Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0646339	12/03/2025
Name of Provider or Supplier	**Street Address, City, State**	
Idaho Bureau Of Laboratories	2220 Old Penitentiary Road, Boise, 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
D0000	Federal surveyors from the Division of Clinical Laboratory Improvement and Quality (DCLIQ) Survey Branch conducted an announced CLIA recertification survey at the Idaho Bureau of Laboratories from December 2, 2025 to December 3, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements, the following standard-level deficiencies were found.
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 standard operating procedures (SOP), lack of a supervisory personnel competency assessment procedure, and interview with the laboratory director (LD), the laboratory failed to establish a competency assessment procedure to assess the competency of laboratory personnel with supervisory responsibilities for two of two years (December 2023 - December 2025). Findings Included: 1. Review of the IBL CLIA QA PLan, version 5.0 authorized on October 29, 2025, revealed, the laboratory SOP lacked a procedure to assess supervisory personnel responsibilities two of two years (December 2023 - December 2025). 2. Interview with the LD on December 2, 2025 at 9:45 am confirmed the laboratory did not establish a written policy for accessing the supervisory responsibilities for technical and general supervisors.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)

	At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of standard operating procedures (SOP), the lack of proficiency testing (PT) / biannual verification records, and an interview with Technical Supervisor (TS) #1, the laboratory failed to perform PT or biannual verification for six of six Centers for Disease Control and Prevention's Laboratory Response Network for Biological Threats (LRN-B) test methods in 2025. Findings Included: 1. Review of the IBL CLIA QA Plan, version 5.0, authorized (Page four) on October 29, 2025, stated, 7. Proficiency Testing and biannual verification, "IBL performs testing on regulated and non-regulated analytes. IBL will enroll in formal Proficiency Testing whenever possible and conduct in-house biannual verification for analyses without a commercial vendor". 2. The laboratory failed to provide Proficiency Testing or biannual verifications records for the below LRN-B test methods: a. Orthopox virus rule out b. Bacillus anthracis rule out c. Brucella sp. rule out d. Burkholderia mallei /pseudomallei rule out e. Francisella tularensis rule out f. Yersinia pestis rule out 3. Interview with TS#1 on December 3, 2025, at 2:45 p.m. confirmed the LRN-B PT or biannual verifications were not performed biannually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation of the Centers for Disease Control and Prevention's Laboratory Response Network for Chemical Threats (LRN-C) laboratory (Room 116), an interview with Technical Supervisor (TS) #4, the laboratory failed to ensure expired testing supplies were not available for use (a sampling of 17 out of 17 boxes of blood collection tubes and six of six containers of calibrators). Findings Included: 1. Observation of the laboratory on December 3, 2025 at 12:15 pm revealed expired reagents, calibration materials and other supplies were available for use. 2. A sampling of the following expired calibration materials and blood collection tubes were observed: a. Four boxes of Becton Dickinson (BD) Blood Collection Tubes - Lavender Top. Lot#4045192 - Expired: 06/30/2025. b. Eight boxes of BD Blood Collection Tubes - Lavender Top. Lot#4198188 - Expired: 11/30/2025. c. Five Boxes of 8 BD Blood Collection Tubes - Gray Top. Lot#4073042 - Expired: 07/31/2025. d. Two Racks of ABRC7 int. Cals/QCBL Rack 2 - CT043507 - Expired: 08/30/2019 e. Two Racks of ABRC7 int. Cals/QCBL Rack 6 - CT043506 - Expired: 08/30/2019 f. Two Racks of ABRC7 int. Cals/QCBL Rack 7 - CT043506 - Expired: 08/30/2019 3. Interview with TS#4 on December 2, 2025, at 12:15 p.m. confirmed room 116 had expired testing materials available for use.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (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 analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based on review of laboratory standard operating procedures (SOP), lack of documented quality assessment (QA) activities, and interview with the technical supervisor (TS) #2 and the laboratory director (LD), the laboratory failed to establish and follow the IBL CLIA QA plan to ensure ongoing mechanisms to monitor, assess, and document corrective actions for analytic systems for two of two years (December 2023 to December 2025). Findings Included: 1. Review of the IBL CLIA QA Plan, version 5.0 authorized on October 29, 2025, revealed, on page seven under 18. Summary: "Our laboratory uses quality assurance program to improve the diagnostic laboratory services we provide to the citizens of Idaho. Ongoing quality assurance issues are addressed in the technical supervisor meeting and through regular review of non-confirming events, which provide performance data to the management team". 2. The laboratory failed to provide documented technical supervisor meeting addressing QA issues for 2 years (December 2023 to December 2025). 3. The laboratory failed to provide documentation of all non - conforming events reviewed (See DTAG 5793). 4. Interviews with TS#2 and the LD on December 3, 2025 at 4:00 pm confirmed the above findings.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, maintenance records, emails, laboratory corrective action documentation, and interviews with Laboratory Director and serology supervisor (technical supervisor #3), the laboratory failed to follow their procedure in reviewing the effectiveness of corrective action taken to resolve problems in the laboratory in the analytic systems as evidenced by: 1. In review of the laboratory's procedures IBL CLIA QA Plan Version 5.0 states under Corrective Action, "IBL staff monitor testing quality controls to identify errors and problems. For each significant problem found, a Quality Improvement Report (QIR) will be completed, the supervisor is notified, the problem is reviewed, and corrective actions are implemented. All non-conforming event will be reviewed to determine the effectiveness of the corrective action and take additional action if indicated." 2. In review of the maintenance records for EZ1 in June 10-17 2025, the EZ1 was not in use due to trouble shooting. In an email dated June 13, 2025 at 313 pm from the Serology supervisor (technical supervisor #3) stated, "until it can be serviced as there are risks for it to stop completely in mid extraction process and compromise the sample quality." The laboratory failed to provide documentation of the EZ1 service engineer's visit to resolve the issue. 3. In review of the the maintenance records for Cobas 5800 system revealed a instrument service on March 14, 2025 by a Cobas Engineer. In an email to the Serology supervisor on March 11,2025 at 1110am (technical supervisor #3) stated, "The cobas experienced a hardware error during weekly instrument preparation, I called support and am trying on getting them the

	incident report off the instrument..." 4. In review of the laboratory's corrective action system "My_QIR", No QIR reports were available to review the effectiveness of correction action taken for both Cobas 5800 system, March 14, 2025 non-conforming event and the EZ1 June 10-17, 2025, non-conforming event. 5. In interview with the Serology supervisor (technical supervisor #3) at 1120am on December 3,2025 she confirmed that her section need to do better in entering them in the QIR system and then getting the non-conforming events reviewed. 6. In interview with the Laboratory Director at 1220 pm on December 3, 2025 stated that if staff has questions if it non-conforming event should go in the QIR, then the answer is yes all event must be entered.