Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0665090	06/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Idaho National Laboratory - Cfa	Central Facilities Area (Cfa), 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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on an observation, a proficiency testing (PT) review, and an interview with the technical consultant, the laboratory failed to test 5 out 5 complete blood counts (CBC) proficiency samples from the College of American Pathologists (CAP) in the same manner as it tests patient samples for the 2019 event 1 and 2 programs. Findings: 1. An observation on June 24, 2019 at 1:30 PM of the Emerald Cell-Dyn revealed the laboratory had 7 testing personnel perform the tests on the 5 samples 3 times on February 7, 2019, 2 times on February 8, 2019, and 2 times on February 9, 2019. 2. A review of the Cell-Dyn analyzer PT results reports revealed the laboratory failed to test the 5 samples in the same manner as the laboratory tests patient samples by performing the tests by different personnel on 3 consecutive days. 3. An interview with the technical consultant on June 24, 2019 at 1:30 PM, confirmed the laboratory had multiple testing personnel test the 5 samples over 3 days.
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: D2015 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 2:05 PM, confirmed the laboratory director and testing person failed to sign the CAP attestation statements in 2019.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on instrument quality control record reviews, patient reviews, and an interview with the technical consultant, the laboratory failed to retain the Emerald Cell-Dyn complete blood count (CBC) manufacturer's quality control assay reference sheets prior to June 2019 and failed to retain the CBC quality control data from March 7, 2019 through June 3, 2019. Findings: 1. A review of quality control records from the Emerald Cell-Dyn analyzer revealed the laboratory failed to retain the manufacturer's quality control assay reference sheets prior to the current lot number 9070 in use on June 3, 2019. 2. A review of the quality control test results from the Emerald Cell-Dyn analyzer revealed the laboratory failed to retain quality control test results from March 7, 2019 through June 3, 2019. 3. The laboratory performed approximately 250 CBC between March and June 2019. 4. An interview with the technical consultant on June 24, 2019 at 2:30 PM, confirmed the laboratory failed to retain the quality control assay reference sheets and the quality control test records.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on an observation, a procedure review, and an interview with the technical consultant, the laboratory failed to follow the written policy to ensure positive identification of patient's blood and urine specimens on June 24, 2019. Findings: 1. An observation on June 24, 2019 at 12:45 PM, of the laboratory, revealed 4 out of 4

	patient complete blood count specimens failed to be labeled with the patient's name, 'S' number, date, time, and the collector's initials on the label. 2. An observation on June 24, 2019 at 12:45 PM, of the laboratory, revealed 1 out of 1 patient's urine specimen failed to be labeled. 3. A review of the procedure manual revealed the laboratory failed to follow the written procedure to label the patient's specimens with the patient's name, 'S' number, date, time, and the collector's initials on the label. 4. An interview with the technical consultant on June 24, 2019 at 2:10 PM, confirmed the laboratory failed to follow their procedure for labeling specimens.
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 200 urine sediment examinations since June 2018. 3. An interview with the technical consultant on June 24, 2019 at 11:45 AM, 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 and failed to record the daily temperature for the refrigerator and the laboratory room where quality control material for the Emerald Cell-Dyn complete blood counts (CBCs) were stored and patient specimens tested since the start of patient testing on June 29, 2018. Findings: 1. A review of the temperature log worksheet revealed the laboratory failed to state the acceptable temperature ranges on the chart for the refrigerator where CBC 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 record the daily temperatures for the refrigerator for 15 out of 24 days in February 2019. 3. 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. 4. An interview with the technical consultant on June 24, 2019 at 1:45 PM, confirmed the laboratory failed to state the acceptable temperature ranges on the worksheet and record the 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 (CBC) performed on the Emerald Cell-Dyn for each day of patient testing between February 19, 2019 and February 28, 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 19 and February 28, 2019. 2. A review of patient CBC reports between February 19, 2019 and February 28, 2019, revealed 30 patients were reported. 3. An interview with the technical consultant on June 24, 2019 at 2:30 PM, confirmed the laboratory failed to test at least 2 levels of quality control materials prior to performing tests on patient specimens.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met. This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant, the laboratory failed to identify and document corrective actions for temperatures that were out of range for the refrigerator where Cell-Dyn quality control material for complete blood counts (CBCs) were stored since June 2018. Findings: 1. A review of the laboratory refrigerator temperature chart for February 2019, March 2019, and May 2019, revealed the temperature was recorded at -1C and 0C for 5 out of 10 days in February, 7 out of 15 days in March, and 15 out of 15 days in May. 2. A review of the Cell-Dyn manufacturer's storage requirements revealed quality control material should be stored between 2C and 8C. 3. A review of laboratory records revealed the laboratory testing personnel failed to identify and document corrective actions for the temperatures documented below the acceptable range from the manufacturer. 4. An

	interview with the technical consultant on June 24, 2019 at 2:00 PM, confirmed the laboratory staff failed to correct and document the corrective actions for the refrigerator temperature.
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 supervisor, 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 record review of the refrigerator temperature chart where quality control material for complete blood count tests were stored, revealed the laboratory staff failed to identify and document corrective actions for temperature problems with the refrigerator. Refer to D5785. 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 19 and February 28, 2019. Refer to D5445. 3. A review of quality control charts between January 3, 2019 and February 14, 2019, revealed the laboratory staff failed to document corrective actions when level 1 control was tested: 10 times on January 3, 2019, 5 times on January 14, 2019, 12 times on February 4, 2019, and 11 times on February 14, 2019. 4. An interview with the technical supervisor on June 24, 2019 at 2:45 PM, confirmed the laboratory staff failed to monitor, identify, and document corrective actions when problems with the test system occurred.
D6022	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 and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record reviews and an interview with the laboratory director, the laboratory director failed 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 19 and February 28, 2019. Refer to D5445. 2. Based on record reviews and interviews with the technical supervisor, 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 D5791. 3. A record review of the refrigerator temperature chart where quality control material for complete blood count tests were stored, revealed the laboratory

	staff failed to identify and document corrective actions for temperature problems with the refrigerator. Refer to D5785. 4. 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. Refer to D5217. 5. An interview on with the laboratory director on June 24, 2019 at 2:55 PM, confirmed that the laboratory failed to identify and correct failures in the test systems.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical consultant, the laboratory director failed to specify in writing, the responsibilities and duties of the technical consultant and each person engaged in the preanalytic, analytic, and post analytic phases of testing since the start of patient testing on June 29, 2018. Findings: 1. A review of the CMS-209 Personnel Report form and competency records revealed the laboratory director failed to specify in writing the responsibilities and duties of the technical consultant and the testing personnel engaged in patient testing. 2. An interview with the technical consultant on June 24, 2019 at 1:45 PM, confirmed the laboratory director failed to specify in writing the responsibilities for the technical consultant and the testing personnel.