Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0652493	06/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Garfield County Health Center	332 Leavitt Ave, Jordan, MT	

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
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of hematology, and chemistry records, product inserts, and policies, the laboratory failed to follow their procedure and perform the Abbott i-STAT electronic simulator each day of patient testing (See D5441); failed to perform two levels of external quality control each day of patient testing or establish an Individualized Quality Control Plan for the Abbott i-STAT (See D5445); failed to perform two levels of qualiaty control each day of CBC testing performed on the hematology analyzer for 27 out of 64 patients (See D5447); and failed to verify the new lots of hematology quality control material performed on the Horiba Micros 60 analyzer prior to patient testing (See D5469).
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental

	conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of patient results reports, quality control (QC) records for the i-STAT and interview with testing personnel (TP) #1, the laboratory failed to follow their procedure and perform the electronic simulator each day of patient testing for three out of five patients reviewed for December 2021, September 2022, and December 2022. Findings: 1. A review of patient results report (ID 121020212) for prothrombin time dated 12/10/2021, patient results report (ID092720221) for troponin dated 9/27/2022, and patient results report (ID121420222) for troponin and B-type natriuretic peptide (BNP) dated 12/14/2022 performed on the Abbott i-STAT lacked the electronic simulator results for the day of testing. 2. A review of policy "I-STAT External" revealed the laboratory failed to follow their procedure to perform and document the electronic simulator as stated, "The charge nurse will complete an I-STAT simulator test every night shift." 3. An interview with TP #1 on June 29, 2023, at 11:10 AM, confirmed the laboratory failed to follow and perform the electronic simulator at the frequency required by their procedure for the i-STAT cartridges for three out of five patients reviewed for December 2021, September 2022, and December 2022.
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 a review of quality control (QC) records, laboratory policies, and an interview with testing personnel (TP) #1, the laboratory failed to establish, follow, and perform two levels of external quality control each day of patient testing or develop an Individualized Quality Control Plan (IQCP) to perform external controls at the manufacturer's recommended frequency for prothrombin time (PT), B-type natriuretic peptide (BNP) and troponin tests performed on the Abbott i-STAT from June 29, 2021, to June 29, 2023. Findings: 1. A review of QC records revealed the laboratory was performing external QC at the frequency of monthly and new lot or shipment for the Abbott i-STAT for PT, BNP, and troponin cartridges. 2. No IQCP evaluation containing a risk assessment, a quality control plan, and a quality assessment plan was available for review to support QC practices less stringent than the regulatory control procedure. 3. A review of the test volume sheet revealed the laboratory reported 59 BNP results, 37 troponin results and 66 PT results, from June 29, 2022, to June 29, 2023 (12-month period). 4. An interview with the TP #1 on June 29, 2023, at 11:00 AM confirmed the laboratory failed to perform two levels of external QC each day of

	testing or develop an IQCP for alternative QC practices for the Abbott i-STAT from June 29, 2021, to June 29, 2023.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of patient results reports and logs, quality control (QC) records, laboratory policies, and an interview with testing personnel (TP) #1, the laboratory failed to run two levels of complete blood counts (CBC) control materials each day of patient testing for 27 out of 64 patient's tests performed on the Horiba Micros 60 from October 14, 2022, through December 15, 2022. Findings: 1. A review of patient results report (ID 121420222) for complete blood counts (CBC) performed 12/24 /2022 on the Horiba Micros 60 lacked two levels of QC for the day of testing. 2. A review of the Resident/Patient Laboratory Log and quality control records for CBC tests from October 14, 2022, through December 15, 2022, revealed 27 out of 64 patients lacked QC on the day of testing. 3. A review of Horiba Quality Controls policy revealed the laboratory failed to follow their policy as stated, "Quality Control on the Horiba CBC analyzer will be completed: 1. By the night shift charge nurse each morning." 4. An interview with TP #1 on June 29, 2023, at 12:30 PM confirmed the laboratory failed to perform two levels of QC each day of CBC testing performed on the hematology analyzer for 27 out of 64 patients from June 29, 2021, to June 29, 2023.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of hematology quality control (QC) records, policies, and an interview with the with testing personnel (TP) #1, the laboratory failed to verify the new lots of quality control material performed on the Horiba Micros 60 hematology analyzer prior to patient testing from June 29, 2021, to June 29, 2023. Findings: 1. No

	concurrent studies of lot-to-lot changes to verify that the Horiba Minotrol-16 quality control materials (levels Low, Normal, and High) met acceptability requirements prior to patient testing were available for review from June 29, 2021, to June 29, 2023. 2. The laboratory failed to follow the Horiba Minotrol-16 intended use as stated, "Assay values on a new lot of control should be confirmed before it is put into routine use." 3. The laboratory failed to have in their policy how to verify new lots of quality control material performed on the Horiba Micros 60 hematology analyzer. 4. Based off the test volume sheet, 372 complete blood count (CBC) patient tests were performed from June 29, 2022 to June 29, 2023 (12 months). 5. An interview with TP #1 on June 29, 2023, at 12:10 PM, confirmed the laboratory failed to verify new lots of Horiba Minotrol-16 QC material for the hematology analyzer from June 29, 2021, to June 29, 2023.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on record review, policy and procedures, and interview with testing personnel (TP) #1, the laboratory director failed to ensure that the quality control program is established and maintained to assure the quality of chemistry and hematology patient results from June 29, 2021, to June 29, 2023. Findings: 1. A review of quality control (QC) records lacked quality review checks by the laboratory director to ensure laboratory staff performed and recorded quality control at the frequency required by their procedure, manufacturer's instructions or regulation for hematology (CBC and prothrombin time (PT)) and chemistry (troponin and B-type natriuretic peptide (BNP)). (Cross Refer 5441 and D5447) 2. The laboratory director failed to ensure an Individualized Quality Control Plan (IQCP) was established for the Abbott i-STAT to contain a risk assessment, a quality control plan, and a quality assessment plan to perform external controls at the manufacturer's recommended frequency for PT, BNP and troponin tests to support QC practices less stringent than the regulatory control procedure. (Cross Refer D5445) 3. An interview with TP #1 on June 29, 2023, at 1:00 PM, confirmed the laboratory director failed to ensure the quality control program is established and maintained by testing personnel to assure the quality of chemistry and hematology testing results from June 29, 2021, to June 29, 2023.