Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2164244	01/04/2021
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
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 record review of personnel training and competency assessments, the CMS-209 personnel form, and an interview with the laboratory manager on 01/04/21, the laboratory failed to follow written policies and procedures to assess competency for the technical supervisor/consultant and testing personnel. The findings include: 1. The Technical Supervisor/Technical Consultant (TS/TC) listed on the CMS-209 did not have documentation of competency assessments available at the time of survey for 2019 and 2020. 2. Three of four testing personnel listed on the CMS-209 did not have documentation of initial training available at the time of survey. 3. Two of four testing personnel listed on the CMS-209 did not have documentation of 6-month competency assessment available at the time of survey. 4. The laboratory manager confirmed the above findings on 01/04/2021 at 1:30 PM. 5. The laboratory reports performing 60,130 Hematology and 72,600 Routine Chemistry patient specimens annually.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by:

	Based on a review of the laboratory's policies and records, the laboratory failed to establish and follow their own written policies and procedures for monitoring and assessing quality indicators and for implementing corrective actions when needed. The findings include: 1. A review of policies and procedures revealed the polices currently in use could not be identified as belonging to Multicare Rockwood Post Falls Specialty Laboratory. 2. A review of the polices binders revealed a Quality Assurance policy from Northwest Specialty Laboratories and other policies and documents from Northwest Specialty Hospital and Spokane Internal Medicine. 3. An interview with the laboratory manager on January 4, 2021 at approximately 5:15 pm confirmed these findings
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on a review of polices and procedure and an interview with the laboratory manager on January 4, 2021, the laboratory failed to provide a procedural policy for the operation of the Sysmex CA600 coagulation analyzer. The finding include: 1. A request was made by the surveyor and the laboratory was unable to produce an approved policy for the Sysmex CA600 at the time of the survey. 2. An interview with the laboratory manager on January 4, 2021 at approximately 5:15 pm confirmed that there was not an approved policy for this laboratory.
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 laboratory's coagulation records and an interview with the laboratory manager on January 4, 2021, the lab failed to perform an installation validation or to document a new lot study for the use of reagents on the Sysmex CA 600 coagulation analyzer as prescribed by the manufacture, when it was put into use in May 2019. The findings include: 1. A record review of the PT Reagent Worksheets, which evaluates new lots of Innovin prior to use, revealed that the laboratory failed to document the study of new reagent lots prior to 1/27/2020. 2. A record review of the Sysmex CA600 revealed that an installation validation had not been performed prior to placing the instrument into service in this laboratory. 3. An interview with the laboratory manager on January 4, 2021 at approximately 5:25 pm confirmed these findings. 4. The laboratory reports performing 957 prothombin times(PT/INR) and 826 APTTs annually.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

	Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's installation validation study and related records for the Vitros 350 chemistry analyzer and an interview with the laboratory manager on January 4, 2021, the laboratory failed to implement the patient reportable ranges that were established as part of the approved validation study. The findings include: 1. A record review of the raw data for the validation study and the laboratory's published linearity for this instrument revealed that the laboratory failed to implement their validated reportable ranges for the following analytes: Alkaline Phosphatase Amylase Bilirubin (Direct/Indirect) Glucose 2. An interview with the laboratory manager on January 4, 2021 at approximately 3:55 pm confirmed these findings. 3. The laboratory reports performing 72,600 chemistry assays annually.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory failed to document corrective actions for the calibration verification failure on the Picollo chemistry analyzer. The findings include: 1. A record review of the Picollo calibration verification documents revealed that the calibration verification on the Picollo performed on 9/11/2020 failed and no corrective action documented. 2. A review of patient records revealed that complete metabolic panels (CMP) have been performed on the Piccolo chemistry analyzer since the time of the calibration verification failure on 9/11/2020. 3. An interview with the laboratory manager on January 4, 2021 at approximately 4:15 pm confirmed these findings.
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 record reviews and interviews with the laboratory manager and the technical consultant/supervisor at the time of the survey, the laboratory director failed to provide overall direction of the laboratory operations since the laboratory began testing patients in May 2019. Refer to D6086, D6097, D6103, D6106, D6107
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 review of the laboratory's polices and procedures, coagulations documents and an interview with the laboratory manager on January 4, 2021, the laboratory director failed to ensure that the pre analytical validations were established and maintained to assure the quality of coagulation tested being performed. The findings include: 1. A record review of the PT Reagent Worksheets, which evaluates new lots of Innovin prior to use, revealed that the laboratory 2. A record review of the Sysmex CA600 records revealed that an installation validation was not performed prior to placing the instrument into use for patient testing in this laboratory. 3. An interview with the laboratory manager on January 4, 2021 at approximately 5:25 pm confirmed these findings. 4. The laboratory reports performing 957 Prothombin Times and 826 APTT tests annually.
D6097	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) The laboratory director must ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on a record review and an interview with the laboratory manager, the laboratory director failed ensure to that corrective action was taken and documented for the calibration verification failure on the Picollo chemistry analyzer. The findings include: 1. A record review of the Picollo calibration verification documents revealed that the calibration verification on the Picollo performed on 9/11/2020 failed and no corrective action was available at the time of the survey. 2. A review of patient records revealed that patient testing has been performed and reported on the Piccolo chemistry analyzer since the time of the calibration verification failure on 9/11/2020. 3. An interview with the laboratory manager on January 4, 2021 at approximately 4: 15 pm confirmed these findings.
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 record review and an interview with the laboratory manager, the laboratory director failed to ensure that policies and procedures were established and follwed for monitoring the competency of technical consultant/technical supervisor in chemistry and hematology since the start of patient testing began in May 2019. The finding include. 1. A review of personnel competency documents revealed competency assessments for the technical consultant, who is also the technical supervisor had done been documented in 2019 or in 2020. 2. An interview with the laboratory manager on January 4, 2021 at approximately 5:35 pm confirmed these findings. 3. The laboratory reports performing 132,730 patients test annually.
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 a review of polices and procedure and an interview with the laboratory manager on January 4, 2021, the laboratory director failed to approve a procedural policy for the operation of the Sysmex CA600 coagulation analyzer in this laboratory The finding include: 1. A request was made by the surveyor and the laboratory was unable to produce an approved policy for this facility for the Sysmex CA600 at the time of the survey. 2. An interview with the laboratory manager on January 4, 2021 at approximately 5:15 pm confirmed these findings.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and training and competency records, the laboratory director failed to establish in writing a delegation of authority for the duties and responsibilities of the technical consultant/technical supervisor to perform training and competency assesments on the testing personnel. The findings include: 1. A review of personnel training records revealed that 3 of 4 testing personnel did not have documentation of initial training available at the time of survey. 2. A review of personnel competency records revealed that 2 of 4 testing personnel did not have a 6 month competency assessment docuemented. 3. The laboratory reports performing a total of 132,730 patient tests annually. 4. An interview with the laboratory manager on January 4, 2021 at approximately 5:15 pm confirmed these findings.