

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0988200	(X3) Date Survey Completed 10/17/2023
Name of Provider or Supplier Alliance Cancer Specialists	Street Address, City, State 700 Horizon Circle Suite 106, Chalfont, 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
D3037	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4)</p> <p>Proficiency testing records. Retain all proficiency testing records for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview with Testing Personnel (TP) #1, the laboratory failed to provide 1 of 6 API PT events from 11/09/2021 to the day of survey. Findings include: 1. On the day of survey, 10/17/2023 at 10:25 am, the laboratory could not provide the API Hematology/coagulation records for the 3rd event in 2021. 2. During an interview on 10/17/2023 at 10:30 am, TP#1 stated that the laboratory discarded the records.</p>
D5783	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) records and interview with testing personnel (TP)#1, the laboratory failed to provide documentation of the corrective actions taken for QC results that failed to meet the laboratory's established acceptable criteria for hematology testing performed from 12/06/2021 to 12/07/2021.</p>

Findings Included: 1. On the day of survey, 10/17/2023 at 11:30 am, review of the laboratory's QC records revealed that the following QC results for hematology testing performed on the Beckman Coulter Act Diff 2 failed to meet the laboratory's established acceptable criteria: - 12/06/2021 High level control: - Red blood cell Level result: 4.92, acceptable range: (4.95- 5.55) - 12/07/2021 High level control: - Red blood cell Level result: 4.92, acceptable range: (4.95- 5.55) 2. The laboratory could not provide documentation of the corrective actions taken for QC performed on the Beckman Coulter Act Diff 2 that did not meet the laboratory's established acceptable criteria on 12/06/2021 and 12/07/2021. 3. TP #1 confirmed the findings above on 10/17/2023 at 12:10 pm.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES
CFR(s): 493.1413(b)(8)

(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:
Based on review of the Laboratory Personnel Report (CMS-209), the laboratory's technical consultant duties and responsibilities, competency assessment records and interview with Testing Personnel (TP)#1, the Technical Consultant (TC) failed to evaluate the competency of 3 of 7 TP who performed hematology testing in 2022 and 2023. Findings include: 1. On the day of survey 10/17/2023 at 10:00 am, review of CMS-209 and the laboratory's competency assessment records revealed the TC failed to evaluate the competency of 3 of 7 TP (CMS 209 personnel #5, #7 and #8) who performed complete blood cell counts(CBC) on the Beckman Coulter Act Diff 2 in 2022 and 2023. 2. A former employee who was not qualified under 493.1411 performed the competency assessment of 3 of 7 TP in 2022 and 2023. 3. Futher review of personnel credentials provided on the date of survey revealed the former employee has a High School diploma. 4. TC duties and responsibilities signed by the laboratory director on 10/18/2022 states (page 1, point 8): " TC is responsible for evaluating the competency assesment of all testing personnel" 5. TP #1 confirmed the findings above on 10/17/2023 around 12:30 pm.