

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D1086344	<b>(X3) Date Survey Completed</b>  07/26/2018
<b>Name of Provider or Supplier</b>  Colfax Oncology Llc	<b>Street Address, City, State</b>  680 Broadway, Paterson, NJ	
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>D2015</b>	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Supervisor (TS), the laboratory failed to maintain all PT records for Hematology tests performed with the College of American Pathologists (CAP) in 2018. The finding includes: 1. The laboratory did not have the attestation page and work records for PT results in event FH2-A 2018. 2. The TS confirmed on 7/26/18 at 10:00 am that all PT records were not maintained.</p>
<b>D5417</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>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.</p>

	<p>This STANDARD is not met as evidenced by:  Based on surveyor observation of Reagents, Quality Control (QC) material and interview with the Technical Supervisor (TS), the laboratory failed to discard expired QC reagents used for Flow Cytometry setup on the Becton Dickinson (BD) FacsCanto II from 1/1/18 to 6/20/18. The findings include: 1. The BD Set Up Beads expired on 12/31/17 but the laboratory used them until 6/20/18. 2. BD FacsCanto II setup failed during the above time period but the laboratory ran approximately 5-9 patients per week. 3. The TS confirmed on 7/26/18 at 1:20 pm that the laboratory used expired QC.</p>
<p><b>D5429</b></p>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b>  CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p> <p>This STANDARD is not met as evidenced by:  Based on surveyor review of the Maintenance Records (MR) and interview with the Technical Supervisor (TS), the laboratory failed to perform and document preventative maintenance as specified by the manufacturer on the Becton Dickinson (BD) FacsCanto II analyzer used for Flow Cytometry tests from August 2016 to the date of the survey. The TS confirmed on 7/26/18 at 2:15 pm that preventative maintenance as specified by the manufacturer was not performed.</p>
<p><b>D6086</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b>  CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by:  Based on surveyor review of the Performance Specification (PS) records and interview with the Technical Supervisor (TS) the Laboratory Director failed to ensure that PS were adequate to perform Hematology testing on the Horriba ABX - Micros 60 from February 2018 to the date of survey. The finding includes: 1. A review of the PS revealed the laboratory did not evaluate linearity for the automated differential components. 2. The TS confirmed on 7/26/18 at 12:10 pm that the LD did not ensure the PS were adequate.</p>