

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D1046352	<b>(X3) Date Survey Completed</b>  05/25/2021
<b>Name of Provider or Supplier</b>  Idaho Surgery Center	<b>Street Address, City, State</b>  3115 Medical Way, Caldwell, ID	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of laboratory records, the CMS 155D Individual Laboratory Profile and an interview with the Technical Consultant (TC) on 5/25/2021, the laboratory failed to enroll in an approved proficiency testing program or programs for each of the specialties and subspecialties that the laboratory is testing. The findings include: 1. A review of laboratory records and the CMS 155D Individual Laboratory Profile identified that the laboratory failed to enroll in an approved proficiency testing program or programs for pH, pCO<sub>2</sub>, pO<sub>2</sub>, sodium, potassium, calcium, chloride, glucose, lactate, creatinine and hematocrit. 2. An interview with the TC on 5/25/2021 at 9:25 am confirmed that the laboratory failed to enroll in proficiency testing for the above analytes. 3. The laboratory reports performing 365 moderate complexity tests annually.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on a review of training documentation and competency assessments, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview on 5/25/2021 with testing personnel 1 (TP1), the laboratory failed to establish and follow written policies and procedures to assess testing personnel in accordance with 42 C.F.R. 493.1413(b)(7)(8). The findings include: 1. A review of training and competency records identified one (1) of thirteen (13) testing personnel listed on the CMS 209 failed to have documentation of annual competency for 2019 which included the six parameters as listed in 493.1413(b)(7)(8) at the time of survey. 2. A review of training and competency records identified three (3) of thirteen (13) testing personnel listed on the CMS 209 failed to have documentation of annual competency for 2020 which included the six parameters as listed in 493.1413(b)(7)(8) at the time of survey. 3. An interview with TP1 on 5/25/2021 at 11:50 am confirmed the competency assessment documentation was not available for the above testing personnel for 2019 and 2020 at the time of survey performed on 5/25/2021. 4. The laboratory reports performing 365 moderate complexity tests annually.

**D5441**

**CONTROL PROCEDURES**  
CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a record review and an interview with the Technical Consultant (TC) on 5/25/2021, the laboratory failed to perform quality controls (QC) and have a control procedure that monitors the accuracy and precision of the complete analytic process. The findings include: 1. A review of laboratory records identified that the laboratory failed to perform and document controls on the EPOC blood analysis system, serial number 13218521401608, using the BGEM test cards, lot number 11-21068-30, that test the following analytes: pH, pCO<sub>2</sub>, pO<sub>2</sub>, sodium, potassium, calcium, chloride, glucose, creatinine, lactate and hematocrit. 2. An interview with the TC on 5/25/2021 at 9:30 am confirmed that the laboratory did not perform or document QC on the BGEM test cards, lot number 11-21068-30 using the EPOC blood analysis system, serial number 13218521401608. 3. The laboratory reports performing 365 moderate complexity tests annually.

**D6000**

**MODERATE COMPLEXITY LABORATORY DIRECTOR**  
CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.

1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on the systematic nature of the deficient practices identified in proficiency testing (PT), quality control (QC), training and competency, and the lack of testing personnel educational documentation, the Laboratory Director (LD) failed to provide overall management and direction over the laboratory and failed to ensure quality patient results. See D6015, D6020, and D6029.

**D6015**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(4)

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)(4) 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 laboratory records, the CMS 155D Individual Laboratory Profile and an interview with the Technical Consultant (TC) on 5/25/2021, the laboratory director failed to ensure that the laboratory is enrolled in an approved proficiency testing program or programs for each of the specialties and subspecialties that the laboratory is testing. The findings include: 1. A review of laboratory records and the CMS 155D Individual Laboratory Profile identified that the laboratory failed to enroll in an approved proficiency testing program or programs for pH, pCO<sub>2</sub>, pO<sub>2</sub>, sodium, potassium, calcium, chloride, glucose, lactate, creatinine and hematocrit. 2. An interview with the TC on 5/25/2021 at 9:25 am confirmed that the laboratory failed to enroll in proficiency testing for the above analytes since they began performing testing. 3. The laboratory reports performing 365 moderate complexity 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 a record review and an interview with the Technical Consultant (TC) on 5/25/2021, the laboratory director failed to ensure quality controls (QC) were performed to assure the accuracy and precision of the complete analytic process and quality of laboratory services provided. The findings include: 1. A review of laboratory records identified that the laboratory failed to perform and document controls on the EPOC blood analysis system, serial number 13218521401608, using the BGEM test cards,

lot number 11-21068-30, that test the following analytes: pH, pCO<sub>2</sub>, pO<sub>2</sub>, sodium, potassium, calcium, chloride, glucose, creatinine, lactate and hematocrit. 2. An interview with the TC on 5/25/2021 at 9:30 am confirmed that the laboratory did not perform or document QC on the BGEM test cards, lot number 11-21068-30 using the EPOC blood analysis system, serial number 13218521401608. 3. The laboratory reports performing 365 moderate complexity tests annually.

**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 a review of testing personnel qualification documents, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview with testing personnel 2 (TP2) on 5/25/2021, the laboratory director failed to ensure, prior to patient testing, all personnel have the appropriate education, training and are capable of performing all testing reliably and accurately. The findings include: 1. A review educational and training documents, competency assessments and the Centers for Medicare and Medicaid Services (CMS) 209 personnel form identified that the laboratory failed to have educational documents for thirteen (13) of thirteen (13) testing personnel to qualify them to perform moderate complexity test. The laboratory failed to have documentation, at minimum of high school diplomas or equivalent at the time of survey. 2. A review of training and competency records identified one (1) of thirteen (13) testing personnel listed on the CMS 209 failed to have documentation of annual competency for 2019 which included the six parameters as listed in 493.1413(b)(7)(8) at the time of survey. 3. A review of training and competency records identified three (3) of thirteen (13) testing personnel listed on the CMS 209 failed to have documentation of annual competency for 2020 which included the six parameters as listed in 493.1413(b)(7)(8) at the time of survey. 4. An interview with TP2 on 5/25/2021 at 10:10 am confirmed that there was no documentation of education available at the time of survey to qualify the thirteen (13) testing personnel as moderate complexity testing personnel. 5. The laboratory reports performing 365 moderate complexity tests annually.

**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 educational and training documents and the Centers for

Medicare and Medicaid Services (CMS) 209 personnel form, the Laboratory Director (LD) failed to have individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the moderate complexity tests performed on the EPOC blood analysis system. 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 testing personnel qualification documents, the Centers for Medicare and Medicaid Services (CMS) 209 personnel form and an interview with testing personnel 2 (TP2) on 5/25/2021, the laboratory failed to have qualified testing personnel performing testing on the EPOC blood analysis system. The findings include: 1. A review educational and training documents and the Centers for Medicare and Medicaid Services (CMS) 209 personnel form identified that the laboratory failed to have educational documents for thirteen (13) of thirteen (13) testing personnel to qualify them to perform moderate complexity test. The laboratory failed to have documentation, at minimum of high school diplomas or equivalent at the time of survey. 2. An interview with TP2 on 5/25/2021 at 10:10 am confirmed that there was no documentation of education available at the time of survey to qualify the thirteen (13) testing personnel as moderate complexity testing personnel. 3. The laboratory reports performing 365 moderate complexity tests annually.