

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0946520	<b>(X3) Date Survey Completed</b> 08/25/2022
<b>Name of Provider or Supplier</b> Alliance Cancer Specialists Hem Onc Assoc Div	<b>Street Address, City, State</b> 30 Medical Center Blvd, Upland, PA	
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>D5433</b>	<p><b>MAINTENANCE AND FUNCTION CHECKS</b> CFR(s): 493.1254(b)(1)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory and interview with the testing personnel (TP) #1, the laboratory failed to establish a maintenance policy to assess the maintenance /function for 1 of 1 HLTHLG Room Temperature (RT) thermometer used to monitor the temperature of reagents used on the Beckman Coulter AcT Diff 2 hematology analyzer from 07/16/2020 to the day of survey. Findings Include: 1. On the day of survey, 08/25/2022 at 11:07 AM, the surveyor observed 1 of 1 HLTHLG RT thermometer in use to monitor the temperatures of reagents used on the Beckman Coulter AcT Diff 2 hematology analyzer from 07/16/2020 to 08/25/2022. 2. The following reagents were found to be stored at room temperature at the time of inspection. 3 of 3 Beckman Coulter Diff AcT PAK Lot- 112270K, Expiration date- 2023/02/15. 3. The laboratory could not provide a maintenance policy for the thermometers. 4. TP #1 confirmed the findings above on 08/25/2022 around 11:20 AM. 5. This is a repeated deficiency based on the last inspection on 07/16/2020.</p>