Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2164244	08/25/2022
Name of Provider or Supplier	**Street Address, City, State**	
Multicare Rockwood Post Falls Specialty Laboratory	750 N Syringa St Ste 101, Post Falls, ID	

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 a review of proficiency testing (PT) documents from American Proficiency Institute (API), and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory failed to enroll in PT for serum human chorionic gonadotropin (hCG). The findings include: 1. A review of PT documents from API identified that the laboratory failed to enroll or perform PT for serum hCG testing for 2021 and 2022. 2. An interview with the TS on 8/25/2022 at 9:00 am confirmed that the laboratory failed to perform PT for serum hCG testing in 2021 and 2022. 3. The facility reports performing 10 serum hCG tests annually.
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 review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory failed to follow written policies and procedures to assess testing personnel training and competency in 2021. The findings include: 1. A review of training and competency assessment records identified one testing personnel hired in February 2021 failed to have documentation of initial training. 2. A review of training and competency assessment records identified one testing personnel hired in February 2021 failed to have documentation of six month competency. 3. A review of training and competency assessment records identified two testing personnel failed to have an annual competency assessment for 2021. 4. An interview with the TS on 8/25/2022 at 8:15 am confirmed the above findings. 5. The laboratory reports performing 148,883 tests annually. 6. This is a repeat deficiency from the previous inspection on 1/4/2021.
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 a review of proficiency testing (PT) documents from American Proficiency Institute (API) and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory failed to review and evaluate PT scores that were less than 100% in 2021 and 2022. The findings include: 1. A review of PT documents from API for the specialty of chemistry for 2021 identified that the laboratory failed to evaluate results for lipase for event one with a score of 80%. 2. A review of PT documents from API for the specialty of chemistry for 2022 identified that the laboratory failed to evaluate results for lipase for event one with a score of 80%. 3. An interview with the TS on 8 /25/2022 at 9:02 am confirmed that the laboratory failed to evaluate PT scores that were less than 100% in 2021 and 2022. 4. The facility reports performing 292 lipase tests annually.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on a review of proficiency testing (PT) documents from American Proficiency Institute (API), and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory failed to review and evaluate PT scores that were given an artificial 100% in 2021 and 2022. The findings include: 1. A review of PT documents from API for the specialty of chemistry for 2021 identified that the laboratory failed to evaluate results for myoglobin for events one and two that were given an artificial scores of 100% due to lack of participants. 2. A review of PT documents from API for the

	specialty of chemistry for 2022 identified that the laboratory failed to evaluate results for myoglobin and creatine kinase-MB for events one and two that were given an artificial scores of 100% due to lack of participants. 3. An interview with the TS on 8 /25/2022 at 8:58 am confirmed that the laboratory failed to evaluate PT results with artificial scores in 2021 and 2022. 4. The facility reports performing 11 myoglobin and 37 creatine kinase-MB tests annually.
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 a review of the prothrombin time (PT) new reagent lot studies, the Dade Innovin Reagent package insert, a direct observation and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory failed to use the correct international sensitivity index (ISI) for patient International Normalized Ratio (INR) calculations. The findings include: 1. A review of the PT new reagent lot studies for the current reagent in use performed in June 2021 identified an Innovin lot number of 549780 with an ISI of 1.07. 2. A review of the Innovin package insert for lot 549780 confirmed the ISI of 1.07. 3. A direct observation of the ISI in harvest, the laboratory information system (LIS), identified an ISI of 1.02. The laboratory failed to have the correct ISI in the LIS system to calculate the INR for patient reporting. 4. An interview with the TS on 8/25/2022 at 11:52 am confirmed that the laboratory was using the incorrect ISI to calculate patient INR since the new reagents were put in use on 6/29/2022. 5. The laboratory reports performing 1321 PT/INR tests annually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a random review of laboratory temperature logs, a direct observation and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory failed to establish and maintain the correct storage temperature of reagents in the freezer. The findings include: 1. A review of the laboratory temperature logs identified the freezer temperature range was set at -10 to -20 C. 2. A direct observation of reagents and quality controls (QC) in the freezer identified that the Ortho Vitros reagents and calibrators had a storage requirement of -18 C or below and the Biorad Liquichek Immunology QC had a storage requirement of -20 to -80 C. 3. A random review of the laboratory's freezer temperature logs identified that the laboratory failed to have

	temperatures at or below -20 C for 25 of 29 days in March 2021, 26 of 28 days in April of 2021, 24 of 28 days in May 2021, 23 of 28 days in June 2021 and 25 of 27 days in July 2021 as required by manufacturers. 4. An interview with the TS on 8/25 /2022 at 1:29 pm confirmed that the laboratory failed to maintain reagents, calibrators and QC at the proper temperature. 5. The laboratory reports performing 148,883 tests annually.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on a review of the laboratory maintenance logs, instrument manuals and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory failed to perform maintenance as required by the instrument manufacturers. The findings include: 1. A review of Sysmex CA660 maintenance logs identified that the laboratory failed to perform quarterly LED calibration in March 22 and June 22 as required by the manufacturer. 2. A review of the Stratus CS operators manual identified maintenance as monthly replace and clean air filter, clean sample door area, clean lower cannula chamber seal, clean waste container area, clean tip chute and clean the pak shield. A review of Stratus SS maintenance logs identified that the laboratory failed to perform maintenance in 2021 and 2022. 3. A review of the laboratory maintenance logs identified that the laboratory failed to document maintenance on the Vitros 350, Sysmex XS-1000i, and the Sysmex CA-660 in December 2021. 4. An interview with the TS on 8/25/2022 at 11:42 am confirmed the above findings. 5. The laboratory reports performing 148,883 tests annually.
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 the laboratory's policies and procedures, quality control (QC) records for the Stratus CS and the iStat and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory failed to perform QC once each day of patient testing. The findings include: 1. A review of the laboratory's policies and procedures identified that the laboratory failed to have an Individualized Quality Control Plan (IQCP) for testing performed on the Stratus CS and the iStat. 2. A review of QC for blood gas testing on the iStat and cardiac testing on the Stratus CS identified that the laboratory failed to test QC each day of patient testing. 3. An interview with the TS on

	8/25/2022 at 12:41 pm confirmed that the laboratory did not have an IQCP for the Stratus CS and the iStat and only performed QC once per week. 4. The laboratory reports performing 192 tests on the Stratus CS and the iStat annually.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a review of proficiency testing (PT) documents from American Proficiency Institute (API), the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records, the prothrombin time (PT) new reagent lot studies, the Dade Innovin Reagent package insert, laboratory temperature logs, laboratory maintenance logs, quality control (QC) records and direct observations on 8/25/2022, the laboratory director failed to provide direction and management to the laboratory. See D6088, D6091, D6093, D6095 and D6103.
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 a review of proficiency testing (PT) documents from American Proficiency Institute (API), and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory director failed to ensure PT enrollment for serum human chorionic gonadotropin (hCG). The findings include: 1. A review of PT documents from API identified that the laboratory failed to enroll or perform PT for serum hCG testing for 2021 and 2022. 2. An interview with the TS on 8/25/22 at 9:00 am confirmed that the laboratory failed to perform PT for serum hCG testing in 2021 and 2022. 3. The facility reports performing 10 serum hCG tests annually.
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 a review of proficiency testing (PT) documents from the American Proficiency Institute (API), and interviews with the technical supervisor (TS) on 8/25 /2022, the laboratory director failed to ensure the review and evaluation of PT scores that were less than 100% and for scores that were given an artificial 100% in 2021 and 2022. The finding include: 1. A review of PT documents from API for the specialty of chemistry for 2021 and 2022 identified that the laboratory failed to evaluate results for

	myoglobin and creatine kinase-MB that were given an artificial scores of 100% due to lack of participants. See D5215 2. A review of PT documents from API for the specialty of chemistry for 2021 and 2022 identified that the laboratory failed to evaluate results for lipase with a score of 80%. See D5211 3. Interviews with the TS on 8/25/2022 at 8:52 am and 9:02 am confirmed that the laboratory failed to evaluate PT scores that were less than 100% or given an artificial score in 2021 and 2022.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, quality control (QC) records for the Stratus CS and the iStat and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory director failed to ensure that the QC program followed the regulations or established an Individualized Quality Control Plan (IQCP) . The findings include: 1. A review of the laboratory's policies and procedures identified that the laboratory failed to have an IQCP for testing performed on the Stratus CS and the iStat. 2. A review of QC for blood gas testing on the iStat and cardiac testing on the Stratus CS identified that the laboratory failed to test QC each day of patient testing. 3. An interview with the TS on 8/25/2022 at 12:41 pm confirmed that the laboratory did not have an IQCP for the Stratus CS and the iStat and only performed QC once per week. 4. The laboratory reports performing 192 tests on the Stratus CS and the iStat annually.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) The laboratory director must ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. This STANDARD is not met as evidenced by: Based on a review of the prothrombin time (PT) new reagent lot studies, the Dade Innovin Reagent package insert, a direct observation, a review of the laboratory maintenance logs and interviews with the technical supervisor (TS) on 8/25/2022, the laboratory director failed to ensure the use of the correct international sensitivity index (ISI) for patient International Normalized Ratio (INR) calculations and instrument maintenance was being performed to ensure proper analytical test performance. The findings include: 1. A review of the PT new reagent lot studies for the current reagent in use performed in June 2021 identified an Innovin lot number of 549780 with an ISI of 1.07 which matched the Innovin package insert. 2. A direct observation of the ISI in harvest, the laboratory information system (LIS), identified an ISI of 1.02. The laboratory failed to have the correct ISI in the LIS system to calculate the INR for patient testing. See D5411 3. A review of Sysmex CA660 maintenance logs identified that the laboratory failed to perform quarterly LED calibration in March 22 and June 22 as required by the manufacturer. 4. A review of the Stratus CS manual identified maintenance as monthly replace and clean air filter, clean sample door area, clean lower cannula chamber seal, clean waste container area, clean tip chute and clean the

	pak shield. A review of Stratus SS maintenance logs identified that the laboratory failed to perform maintenance in 2021 and 2022. 5. A review of the laboratory maintenance logs identified that the laboratory failed to document maintenance on the Vitros 350, Sysmex XS-1000i, and the Sysmex CA-660 in December 2021. See D6429 6. Interviews with the TS on 8/25/2022 at 11:42 am and 11:52 am confirmed that the laboratory director failed to ensure acceptable levels of analytical testing. 7. The laboratory reports performing 148,883 tests annually.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, training and competency assessment records and an interview with the technical supervisor (TS) on 8/25/2022, the laboratory director failed to ensure that written policies and procedures to assess testing personnel training and competency were followed in 2021. The findings include: 1. A review of training and competency assessment records identified one testing personnel hired in February 2021 that failed to have documentation of initial training and documentation of six month competency. 2. A review of training and competency assessment records identified two testing personnel that failed to have an annual competency assessment for 2021. 3. An interview with the TS on 8/25/2022 at 8:15 am confirmed the above findings. 4. The laboratory reports performing 148,883 tests annually. 5. This is a repeat deficiency from the previous inspection on 1/4/2021.