Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0711426	06/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Idaho National Laboratory -Wcb	Willow Creek Building, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) record review and an interview with the technical consultant, the laboratory director and the testing personnel failed to sign the College of American Pathologists (CAP) attestation statements for the complete blood counts (CBCs) performed during 2019 events 1 and 2. Findings: 1. A review of PT documents revealed the laboratory director and the testing person failed to sign the CAP attestation statements for the CBCs performed during events 1 and 2 in 2019. 2. An interview with the technical consultant on June 24, 2019 at 4:05 PM, confirmed the laboratory director and testing person failed to sign the CAP attestation statements in 2019.
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 record review and an interview with the technical consultant, the laboratory failed to verify the accuracy of microscopic urine sediment examinations at least twice annually since June 2018. Findings: 1. A record review of proficiency testing from the College of American Pathologists and laboratory documents, revealed the laboratory failed to document the accuracy of microscopic urine sediment analysis at least semiannually since the start of patient testing in June 2018. 2. The laboratory performed approximately 150 urine sediment examinations since June 2018. 3. An interview with the technical consultant on June 24, 2019 at 6:45 PM, confirmed the laboratory failed to document the accuracy of urine sediment exams at least semiannually.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant, the laboratory failed to state the acceptable refrigerator and room temperature ranges on the laboratory worksheet to record daily temperatures since June 29, 2019. Findings: 1. A review of laboratory documents revealed the laboratory failed to state the acceptable temperature ranges on the chart for the refrigerator where complete blood count quality control material was stored and the room temperature where patient specimens were tested. 2. A review of the temperature log worksheet revealed the laboratory failed to monitor and record the daily room temperature of the laboratory since the start of patient testing on June 29, 2018. 3. An interview with the technical consultant on June 24, 2019 at 6:45 PM, confirmed the laboratory failed to indicate the acceptable temperature ranges on the worksheet and record the daily room temperatures.
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 a review of quality control records, a review of patient test reports, and an interview with the technical consultant, the laboratory failed to test at least 2 levels of quality control materials for complete blood counts (CBCs) performed on the Emerald Cell-Dyn for each day of patient testing between February 28, 2019 and March 11, 2019. Findings: 1. A review of the quality control records for the Emerald Cell-Dyn hematology analyzer revealed the laboratory failed to test at least 2 levels of quality control materials each day of patient testing between February 28 and March 11, 2019. 2. A review of patient CBC reports between February 28 and March 11, 2019, revealed 7 patient CBC test results were reported. 3. An interview with the technical consultant on June 24, 2019 at 7:00 PM, confirmed the laboratory failed to test at least 2 levels of quality control materials prior to performing tests on patient specimens.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on an observation, a record review, and an interview with the technical consultant, the laboratory failed to identify and document corrective actions for the broken liquid column in the thermometer used to monitor the refrigerator temperature where quality control material for the Emerald Cell-Dyn hematology analyzer was stored. Findings: 1. An observation on June 24, 2019 at 6:30 PM, revealed 1 thermometer inside the laboratory refrigerator where quality control testing material was stored, which the liquid column was separated into several pieces. 2. A review of laboratory records revealed the laboratory staff failed to identify and document the corrective actions for the broken thermometer. 3. An interview with the technical consultant on June 24, 2019 at 6:45 PM, confirmed the laboratory staff failed to identify the broken thermometer and continued to use the thermometer for daily recordings.
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. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on record reviews and interviews with the technical consultant, the laboratory failed to establish and follow a written procedure or policy for a system to monitor,

	identify, and correct problems in the hematology test system since June 29, 2018. Findings: 1. A review of laboratory records and an observation revealed the laboratory failed to identify and document corrective actions for the broken liquid column in the thermometer used to monitor the refrigerator temperature where quality control material for the Emerald Cell-Dyn was stored. Refer to D5781. 2. A review of the quality control records for the Emerald Cell-Dyn hematology analyzer revealed the laboratory failed to test at least 2 levels of quality control materials each day of patient testing between February 28 and March 11, 2019. Refer to D5445. 3. A review of quality control records between March 11, 2019 and April 15, 2019, revealed the laboratory staff failed to identify and document corrective actions when the low level control failed to meet the manufacturer's acceptability ranges for 13 out of 19 days of patient testing. 4. An interview with the technical consultant on June 24, 2019 at 7:05 PM, confirmed the laboratory staff failed to monitor, identify, and document corrective actions when problems with the test system occurred.
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 record reviews and an interview with the technical consultant, the laboratory director failed to assure the quality assessment activities for the laboratory were maintained to identify failures in the test system since June 29, 2018. Findings: 1. A review of the quality control records for the Emerald Cell-Dyn hematology analyzer revealed the laboratory failed to test at least 2 levels of quality control materials each day of patient testing between February 28 and March 11, 2019. Refer to D5445. 2. Based on record reviews and interviews with the technical consultant, the laboratory failed to establish and follow a written procedure or policy for a system to monitor, identify, and correct problems in the hematology test system since June 29, 2018. Refer to D5445, D5781 and D5791. 3. An interview with the technical consultant on June 24, 2019 at 7:05 PM, confirmed the laboratory failed to establish a system to monitor the quality assessment activities for the laboratory.