

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0199453	(X3) Date Survey Completed 09/16/2020
Name of Provider or Supplier Cancer Center At Center One	Street Address, City, State 9880 Bustleton Ave, Philadelphia, 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 the American Association of Bioanalysts (AAB) proficiency testing (PT) records and interview with the General Supervisor (GS), the Laboratory Director (LD) failed to provide 1 of 3 Hematology AAB PT attestation statement document from 2019. Findings include: 1. On the day of survey, 09/16/2020, the GS could not provide the 2019 Hematology Event 3 attestation statement. 2. The GS confirmed the finding above on 09/16/2020 at 10:00 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 competency policy and interview with the General Supervisor (GS), the laboratory failed to follow their policy for the assessment of 1 of 2 Clinical Consultant and 1 of 1 General Supervisor (on the CMS 209 form, listed as personnel #2 and #3) for their supervisory responsibilities involved for hematology testing from 05/22/2018 to the date of inspection. Findings include: 1. The Competency Policy states "Staff who hold CLIA Supervisor positions: (General supervisor, Technical Consultant, Technical Supervisor, or Clinical Consultant), will be assessed annually, for their supervisory competence in addition to laboratory</p>

testing competence, if performing any lab testing". 2. On the day of survey, 09/16/2020, the GS, could not provide a complete policy that reviews how to assess the competency for 1 of 2 Clinical Consultant (personnel #2) and 1 of 1 General Supervisor (personnel #3) for their supervisory responsibilities in 2018, 2019, and 2020. 3. The GS confirmed the finding above on 09/16/2020 around 09:35 am.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on American Association of Bioanalysts (AAB) proficiency testing (PT) records, review of Handling of proficiency surveys policy, and interview with the General Supervisor (GS), the Laboratory Director's (LD) failed to identify problems that required a corrective action for the Hematology 2018 3rd event Findings include:

1. The Handling of Proficiency Surveys policy states in point 5 "Results of proficiency testing are reviewed by supervisor and director".
2. The Handling of Proficiency Surveys policy states in point 6 "Corrective action reports are submitted to director for review and discussion".
3. On the date of survey, 09/16/2020, the review of PT records revealed, 2018 AAB Hematology- 3rd event did not have a plan of correction for Platelets. The laboratory received a 80% score.
4. The GS confirmed the findings above on 09/16/2020 at 10:05 am.