

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 39D0946520	<b>(X3) Date Survey Completed</b> 07/16/2020
<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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory competency assessment policy and interview with testing personnel (TP) #1 and #2, the laboratory failed to follow their policy to assess the competency 5 of 6 clinical consultants (CC) from 2018 to 2020. Findings include: 1. The Standard Operating Procedure, Laboratory Competency Assessment Policy, point #5 states "staff that hold CLIA supervisors positions (general supervisor, technical consultant, technical supervisor, or clinical consultant), will be assessed annually for their supervisory competence in addition to laboratory testing competency if performing any lab testing". 1. On the day of survey, 07/16/2020, the laboratory could not the provide the competency assessments performed on 5 of 6 CC in 2018, 2019 and 2020. 3. TP #1 and #2 confirmed the findings above on 07/16/2020 around 10:15 am.</p>
<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>

This STANDARD is not met as evidenced by:

Based on observation of the laboratory and interview with the testing personnel (TP) #1 and #2, the laboratory failed to establish a maintenance policy to assess the maintenance/function for 2 of 2 unlabelled thermometers used to monitor the temperature of reagents used on the Beckman Coulter AcT diff 2 hematology analyzer from 2018 to the day of survey. Findings Include: 1. On the day of survey, 07/16/2020, the surveyor observed 1 of 1 unlabeled refrigerator thermometer and 1 of 1 unlabelled room temperature thermometer in use to monitor the temperatures of reagents used on the Beckman Coulter AcT diff 2 hematology analyzer from 01/22/2018 to 07/16/2020. 2. The laboratory could not provide a maintenance policy for the thermometers. 3. TP #1 and #2 confirmed the findings above on 07/16/2020 around 11:00 am.