Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D2173071	11/06/2020
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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on record review of the laboratory's proficiency testing (PT) attestation records from the American Proficiency Institute (API) and interview with the laboratory Technical Consultant (TC) on 11/6/2020 at 09:30 a.m., the laboratory failed to test their blood gas proficiency testing (PT) samples to be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory. The findings include: 1. The laboratory is responsible for nine (9) ABX blood gas analyzers that are located in the nursing units in the Catherization lab (2), the general surgery department(1), the emergency room (2), the med-surge department, and the Intensive Care unit (2), general laboratory. 2. The personnel who routinely perform the blood gas analysis are the nursing staff in each department (146). 3. Review of the College of American Pathologists (CAP) PT attestation sheets revealed that the technical consultant (TC) performed the blood gas and hematology for event 1 of 2020, the TC performed the all five specimens for hematology event 2 of 2020, and 2/5 of the PT specimens of the Blood gas PT in event 2 of 2020, and the TC performed 2 of 5 blood gas specimens for event 3 of 2020. Only five (5) of the 146 testing personnel performed the blood gas PT during the PT testing year of 2020. The TC does not routinely perform blood gas analysis. 4. The laboratory technical consultant and laboratory director confirmed by interview on 11/6/2020 at 10:15 a.m., the technical consultant did not routinely perform the blood gas analysis. 5. The laboratory reports performing 1700 blood gas patient specimens 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 review of the laboratory's Policy's and Procedures and interview with the laboratory technical consultant (TC) on 11/06/2020, the laboratory failed to establish and follow written policies and procedures to assess employee and consultant competency. in accordance with 42 C.F.R. 493.1413(b)(8)(9). The findings include: 1. The laboratory personnel form (CMS-209) lists (142) testing personnel who are high school graduates or higher degreed individuals. 2. The laboratory had no documentation of initial training or competency for 7 of the 142 testing personnel listed on the CMS-209. 3. The laboratory had no documentation of semi-annual competency for 104 of the 142 testing personnel listed on the CMS-209. 4. The laboratory had no documentation of annual competency for 15 of the 142 testing personnel listed on the CMS-209. 5. The laboratory had a check list sheet that does not indicate or identify which of the six parameters listed in 42 C.F.R. 493.1413(b)(8) were used to determine competency for initial, semi-annual or annual competency. 6. The technical consultant confirmed by interview on 11/06/2020 at 2:00 p.m. that the laboratory does not have a policy or procedure for initial training and competency, semi-annual competency or annual competency which include the six parameters listed in 42 C.F.R. 493.1413(b)(8). (i) Direct observations of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing; (ii) Monitoring the recording and reporting of test results; (iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records; (iv) Direct observation of performance of instrument maintenance and function checks; (v) Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples; and (vi) Assessment of problem solving skills 7. The laboratory has 142 testing personnel and reports performing 28,105 patient test annually.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of the laboratory's polices and procedures, and interview with the laboratory director (LD) and the technical consultant (TC) on 11/6/2020, the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. The findings include: 1. The laboratory is responsible for Point of Care arterial blood gas (ABG) and Act Tdiff activated partial thromboplastin time (aPTT) testing by multiple hospital nursing department staff. 2. The LD and TC

	confirmed by interview on 11/6/2020 at 3:00 p.m., the laboratory did not have policies and procedures to perform and document quality assessments (QA) for the POC testing performed by the hospital nursing staff. 3. The laboratory reports performing 25 aPTT tests and 1,700 ABG's 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 review of the manufacturers manual for the Medtronic ACT diff, review of the laboratory's quality control logs and interview with the technical consultant (TC) on 11/6/2020, the laboratory failed to perform quality control (QC) testing following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for the Medtronic ACT Diff activated partial thromboplastin time. The findings include: 1. The Medtronic ACT diff manual states that two external controls are to be ran each day of patient testing. The laboratory QC records revealed that the laboratory is performing two levels of external QC every seven days, and the electronic QC simulator is ran each day of patient testing testing. 2. The manufacturers manual specifically states that the electronic simulator may be used to enhance the QC program but "is not to replace the requirements of external controls". 3. The laboratory initiated an individual quality control plan (IQCP) to modify the requirements for the QC testing for the Medtronic ACT testing. The IQCP plan did not include precision studies for validating the IQCP. 4. The laboratory TC confirmed by interview on 11/6/2020 at 1:45 p.m., the laboratory did not have a complete IQCP for the Medtronic ACT testing and do not perform external QC each day of patient testing. 5. The laboratory reports performing 25 aPTT tests 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 review of the laboratory's verification records for the Medtronic ACT point of care (POC) activated thromboplastin time (aPTT) and interview with the laboratory director (LD) and the technical consultant (TC) on 11/6/2020 at 11:55 a.m., the laboratory failed to demonstrate that it can obtain performance specifications by testing known positive and negative samples in order to verify the Medtronic ACT analyzers accuracy and precision. The findings include: 1. Review of the validation

	and verification records performed on the Medtronic ACT POC analyzers revealed that the laboratory did not verify the manufacturer's specifications by testing known positive and negative samples to ensure that the expected results are obtained, but utilized the systems electronic simulator to verify precision data. 2. The laboratory director and the technical consultant confirmed by interview on 11/6/2020 at 1:30 p. m., the laboratory did not perform adequate precision studies to verify the Medtronic ACT POC analyzer. 3. The laboratory reports performing 23 ACT POC 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 review of the Medtronic ACT activated platelet thromboplastin time (aPTT) manufacturers manual, review of the laboratory's quality control (QC) records and interview with the laboratory manager and the laboratory technical consultant on 11/6 /2020, the laboratory failed to 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. The findings include: 1. The laboratory performs external QC on the Medtronic ACT for aPTT every seven (7) days and the systems electronic simulator each day of testing in accordance with their developed individual quality control plan (IQCP). 2. The manufacturers manual states that the electronic simulator can be used to enhance the laboratory's QC program, but must not replace the use of external QC levels on each day of patient testing. See D5411. 3. The laboratory manager and the TC confirmed by interview on 11/6/2020 at 2:00 p.m., the laboratory's IQCP was not complete in establishing accuracy and precision, and that the laboratory has not been performing two external controls each day of patient testing for the ACT aPTT testing. 4. The laboratory reports performing 25 POC aPTT tests annually.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the manufacturers manual for the Medtronic ACT diff, review of

	the laboratory's quality control logs and interview with the technical consultant (TC) on 11/6/2020, the laboratory director failed to ensure that the quality control program for the Medtronic ATC dif was established and maintained as stated by the manufacturer to assure the quality of laboratory services provided. The findings include: 1. The laboratory director failed to ensure that control procedures are performed using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements as specified by the manufacturer. See D5445.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's polices and procedures, and interview with the technical consultant (TC) on 11/6/2020, the laboratory director failed to ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. 1. The laboratory director failed to establish and ensure written policies and procedures are available to assess and maintain the quality of laboratory services provided. See D5291
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on laboratory testing personnel training and competency records and interview with the technical consultant on 11/6/2020, the laboratory director failed to ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, received the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. The findings include: 1. Based on review of the Centers for Medicare and Medicaid Services (CMS) laboratory personnel form (209), and interview with the technical consultant (TC) on 11/06 /2020, the laboratory director failed to ensure policy and procedures were developed to ensure all testing personnel had appropriate training and could demonstrate competency prior to testing patients' specimens. See D5209.