Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2173071	09/10/2024
Name of Provider or Supplier	**Street Address, City, State**	
Idaho Falls Community Hospital	2327 Coronado St, Idaho 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 a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, laboratory procedures, training and competency assessment records and an interview with the laboratory manager on 9/10/2024, the laboratory failed to follow written policies and procedures to assess testing personnel competency in 2023 and 2024. The findings include: 1. The CMS 209 identified 104 testing personnel (TP) performing moderate complexity testing of which 55 were new since the last inspection on 7/11/2022. 2. A review of laboratory procedures identified that the laboratory established policies and procedures to assess TP initial training, semiannual and annual competency. 3. A review of training and competency assessment records identified that the laboratory failed to have initial training for six (6) of 55 new TP. 4. A review of training and competency assessment records identified that the laboratory failed to have six month competency assessments for six (6) TP. 5. A review of training and competency assessment records identified that the laboratory failed to have annual competency assessments for seven (7) TP in 2023 and two (2) TP in 2024. 6. An interview with the laboratory manager on 9/10/2024 at 9:40 am confirmed the above findings. 7. The laboratory reports performing 10,085 moderate complexity tests annually. 8. This is a repeat deficiency from the previous inspections on 11/6/2020 and 7/11/2022. The laboratory failed to implement and follow their plan of correction.
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) documentation from the American Pathology Institute (API), and an interview with the laboratory manager on 9/10/2024, the laboratory director or delegated designee failed to review PT results in 2022 and 2023. The findings include: 1. A review of PT documents for 2022 from API identified that the laboratory director failed to review results for Chemistry Core event three. 2. A review of PT documents for 2023 from API identified that the laboratory director failed to review results for Hematology/Coagulation event three. 3. An interview with the laboratory manager on 9/10/2024 at 10:10 am confirmed that the laboratory director failed review the above PT results. 4. The laboratory reports performing 10,085 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 laboratory manager on 9/10/2024, the laboratory failed to perform maintenance as required by the Radiometer ABL90 manufacturer. The findings include: 1. A review of maintenance logs for the seven (7) Radiometer ABL90 instruments identified that the laboratory failed to perform the daily maintenance of: temperature, humidity, verify calibrations are acceptable, verify three levels of quality control are within range, verify the number of tests available on the sensor cassette and solution pack, and clean the inlet gasket. The laboratory failed to perform the following daily maintenance: Medical-Surgical ABL90 January 2024: 5 of 31 days February 2024: 9 of 29 days March 2024: 4 of 31 days April 2024: 6 of 30 days July 2024: 3 of 31 days August 2024: 17 of 30 days Emergency Department ABL90 January 2024: 6 of 31 days February 2024: 4 of 29 days March 2024: 3 of 31 days April 2024: 9 of 30 days Cardiac Catheterization Laboratory ABL90 July 2024: 1 of 21 days August 2024: 2 of 23 days 2. An interview with the laboratory manager on 9 /10/2024 at 11:20 am confirmed the above findings. 3. The laboratory reports performing 10,085 tests annually.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by:

	Based on a review of the laboratory maintenance logs, instrument manuals and an interview with the laboratory manager on 9/10/2024, the laboratory failed to perform function checks as required by the Medtronic ACT Plus manufacturer. The findings include: 1. A review of the Medtronic ACT Plus user manual identified that the temperature of the actuator heat block is to be verified monthly to ensure an accurate temperature. 2. A review of maintenance logs for the three (3) Medtronic ACT Plus instruments identified that the laboratory failed to perform verification of the ACT Plus actuator heat block temperature in March 2024, April 2024, May 2024, June 2024, July 2024 and August 2024 for the three (3) Medtronic ACT Plus instruments. 3. An interview with the laboratory manager on 9/10/2024 at 11:56 am confirmed the above finding. 4. The laboratory reports performing 85 tests annually on the Medtronic ACT Plus instruments.
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 a lack of documentation and an interview with the laboratory manager on 9 /10/2024, the laboratory failed to evaluate results for analytes performed on multiple analyzers to ensure that they are within the allowed acceptable difference between analyzers at least twice annually in 2023 and 2024. The findings include: 1. A lack of documentation for analyte result comparison between the laboratory's three (3) Medtronic ACT Plus analyzers identified that the laboratory failed to evaluate test results for activated clot time to ensure that they were within the allowed acceptable difference between the three analyzers at least twice annually in 2023 and 2024. 2. An interview with the laboratory manager on 9/10/2024 at 10:42 am confirmed that the laboratory failed to compare analyte results between analyzers to ensure accurate patient testing. 3. The laboratory reports performing 85 tests annually on the Medtronic ACT Plus analyzers.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, educational documents and an interview with the laboratory manager on 9/10/2024, the laboratory failed to have three (3) of 55 new testing personnel qualified with the minimum educational requirements. See D6065
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

	(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, educational documents and an interview with the laboratory manager on 9/10/2024, the laboratory failed to ensure that all testing personnel met the educational requirements for testing. The findings include: 1. A review of the CMS 209 identified 55 new testing personnel since the last survey on 7/11/2022. 2. A review of educational documents for the 55 new testing personnel identified that the laboratory failed to have educational documentation for three (3) testing personnel to verify that they met the minimum educational requirements before performing patient testing. 3. An interview with the laboratory manager on 9/10/2024 at 9:40 am confirmed the above finding. 4. The laboratory reports performing 10,085 tests annually. 5. This is a repeat deficiency from the previous inspection on 7/11/2022. The laboratory failed to implement and follow their plan of correction.