bodies..." 3. Interview with the lead respiratory therapist on 8/31/22 at 9:43 AM confirmed no further documentation was available.
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 records, 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 once a month, with a new shipment, or with a new lot number for 7 months of testing reviewed (January 2022 through August 2022). This failure affected 3 patient samples (#AO5694872, #AO5718879, #AO5716717). The findings were: 1. An arterial blood gas was performed on patient AO5694872 using test cartridge lot number 226N212680243 on 5/18/22. Review of the QC records showed the last QC was performed on test cartridge lot number 226N212680243 was 4/11/22. 2. An arterial blood gas was performed on patient AO5716717 using test cartridge lot number 226N220020243 on 6/1/22. Review of the QC records showed QC was not performed on test cartridge lot number 226N220020243 until 6/13/22. 3. A venous blood gas was performed on patient AO5718879 using test cartridge lot number 226N220020243 on 6/3/22. Review of the QC records showed QC was not performed on test cartridge lot number 226N220020243 until 6/13/22. 4. Review of the laboratory's IQCP, last reviewed 7/25/22, showed external QC must be performed monthly, with each new test cartridge or shipment, and with each software update. 5. Interview with the lead respiratory therapist on 8/30/22 at 5:04 PM confirmed no further documentation was available.