Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0665042	11/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Roundup Memorial Healthcare	1202 3rd Street West, Roundup, 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
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on record review and interview with Technical Supervisor (TS) #1, the laboratory failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Hematology (Complete Blood Counts (CBC) with differential: Cell Identification, WBC Differential, Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, Platelet Count), Chemistry (Blood Gas: PH, pCO2, pO2) and (Alcohol), Immunology (Infectious Mononucleosis), Mycology (KOH Preps), Parasitology (Wet Preps), and Urinalysis (Microscopic Urinalysis) from January 1, 2021 to May 06, 2022. See D6088 and D6116 Findings: 1. A review of Test Volume Report revealed 3972 Complete Blood Counts with automated differentials (CBC), 55 manual White Cell differentials, 102 Blood Gas, 108 Ethyl Alcohol, 18 Infectious Mononucleosis, 2 KOH, 8 Wet Preps, 2 Stool prep for WBC were performed from November 1, 2021 to November 1, 2022 (12 months). 2. A review of 2021 and 2022 American Proficiency Institute (API), testing program records lacked documentation of proficiency testing for all of year 2021 and the 1st Event of 2022. 3. An interview on November 1, 2022, at 10:30 AM with the TS #1 confirmed the laboratory failed to enroll in an HHS-approved proficiency testing program for Complete Blood Counts (CBC) with differential: Cell Identification,

	WBC Differential, Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, Platelet Count, PH, pCO2, pO2, Alcohol, Infectious Mononucleosis, KOH Preps, Wet Preps, Stool prep for WBC and Microscopic Urinalysis from January 1, 2021 to May 06, 2022
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on record review, and interview with the Technical Supervisor (TS) #1, the laboratory failed to retain the quality control (QC) documentation for D-Dimer performed on the Triage Analyzer for the year 2021. Findings: 1. No QC documentation for D-Dimer performed in 2021 on the Triage Analyzer were available for review. 2. Interview on November 01. 2022 at 2:00 PM with TS #1 confirmed the QC documentation for D-Dimer performed on the Triage Analyzer was not retained for the year 2021.
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 a record review and an interview with the Technical Supervisor (TS) #1, the laboratory failed to follow their procedures and perform competency assessment for two out of three Technical Supervisors and one out of one General Supervisor (GS) listed on the CLIA CMS-209 Personnel Report form. Findings: 1. A record review of the CMS-209 Personnel Report Form revealed two out of three TS and one out of one GS listed failed to have either an initial and six-month competency review for new personnel or an annual competency assessment performed for the year 2022. 2. A review of Competency Assessment Plan revealed the laboratory failed to follow their policy and procedure as stated, "The following staff will need to complete an annual competency (as applicable): A. Technical Staff; B. General Supervisor; C. Technical Supervisor". 3. An interview on November 01, 2022, at 11:00 AM, confirmed the laboratory failed to follow their policy and procedure and perform competency assessments for the positions of technical supervisors and general supervisor listed on the CMS-209 Personnel Report Form from January 1, 2022 to November 1, 2022
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

	This STANDARD is not met as evidenced by: Based on a review of testing and proficiency testing records for 2021 and 2022, and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform twice annually accuracy verification or proficiency testing for two of two analytes (PSA and ESR) during January 1, 2021 to May 6, 2022 and for seven of seven new analytes (glycated hemoglobin (A1c), ammonia, C-Reactive Protein (CRP), Ferritin, N-terminal pro b-type natriuretic peptide (NT-proBNP), Vitamin B12 and Vitamin D) from November 1, 2021 to May 6, 2022. Findings: 1. A review of proficiency testing records for 2021 and 2022 lacked documentation of American Proficiency Institute (API) testing records or twice annually accuracy verification studies as follows: ESR and PSA from January 1, 2021 to May 6, 2022; and new analytes (A1c, ammonia, CRP, Ferritin, NT-proBNP, Vitamin B12 and Vitamin D) from November 1, 2021 to May 6, 2022. 2. A review of Test Volume Report revealed 451 A1c, 35 Ammonia, 220 CRP, 131 Ferritin, 246 NT-proBNP, 286 PSA, 54 Vitamin B12, and 278 Vitamin D were performed from November 1, 2021 to November 1, 2022 (12 months). 3. A review of Proficiency Testing policy and procedures revealed the laboratory failed to follow their procedure as stated, "4. Any analytes for which compatible proficiency testing specimens are not available will undergo and alternative performance assessment approved by the laboratory medical director and performed twice per year." 4. An interview with the TS #1 on November 1, 2022, at 10:40 AM confirmed the laboratory failed to follow their procedure and perform either a proficiency testing program or a twice-yearly accuracy verification for the analytes listed above.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review, policies and procedures, and interview with technical supervisor (TS) #1, the laboratory failed to perform a corrective action for patient testing performed during the time frame PT or twice a year verification was not performed for Cell Identification, WBC Differential, Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, Platelet Count, PH, pCO2, pO2, Alcohol, Infectious Mononucleosis, KOH Preps, Wet Preps, Stool prep for WBC, Microscopic Urinalysis, ESR, PSA, A1c, ammonia, CRP, Ferritin, NT-proBNP, Vitamin B12 and Vitamin D from November 1, 2021 to May 6, 2022. (Cross Refer D2000 and D5217) Findings: 1. A review of "Proficiency Testing" policies and procedures revealed the laboratory failed to identify and document corrective action for, "will remain continuously enrolled in a proficiency testing program for each analyte tested" and "New tests will be enrolled in a proficiency testing program within 60 days of addition to the test menu." 2. A review of test volume sheet recording the last 12 months of patients' results showed 3972 Complete Blood Counts with automated differentials (CBC), 55 manual White Cell differentials, 102 Blood Gas, 108 Ethyl Alcohol, 18, Infectious Mononucleosis, 2 KOH, 8 Wet Preps, 2 Stool prep for WBC, 451 A1c, 35 Ammonia, 220 CRP, 131 Ferritin, 246 NT-proBNP, 286 PSA, 54 Vitamin B12, and 278 Vitamin D were reported from 11/01/21 to 11/01/22. 3. No corrective or remedial action to ensure accurate patient test results was available for review due to lack of PT or twice

	a year evaluation of analytes listed. 4. An interview with the TS #1 on November 1, 2021, at 1:25 PM. confirmed the lack of corrective action for patient testing performed during the time frame PT or twice a year verification was not performed for the analytes listed from November 1, 2021 to May 6, 2022.
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 bacteriology, chemistry, hematology, and blood bank records, instrument manuals, product inserts, and policies and procedures, the laboratory failed to have two of two instruments' preventive maintenance serviced by the manufacture for the Sysmex CA 620 coagulation analyzer (See D5433); failed to perform at least a three-point calibration for D-dimer on the Triage Meter every six months (See D5439); failed to establish acceptable criteria (statistical parameters/standard deviation) for assayed Bio-Rad controls (See D5469); failed to perform and document quarterly alarm inspection checks for 1 of 1 blood bank refrigerator and freezer used to store blood and blood products (See D5555); and failed to assess their analytic system's quality assessment (QA) for its effectiveness to identify, resolve and prevent recurrence of problems (See D5793).
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a review of maintenance documentation and interview with Technical Supervisor (TS) #1, the laboratory failed to have one of one instruments preventive maintenance serviced by the manufacture for the Sysmex CA 620 coagulation analyzer from January 1, 2021 to November 1, 2022. Findings: 1. A review Sysmex CA 620 coagulation analyzer lacked manufacture's service records for preventative maintenance from January 1, 2021 to November 1, 2022. 2. An interview with TS #1, on November 1, 2022, at 4:15 PM, confirmed the laboratory lacked preventative maintenance service records for the Sysmex CA 620 coagulation analyzer (2021 and 2022).
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 Triage Meter for analyte D-Dimer and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform at least three-point (a minimal, mid-point, and maximum) calibration verification every six months from January 1, 2021 to January 1, 2022. Findings: 1. No calibration verification records for the Triage Meter for analyte D-Dimer were available to review. 2. The Laboratory Quality Control Program policy and procedure failed to include the frequency and type of quality control performed and calibration verification requirements for Triage analyzer for analyte D-Dimer. 3. An interview with the TS #1 on November 1, 2022 at 2:30 PM, confirmed the laboratory failed to perform at least a three-point calibration for D-dimer on the Triage Meter every six months from January 1, 2021 to January 1, 2022.
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 and manual, and interview with the Technical Supervisor (TS) #1, the laboratory failed to establish acceptable criteria (statistical parameters/standard deviation) for assayed Bio-Rad controls: Liquid Assayed Multiqual controls, level 1 (lot #45891) and level 3 (lot #45893) for chemistry analytes Urea Nitrogen (BUN), Amylase, Calcium, Magnesium, Phosphorus; Lyphocheck Diabetes Control Level 1 (Lot# 85831) and Level 2 (Lot #85832) for analyte Hemoglobin A1C; Liguickeck Cardiac Markers Plus Control LT Level 1B (Lot#67665) Level 2 (Lot# 67662) and Level 3 (Lot #67663) for analyte Troponin I (TNIH) performed on the Siemens Dimension EXL 200 from January 1, 2021 to November 1, 2022. Findings: 1. The laboratory failed to follow the Dimension EXL System Operator's Guide manual which states, "Each new quality control product of new lot of quality control material introduced should be evaluated in conjunction with the old lot during a trial period. This allows the newly established mean and standard deviation to be compared to the values of the old material." 2. No concurrent studies of lot-to-lot changes of quality control materials to establish statistical limits were available for review. 3. A review of test volume sheet recording the last 12 months of patients' results showed 2814 Urea Nitrogen (BUN), 93 Amylase, 2826 Calcium, 172 Magnesium, 116 Phosphorus, 451 Hemoglobin A1C results and 543 Troponin I (TNIH) were reported from 11/01/21 to 11/01/22. 4. An interview with (TS) #1 on November 1, 2022, at 3:22 PM, confirmed the laboratory failed to establish acceptable QC statistical parameters for each analyte tested on the Siemens Dimension EXL 200 analyzer from January 1, 2021 to November 1, 2022.
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 observation, review of blood bank records, and interview with the Technical Supervisor (TS) #1, the laboratory failed to perform and document quarterly alarm inspection checks for 1 of 1 blood bank refrigerator and freezer used to store blood and blood products from Janurary 1, 2021 to November 1, 2022. Findings: 1.Observed in the laboratory on November 1, 2022 at 4:45 PM, two Thermo Scientific units used for blood bank, one refrigerator and one freezer containing blood and blood products for storage. 2. No quarterly blood bank alarms checks records for the refrigerator or freezer were available for review from January 1, 2021 to November 1, 2022. 3. An interview with TS #1 on November 1, 2022, at 5:00 PM, confirmed the laboratory failed to perform quarterly blood bank alarm checks for the blood bank refrigerator and freezer from January 1, 2021 to November 1, 2022.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures

	necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record review, policy and procedures, and interview with Technical Supervisor (TS) #1, the laboratory failed to assess their analytic system's quality assessment (QA) for its effectiveness to identify, resolve and prevent recurrence of problems from January 1, 2021 to November 1, 2022. Findings: 1. A review of policy and procedures for "Laboratory Quality Control Program" revealed the laboratory failed to follow their procedure by performing monthly "reviews of all L-J charts, maintenance records, temperature control records." to prevent the lack blood bank temperature alarm checks for 2021 and 2022. (See 5555); and the lack of manufacturer's preventative service records of the Siemens Dimensions EXL for 2021 and Sysmex CA 620 analyzers for 2021 and 2022 (see 5439). 2. No IQCP quality assessment review of serum hCG, infectious mononucleosis, and D-dimer were available for review from January 1, 2021 to November 1, 2022. 3. An interview with (TS) #1 on November 1, 2022, at 5:00 PM, confirmed these findings.
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on record review and interview with Technical Supervisor (TS) #1, the laboratory director failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Cell Identification, WBC Differential, Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, Platelet Count, PH, pCO2, pO2, Alcohol, Infectious Mononucleosis, KOH Preps, Wet Preps, and Microscopic Urinalysis from January 1, 2021 to May 6, 2022; and failed to perform twice annually accuracy verification or proficiency testing for PSA and ESR during January 1, 2021 to May 6, 2022 and glycated hemoglobin (A1c), ammonia, C-Reactive Protein (CRP), Ferritin, N-terminal pro b-type natriuretic peptide (NT-proBNP), Vitamin B12 and Vitamin D from November 1, 2021 to May 6, 2022. Findings: 1. A review of 2021 and 2022 American Proficiency Institute (API) records lacked documentation of proficiency testing for Complete Blood Counts (CBC) with differential: Cell Identification, WBC Differential, Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, Platelet Count, PH, pCO2, pO2, Alcohol, Infectious Mononucleosis, KOH Preps, Wet Preps, and (Microscopic Urinalysis for all of year 2021 and the 1st Event of 2022. 2. A review of proficiency testing records for 2021 and 2022 lacked documentation of American Proficiency Institute (API) testing records or twice annually accuracy verification studies as follows: ESR and PSA from January 1, 2021 to May 6, 2022; and new analytes (A1c, ammonia, CRP, Ferritin, NT-proBNP, Vitamin B12 and Vitamin D) from November 1, 2021 to May 6, 2022. 3. A review of Delegation of Duties policy and procedures revealed the lab director failed to ensure that a "quality management plan is in place and effectively addresses communication, quality assessments, proficiency testing compliance with CLIA requirements, personnel evaluation, and analytic performance of test systems." 4. An interview on November 1, 2022, at 10:30 AM with the TS #1 confirmed the

	laboratory director failed to enroll in an HHS-approved proficiency testing program or perform twice annually accuracy verification for the analytes listed and corresponding time frames.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section. This STANDARD is not met as evidenced by: Based on record review, policy and procedures, and interview with Technical Supervisor (TS) #1, the technical supervisors (TS #1, TS#2, and TS#3 listed on the CMS-209 Form) failed to perform their delegated duties and assess the effectiveness of their quality monitoring as stated in their policy and procedures from January 1, 2022 to November 1, 2022. (See D5400) Findings: 1. A review of policy and procedures for "Laboratory Quality Control Program" revealed the technical supervisors failed to follow the procedure and ensure to "Establishing a New QC Range" for assayed quality control by "new lot number must be run in parallel with the old lot of the same controls" and "a mean and range (SD) must be established /verified on each new lot of an assayed control." See 5469 2. A review of policy and procedures for "Delegations of Duties" revealed the technical supervisors failed to perform their duties by "ensures that quality assessment and quality control programs are established and maintained" (See D5793) and "ensures that acceptable analytical test performance is established and maintained for each test system." (See D5433, D5439, and D5555) 3. An interview with (TS) #1 on November 1, 2022, at 4:00 PM, confirmed the technical supervisors failed to perform their delegated duties to assess the effectiveness of their quality monitoring as stated in their policies and procedures from January 1, 2021, to November 1, 2022.
D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3) The technical supervisor is responsible for 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 record review and interview with Technical Supervisor (TS) #1, the three out of three technical supervisors failed to ensure the laboratory was enrolled in an HHS-approved proficiency testing program for Cell Identification, WBC Differential, Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, Platelet Count, PH, pCO2, pO2, Alcohol, Infectious Mononucleosis, KOH Preps, Wet Preps, and Microscopic Urinalysis from January 1, 2021 to May 6, 2022; and failed to perform twice annually accuracy verification or proficiency testing for PSA and ESR during January 1, 2021 to May 6, 2022 and glycated hemoglobin (A1c), ammonia, C-Reactive Protein (CRP), Ferritin, N-terminal pro b-type natriuretic peptide (NT-proBNP), Vitamin B12 and Vitamin D from November 1, 2021 to May 6, 2022. Findings: 1. A review of 2021 and 2022 American Proficiency Institute (API), testing program records lacked documentation of proficiency testing for Complete Blood

	Counts (CBC) with differential: Cell Identification, WBC Differential, Erythrocyte Count, Hematocrit, Hemoglobin, Leukocyte Count, Platelet Count, PH, pCO2, pO2, Alcohol, Infectious Mononucleosis, KOH Preps, Wet Preps, and (Microscopic Urinalysis for all of year 2021 and the 1st Event of 2022. 2. A review of proficiency testing records for 2021 and 2022 lacked documentation of American Proficiency Institute (API) testing records or twice annually accuracy verification studies as follows: ESR and PSA from January 1, 2021 to May 6, 2022; and new analytes (A1c, ammonia, CRP, Ferritin, NT-proBNP, Vitamin B12 and Vitamin D) from November 1, 2021 to May 6, 2022. 3. A review of Delegation of Duties policy and procedures revealed the technical supervisors (TS#1, TS#2 and TS#3 listed on the CMS-209 Form Personnel) failed to perform their delegated duties to ensure "Enrollment of the laboratory in a CMS approved proficiency testing program". 4. An interview on November 1, 2022, at 10:30 AM with the TS #1 confirmed these findings.