Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0410751	01/26/2021
Name of Provider or Supplier	**Street Address, City, State**	
Ruby Valley Hospital	321 Madison St, Sheridan, 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 review of chemistry, hematology, and blood bank procedures, the laboratory failed to include normal values for complete blood counts, microscopic urinalysis and failed to have a step-by-step procedure for review of historical blood bank testing (refer to D5403); failed to perform regular blood bank alarm checks (refer to D5555) and failed to establish or verify the criteria for acceptability of all control materials (refer to D5469).
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 review of the hematology, urinalysis, blood bank procedures, and interview with testing personnel (TP) #2, the laboratory failed to include in their procedure manuals reference intervals (normal values) for complete blood counts, and microscopic urinalysis and failed to have a step by step procedure for review of historical blood bank patient data to determine previously identified antibodies and any other serological anomalies. Findings: 1. No reference intervals (normal values) were available in the hematology procedure manual for complete blood counts. 2. No reference intervals (normal values) were available in the urinalysis procedure manual for microscopic urinalysis. 3. No procedure for checking historical blood bank patient data was available for review. 4. Interview with the TP #2 on January 26, 2021 at 11: 00 AM confirmed the laboratory failed to include normal values for complete blood counts, microscopic urinalysis, and failed to have a step-by-step procedure for review of historical blood bank testing results.
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 review of the calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes of sodium, potassium, and chloride, and interview with the testing personnel (TP) #2, the laboratory failed to perform at least a three

	point (a minimal, mid-point, and maximum) calibration verification every six months. Findings: 1. Review of 2019 and 2020 calibration records for the Siemens Dimension EXL 200 chemistry analyzer for the analytes: sodium, potassium, and chloride, revealed the laboratory failed to perform a calibration including, at least, a minimal, midpoint, and maximum value for each analyte, every six months. 2. Interview with the TP #2 on January 26, 2021 at 2:00 PM confirmed the laboratory failed to perform at least a three point calibration for sodium, potassium, and chloride on the Siemens Dimension EXL 200 chemistry analyzer every six months.
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 chemistry quality control (QC) records, manufacturer's inserts, patient reports, and interview with the testing personnel (TP) #2, the laboratory failed to establish acceptable criteria (statistical parameters/standard deviation) for assayed controls. Three of three selected chemistry analytes performed on the Siemens Dimension EXL 200 analyzer failed to have acceptable standard deviation (SD) and ranges for QC level I for Biorad MultiQual and Lyphocheck Immunoassay. Findings: 1. Review of Biorad MultiQual and Lyphocheck level I QC ranges in the Siemens Dimension EXL 200 showed the following data: sodium--lot #45831 with a range of 105-129 mmol/L, a mean of 117 mmol/L and a SD of 6.0 glucose--lot #45831 with a range of 41.8-71.8 mg/dL, a mean of 56.8 mg/dL and SD of 5.0 TSH--lot #40381 with a range of 0.3260-0.5260 uIU/mL, a mean of .4260 uIU/mL and a SD of .10 2. Review of Biorad MultiQual and Lyphocheck level I QC package inserts showed: sodium--lot #45831 with a range of 110-122 mmol/L and a mean of 116 mmol/L glucose--lot #45831 with a range of 54.9-65.8 mg/dL and a mean of 60.3 mg/dL TSH--lot #40381 with a range of 0.385-0.531 uIU/mL and a mean of 0.458 uIU/mL 3. Review of patient reports showed 922 glucose, 920 sodium, and 204 TSH results were reported for 2020. 4. Interview with TP#2 on January 26, 2021 at 2:00 PM confirmed the laboratory failed to establish acceptable QC statistical parameters for each analyte tested on the Siemens Dimension EXL 200 analyzer.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document

	all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of 2020 chemistry quality control (QC) records, the blood gas policy, patient reports and interview with testing personnel (TP) #2, the laboratory failed to test a control each 8 hours of patient testing for one out of nine patients reviewed. Findings: 1. Review of QC records on the iSTAT blood gas analyzer revealed no controls performed for one out of nine patients reviewed. 2. Review of laboratory policy, Monitoring of Quality Control revealed "The iSTAT blood gas analyzer will have two levels of liquid QC ran every day of patient testing. There is no IQCP policy for this instrument." 3. Interview with TP#2 on January 1, 2021 at 1:35 PM confirmed the laboratory failed to run a control each 8 hours of patient testing on the blood gas analyzer for one out of nine patients reviewed.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the blood bank procedure manual, documentation of 2019, 2020 blood bank refrigerator alarm checks, and interview with the testing personnel (TP) #2, the laboratory failed to perform and document regular alarm inspection checks for 1 of 1 blood bank refrigerator. Findings: 1. Review of the "Blood Storage" procedure showed "alarm checks are performed every 3-4 months." 2. Review of the 2019, 2020 documentation for alarm checks revealed the laboratory performed alarm checks on January 31, 2019; August 4, 2019; December 24, 2019; May 16, 2020; August 4, 2020 and January 1, 2021. 3. Interview with the TP #2 on January 26, 2021 at 11:00 AM confirmed the laboratory failed to regularly perform and document the alarm checks every 3-4 months to monitor proper blood and blood product storage temperatures.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on record review of 2019, 2020 instrument comparison documentation and interview with testing personnel (TP) #2, the laboratory failed to perform instrument comparison for the analyzers, Alere Triage and the Siemens Dimension EXL for

	troponin and the analyzers Siemens Dimension EXL and the Abbott iSTAT for basic metabolic panel testing two times a year. Findings: 1. Review of laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies for the Alere Triage and the Siemens Dimension EXL analyzers performing troponin analyte testing for 2019 and 2020. 2. Review of laboratory instrument comparison documentation showed the laboratory failed to perform and document comparison studies for the Siemens Dimension EXL and the Abbott iSTAT analyzers performing sodium, potassium, chloride, ionized calcium, total CO(2), glucose, blood urea nitrogen (BUN) and creatinine analyte testing for 2019 and 2020. 3. Interview with testing personnel TP #2 on January 26, 2021 at 10:10 AM confirmed the laboratory failed to perform twice a year instrument comparison.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on the review of the BioFire Respiratory Panel 2 validation records and interview with testing personnel (TP) #2, the laboratory director (LD) failed to approve and sign verification procedures for the BioFire Respiratory Panel 2. Findings: 1. Review of the BioFire Respiratory Panel 2 verification documents showed no approval by the LD. 2. Review of patient reports for the BioFire Respiratory Panel 2 revealed the laboratory tested 20 samples over two days on September 9, 2020, and September 10, 2020, without the approval by the LD of the verification procedures. 3. Interview with the TP #2 on January 26, 2021, at 2:30 PM confirmed the LD failed to approve and sign the BioFire Respiratory Panel 2 verification procedures.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on the review of American Proficiency Institute (API) proficiency testing records for 2019 and 2020 and interview with testing personnel (TP) #2, the laboratory director failed to ensure all proficiency testing (PT) reports received for the chemistry and hematology specialties were reviewed and corrective actions were taken to evaluate the laboratory's performance and to identify any problems. Findings: 1. Review of the second Chemistry Core PT event of 2019 revealed the laboratory scored 80% for the analytes of low-density lipoprotein (LDL), partial pressure of carbon dioxide (pCO2), pH, and hemoglobin (Hgb i-STAT) with no documentation of investigation or corrective actions taken. 2. Review of the third Chemistry Core PT event of 2019 revealed the laboratory scored 80% for the glucose analyte with no documentation of investigation or corrective actions taken. 3. Review of the third Chemistry Core PT event of 2020 revealed the laboratory scored 80% for total

	cholesterol analyte with no documentation of investigation or corrective actions taken. 4. Review of the first Hematology/Coagulation PT event of 2020 revealed the laboratory scored 80% for blood cell identification with no documentation of investigation or corrective actions taken. 5. Review of the second Hematology /Coagulation PT event of 2020 revealed the laboratory scored 80% for the analytes of mean platelet volume (MPV) and red blood cell distribution width standard deviation (RDW-SD) with no documentation of investigation or corrective actions taken. 6. Interview with TP #2 on January 26, 2021, at 12:30 PM confirmed that the laboratory director failed to ensure review and corrective actions were taken for PT scores of 80%.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on review of the Sysmex XS 1000i hematology analyzer procedure manual and interview with the testing personnel (TP) #2 and the technical supervisor (TS) #1, the laboratory director (LD) failed to ensure an approved procedure manual was available to all testing personnel. Frindings 1. Review of the Sysmex XS 1000i procedure manual for CBC testing showed no approval by the LD. 2. Interview with the TP #2 and TS #1 on January 26, 2021 at 3:00 PM confirmed the LD failed to approve the Sysmex XS 1000i hematology procedure manual.
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 review of 2020 competency records, competency procedure, and interview, the technical supervisor (TS) #1 failed to perform annual competency assessments on 2 of 3 testing personnel (TP). Findings: 1. Review of personnel competency evaluations revealed that laboratory failed to provide proof of annual competency assessments for TP #1 and TP #2 for 2020. 2. Review of the "Competency Assessments" procedure revealed. "Competency must be assessed at initial hire (during training), at 6 months after employment and annually thereafter." 3. Interview with TP #1 on January 26, 2021 at 12:15 AM confirmed the laboratory failed to perform annual competency assessment for year 2020.