

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0194456	(X3) Date Survey Completed 10/06/2021
Name of Provider or Supplier Alliance Cancer Specialists	Street Address, City, State 201 Gibraltar Rd, Horsham, PA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES 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 laboratory procedure manuals and interview with the Technical Supervisor (TS)#2, the laboratory failed to establish a complete competency assessment procedure to assess the competency of 1 of 2 Technical supervisors, 1 of 1 Technical Consultant (TC), and 1 of 1 General Supervisor (GS) for 2019, 2020 and 2021. Findings Include: 1. On the day of survey, 10/06/2021, the laboratory could not provide a written procedure to assess the competency of 1 of 2 TS (CMS 209 personnel #2), 1 of 1 TC, and 1 of 1 GS for Hematology patient testing from 10/06/2019 to 10/06/2021. 2. The TS#2 confirmed the finding above on 10/06/2021 around 10:45 a.m.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS 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 observation of the laboratory and interview with the Technical Supervisor (TS) #2, the laboratory failed to establish a maintenance policy to assess the maintenance/function for 1 of 1 unlabeled thermometer used to monitor the</p>

temperature for the refrigerator use for the storage of quality controls (QC) for the Sysmex XN450 analyzer and 1 of 1 Thermo Fisher Scientific digital thermometer for room temperature in hematology for 2019, 2020 and 2021. Findings Include: 1. On the day of survey, 10/06/2021, the laboratory could not provide a maintenance policy for the thermometers. 2. The laboratory could not provide maintenance records for 1 of 1 unlabeled thermometer used to store quality control materials for the Sysmex XN450 analyzer. 3. An expiration date of 03/28/2016 was observed on the sticker posted on the Thermo Fisher Scientific digital thermometer for room temperature. 4. TS #2 confirmed the findings above on 10/06/2021 at 11:25 a.m.

D6091

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(4)(iii)

The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action.

This STANDARD is not met as evidenced by:
Based on the review of American Proficiency Institute (API) proficiency testing (PT) scores and interview with the Technical supervisor (TS)#2, the laboratory failed to identify problems that required a corrective action for API PT results for Segmented Neutrophil in 2020. Findings Include: 1. On the day of survey, 10/06/2021, review of API 2020 proficiency Testing revealed: Segmented Neutrophil - Event # 3 - score of 80%. 2. The laboratory director acknowledged the score of 80% with their signature, but no assessment was made. 3. The TS#2 confirmed the findings above on 10/06/2021 at 10:25 a.m.