

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2004557	<b>(X3) Date Survey Completed</b>  05/19/2020
<b>Name of Provider or Supplier</b>  Comprehensive Hematology Oncology, Llc	<b>Street Address, City, State</b>  5000 Park St N Ste 1017 North, Saint Petersburg, FL	
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>D0000</b>	An announced CLIA recertification survey was conducted at Comprehensive Hematology Oncology LLC on 05/19/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D5481</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(f)(g)</p> <p>(f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Technical Consultant and Testing Person #A the laboratory failed to ensure controls were acceptable prior to reporting patients for 3 days (09/25/18, 09/27/18, and 09/28/18) out of 4 months reviewed (March 2020, November 2019, April 2019, and September 2018) in the specialty of Hematology. Findings Included: Review of manufacturer's instructions for the Beckman Coulter AcT diff hematology analyzer revealed that when the instrument flagged with an "X" it "Indicates that one of the multiple Aperture Alert criteria was not met." When this flag occurs the action is "1. Thoroughly mix and rerun the sample. 2. If flag does not repeat, report results. 3. If flag repeats, clean the aperture as instructed in heading 6.3. 4. If after cleaning, problem persists, contact your Beckman Coulter Representative." Review of Low, Normal, and High controls on the Hematology analyzer for 09/25/18, 09/27/18, and 09/28/18 revealed a "X" for white blood cell count (WBC), Lymphocyte %, Monocyte%, Granulocyte%, Lymphocyte#, Monocyte#, and Granulocyte#. On 09/25/18 the high and normal control were ran once each with "X" on WBC, Lymphocyte %, Monocyte%, Granulocyte%, Lymphocyte#, Monocyte#, and Granulocyte#. On 09/27/18 the low and high controls were ran once each with "X" on WBC, Lymphocyte %, Monocyte%, Granulocyte%,</p>

Lymphocyte#, Monocyte#, and Granulocyte#, and normal was ran twice with "X" on all WBC, Lymphocyte %, Monocyte%, Granulocyte%, Lymphocyte#, Monocyte#, and Granulocyte#. On 09/28/18 the low, normal, and high controls were ran twice each with "X" on WBC, Lymphocyte %, Monocyte%, Granulocyte%, Lymphocyte#, Monocyte#, and Granulocyte#. A review of the daily activity sheet revealed "Valid QC" for 09/25/18, "Good" for 09/27/18, and "Hgb lowerside changed cal. factor-good." for 09/28/18. No additional corrective action was documented. Interview on 05/19/20 at 1:55 PM with the Technical Consultant confirmed that QC was not ran per manufacturer's instruction. Interview on 05/19/20 at 2:30 PM with Testing Person #A confirmed that there were 15 patients reported on 09/25/18, 25 patients reported on 09/27/18, and 7 patients reported on 09/28/18.