

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0196896	(X3) Date Survey Completed 08/21/2019
Name of Provider or Supplier Alliance Cancer Spec - Hem Onc	Street Address, City, State 33 Chester Pike, Ridley Park, 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
D3029	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(2)</p> <p>Test procedures. Retain a copy of each test procedure for at least 2 years after a procedure has been discontinued. Each test procedure must include the dates of initial use and discontinuance.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedure manuals and interview with laboratory supervisor, the laboratory failed to retain 1 of 1 differential smear examination procedure manual for 2 years after discontinuation on December of 2018. Findings include: 1. On the day of survey, 08/21/2019, the laboratory could not provide 1 of 1 differential smear examination procedure manual discontinued December of 2018. 2. The laboratory supervisor confirmed the finding above on 08/21/2019 around 10:12 am.</p>
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 laboratory supervisor, the laboratory failed to establish a complete competency assessment procedure to assess the competency of 2 of 2 clinical consultants from 09/28/2017 to the date of survey. Findings Include: 1. On the day of survey, 08/21/2019, the laboratory could not provide a written procedure to assess the competency of 2 of 2</p>

clinical consultants for complete blood patient testing from 09/28/2017 to 08/21/2019.
2. The laboratory supervisor confirmed the finding above on 08/21/2019 around 09:21 am.

D6051

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

The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples.

This STANDARD is not met as evidenced by:
Based on the review of testing personnel (TP) competency assessment records, proficiency testing (PT) records and interview with the laboratory supervisor, the technical consultant (laboratory director) failed to assess the competency of all (5 of 6) TP through internal blind testing samples or external PT samples for complete blood count (CBC) testing in 2018. Findings Include: 1. On the day of survey, 08/21 /2019, review of TP competency assessment records and PT records revealed the laboratory did not assess test performance of TP through internal blind testing samples or external PT samples for 5 of 6 TP in 2018 for CBC testing performed on the Beckman Coulter AcT Diff 2 . 2. The laboratory supervisor confirmed the finding above on 08/21/2019 around 9:43 am.