

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  13D0711424	<b>(X3) Date Survey Completed</b>  07/14/2021
<b>Name of Provider or Supplier</b>  Idaho National Laboratory - Mfc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5447</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g)</p> <p>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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a random record review of quality control (QC) documentation and an interview with the technical consultant (TC) on 7/14/2021, the laboratory failed to successfully perform two levels of QC daily for each quantitative test. The findings include: 1. A random record review of QC from the Cell-Dyn Emerald CBC analyzer identified that the laboratory failed to have acceptable results for two of three levels of QC performed for platelet counts on 3/24/2021. The laboratory performed and released two patient complete blood count (CBC) test which include a platelet count on 3/24/2021. 2. An interview with the TC on 7/14/2021 confirmed that the laboratory failed to have two acceptable levels of QC for platelet counts on 3/24/2021.</p>