Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0678565	04/06/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mountainview Medical Center	16 West Main St, White Sulphur Springs, 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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on routine desk audit of CMS-153 and 155 reports for proficiency testing performance and interview with the technical supervisor (TS) #1, the laboratory failed to achieve satisfactory performance scores in chemistry for pH Blood Gas for two out of three events (2021 Event 3 and 2022 Event 1), resulting in unsuccessful proficiency testing performance. See D2096
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f)

	Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing scores and interview with technical supervisor (TS) #1, the laboratory failed to achieve a score of 80% for pH Blood Gas for two out of three events (2021 Event 3 and 2022 Event 1). Findings: 1. Review of CMS-153 Unsuccessful Proficiency Testing Report on 03/31/2022 at 10:20 AM included Mountainview Medical Center, with unsuccessful proficiency testing scores for pH Blood Gas. 2. Review of the CMS-155 Individual Laboratory Profile on 03/31/2022 at 10:30 AM revealed the American Proficiency Institute (API) pH Blood Gas scores for 2021 Event 3 was 20% and 2022 Event 1 was 60%. 3. Onsite review of API scores on 04/01/2022 at 8:20 AM confirmed the pH Blood Gas unsuccessful scores for 2021 Event 3 and 2022 Event 1. 4. Interview with TS #1 on 04/01/2022 at 8:30 AM confirmed the laboratory failed to achieve a score of 80% for pH Blood Gas for two out of three events.
D5016	ROUTINE CHEMISTRY CFR(s): 493.1210 If the laboratory provides services in the subspecialty of Routine Chemistry, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1267, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of chemistry records, instrument manuals, product inserts, and procedures, the laboratory failed to perform calibration verification for sodium, potassium and chloride on the Siemens Dimension EXL 200 chemistry analyzer and for brain natriuretic peptide (BNP) and D-Dimer on the Alere Triage analyzer, (refer to D5439); failed to follow manufacture's instruction for frequency of quality controls (QC) testing for hCG kits and establish external QC for serum hCG testing (refer to D5445); and failed to calibrate or verify calibration according to the manufacturer's specifications for blood gas (refer to D5535).
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 sodium, potassium, and chloride; and Alere Triage for analytes brain natriuretic peptide (BNP) and D-Dimer and interview with the technical supervisor (TS) #1, the laboratory failed to perform at least a three point (a minimal, mid-point, and maximum) calibration verification every six months from April 1, 2020 to April 5, 2022 Findings: 1. No records containing at least a three point (a minimal, mid-point, and maximum) calibration verification for analytes: sodium, potassium, and chloride performed on the Siemens Dimension EXL 200 chemistry analyzer, were available for review. 2. No calibration verification records for the Alere Triage for analytes BNP and D-Dimer were available to review. 3. Review of the Quidel Alere Triage User Manual revealed, "If appropriate, run Calibration Verification Set as a Misc Test sample for each test panel type to be used. (Refer to the applicable Procedure Manual and Calibration Verification Set Package insert for detailed instructions." 4. Review of Quidel Triage Total 5 Calibration Verification Product Insert revealed, "Intended Use; The Quidel Triage Total 5 Calibration Verification materials are to be used with the Quidel Triage Cardiac Panel, Quidel Triage Profiler SOB Panel, Quidel Triage BNP Test, Quidel Triage D-Dimer Test and Quidel Triage Meters to verify the calibration of the Test Devices throughout the measurable range." 5. Interview with the TS #1 on April 5, 2022 at 11:30 AM 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 and BNP and D-dimer on the Quidel Alere Triage every six months.
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 record review and interview with technical supervisor (TS) #1, the laboratory failed to perform external serum quality controls (QC) for serum specimens tested with McKesson Consult Diagnostics hCG Combo Cassette and follow manufacture's instruction on frequency of QC testing from April 1, 2020 through April 6, 2022. Findings: 1. A review of hCG testing logs lacked record of external serum hCG controls and monthly QC checks being performed. 2. McKesson Consult Diagnostics hCG Combo Cassette product insert revealed " It is recommended that a

	positive hCG control (containing 20 mIU/mL hCG in urine or 10 mIU/mL hCG in serum) and a negative hCG control (containing "0" mIU/mL hCG) be evaluated to verify proper test performance. For urine testing, controls should be tested with each new lot or shipment of product, with each new operator, monthly as a check on continued storage conditions, or as otherwise required by your laboratory's internal quality system procedures. For serum testing, federal, state, and local guidelines should be followed." 3. Review of procedure, hCG Combo Cassette-Consult Diagnostics and IQCP for hCG (urine/serum) lacked instructions for serum controls and monthly QC checks. 4. Interview with TS #1 on April 6, 2022 at 12:20 P.M., confirmed the laboratory failed to perform external serum quality control (QC) for serum specimens tested with McKesson Consult Diagnostics hCG Combo Cassette and follow manufactures instruction on frequency of QC testing for continued storage conditions from April 1, 2020 through April 6, 2022.
D5535	ROUTINE CHEMISTRY CFR(s): 493.1267(a)(d) For blood gas analyses, the laboratory must perform the following: (a) Calibrate or verify calibration according to the manufacturer's specifications and with at least the frequency recommended by the manufacturer. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review of blood gas, procedures, instrument manual and interview with Technical Supervisor (TS) #1, the laboratory failed to perform quarterly tHb calibration and calibration verification in accordance with the manufacturer's instructions for OPTI CCA-TS for analytes pH, carbon dioxide partial pressure (PCO2), oxygen partial pressure (PO2), total hemoglobin concentration (tHb) and hemoglobin oxygen saturation (SO2) from April 1, 2020 to April 6, 2022. Findings 1. Review of patient results report #1005484 resulted on 10/16/21 revealed results for Arterial Blood Gas for analytes pH, pCO2, pO2, HCO3, Base Excess, TCO2 and O2 SAT. 2. No quarterly tHb calibration or calibration verification records for the OPTI CCA-TS for pH, carbon dioxide partial pressure (PCO2), oxygen partial pressure (PO2), and oxygen saturation (SO2) were available to review. 3. Review of Blood Gases-patient sample procedure revealed, "Calibration and QC: Calibration is internal and performed on each cassette used in the analyzer before patient or QC material is introduced. Calibration of the tHb (hemoglobin) channel is required every three months. The analyzer will prompt the user for this when needed." 4. Review of the OPTI CCA-TS Operator's Manual states the following: 4.1 Calibration: "Calibration of the tHb channel is required every 3 months ... The tHb calibration verifies the measurement optics and electronics and corrects any potential drift." 4.4 Calibration Verification: "Calibration verification allows for the validation of the blood gas analyzer's ability to recover known values at various points within the reportable range of all parameters and may be required by various regulatory agencies." Appendix A: Base excess at actual oxygen saturation BE(act) Base excess at actual oxygen saturation [mmol/L]. BE = (1- 0.0143 tHb)[(1.63 tHb 9.5)(pH- 7.4)- 24.26 + HCO3] -0.2 tHb (1- SO2/100) 5. Interview with TS #1 on April 6, 2022 at 2:00 P.M., confirmed the laboratory failed to perform quarterly tHb Calibration and calibration verification for pH, carbon dioxide partial pressure (PCO2), oxygen partial pressure (PO2), and oxygen saturation (SO2)
D5553	IMMUNOHEMATOLOGY

	CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (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 Immunohematology records, procedure, and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and of returned blood not used for transfusion from April 1, 2020 to April 6, 2022. Findings: 1. Review of Immunohematology records lacked documentation of temperatures of blood upon receipt of new shipments and unused blood returned to the laboratory from April 1, 2020 to April 6, 2022. 2. Review of Procedure, Procurement and availability of blood products lacks temperature requirements for acceptance of blood or returned blood products not used for transfusion. 3. Interview with TS #1 on April 6, 2022 at 3:00 PM, confirmed the laboratory failed to ensure the temperature is documented upon receipt of new shipments of blood and returned blood not used for transfusion from April 1, 2020 to April 6, 2022.