Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	13D0711424	06/24/2019
Name of Provider or Supplier	**Street Address, City, State**	
Idaho National Laboratory - Mfc	Materials & Fuels Complex (Mfc), 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 proficiency testing (PT) record review and an interview with the technical consultant, the laboratory director and the testing person failed to sign the College of American Pathologists (CAP) attestation statements and failed to maintain instrument copies for 5 out of 5 complete blood counts (CBCs)sample test results performed during the 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 for events 1 and 2 in 2019. 2. A review of PT documents revealed the laboratory failed to maintain the Emerald Cell-Dyn instrument test results for 5 out of 5 PT samples. 3. 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 and failed to maintain instrument test results.
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 quality control record reviews and an interview with the technical consultant, the laboratory failed to retain the Emerald Cell-Dyn complete blood count (CBC) quality control test results and the manufacturer's quality control assay reference sheets from January 2019 through April 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 May 2019. 2. A review of the quality control test results from the Emerald Cell-Dyn analyzer revealed the laboratory failed to retain the quality control test results from the analyzer between January 2019 and April 2019. 3. The laboratory performed approximately 830 CBC since June 29, 2018. 4. An interview with the technical consultant on June 24, 2019 at 4:30 PM, confirmed the laboratory failed to retain the quality control assay reference sheets and the quality control test records.
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 temperature range for the refrigerator on the laboratory worksheet for the where the quality control material for the Emerald Cell-Dyn complete blood counts (CBCs) were stored, as well as the room temperature where patient specimens were 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 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 4:45 PM, confirmed the laboratory failed to indicate the acceptable temperature ranges on the worksheet and record the temperatures.
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 an interview 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 quality control test results for the Emerald Cell-Dyn revealed the laboratory staff failed to document corrective actions when the low level control was tested 5 times on May 28, 2019 and the high control was tested 9 times on May 29, 2019. 2. A review of the quality control test records from the Emerald Cell-Dyn analyzer revealed the laboratory failed to monitor and identify problems with quality control test results between January 2019 and May 2019. Refer to D3031. 3. An interview with the technical consultant on June 24, 2019 at 4:45 PM, confirmed the laboratory staff failed to monitor and identify problems, as well as, 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 a record review and an interview with the technical consultant, the laboratory director failed to ensure a quality assessment program was established to monitor, identify, and correct problems with the hematology test system since June 29, 2018. Refer to D3031, D5791 and D2015. Findings: 1. A review of the quality assessment activities for the laboratory revealed the laboratory failed to have a system to review and document problems with monitoring, identifying, and documenting problems with quality control testing, retention of documents, and proficiency testing. 2. An interview with the technical consultant on June 24, 2019 at 4:45 PM, confirmed the laboratory failed to establish a system to monitor the quality assessment activities for the laboratory.