

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0708828	(X3) Date Survey Completed 03/06/2019
Name of Provider or Supplier Hematology Oncology Physicians Of Englewood, Pa	Street Address, City, State 350 Engle Street Berrie Building 5th Floor, Englewood, NJ	
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 surveyor review of the Competency Assessment (CA) records and interview with the Technical Consultant (TC), the laboratory failed to perform CA correctly on three of three Testing Personnel in the calendar years 2017 and 2018. The finding includes: 1. The CA did not include monitoring the recording and reporting of results in 2018. 2. CA was not performed in the calendar year 2017. 3. The TC confirmed on 3/6/19 at 10:30 am that CA was not done correctly.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Technical Consultant (TC), the laboratory failed to review and evaluate PT results obtained from Medical Laboratory Evaluators (MLE) for Hematology events performed in 2018. The findings include: 1. There was no evaluation documented when the laboratory received Not graded - Educational Challenge (see participant summary) for Blood Cell Identification as follows: a. MLE - M1 sample BC-6 b.</p>

MLE - M2 sample BC-12 c. MLE - ML3 sample BC-18 2. The TC confirmed on 3/6/19 at 11:45 am that the laboratory did not review and evaluate all PT results.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

Based on surveyor observation of the Quality Control (QC) material and interview with the Technical Consultant (TC), the laboratory failed to put expiration dates on QC material for Hematology tests at the time of the survey. The findings include: 1. The expiration date of control material shortens once opened. 2. The laboratory did not put new expiration dates on the Coulter 4C controls in use. 3. The TC confirmed on 3/6/19 at 10:10 am the laboratory failed to put expiration dates on the control material.

D5787

TEST RECORDS
CFR(s): 493.1283(a)

The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s).

This STANDARD is not met as evidenced by:

Based on surveyor review of the Accession Log (AL) and interview with the Technical Consultant (TC), the laboratory failed to maintain an accurate AL to ensure positive Identification (ID) of patients in the calendar year 2018. The finding includes: 1. A review of 50 patient entries in the AL revealed 33 did not have both a first and last name or other patient identifier. 2. Two patients were identified with two letters of their name. 3. The TC confirmed on 3/6/19 at 12:00 pm that the laboratory did not maintain an accurate AL.