

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2037524	(X3) Date Survey Completed 07/27/2018
Name of Provider or Supplier Penn Medicine Hematology/Oncology	Street Address, City, State 200 Bowman Drive, Voorhees, 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 Supervisor (TS), the laboratory failed to perform a CA on two out of three Testing Personnel (TP) and TS annually. The finding includes: 1. Two TP's had last CA done on 2/21/17. 2. There was no CA done on TS. 3. The TS confirmed on 7/27/18 at 1:05 pm that the CA was not performed annually.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory failed to follow calibration procedures at the time of survey. The finding includes: 1. The calibration procedure stated to calibrate hematology analyzer every six months but the last two calibrations on AcT</p>

Diff 2 analyzer was performed in July 2017 and June 2018 which was 11 months apart. 2. The TS confirmed on 7/27/18 at 1:30 pm that the laboratory did not perform calibration every six months.

D5791

ANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1289(a)(c)

(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:
Based on the surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory failed to establish hematology instruments correlation policy at the time of survey. The TS confirmed on 7/27/18 at 11:30 am the laboratory did not establish above mention policy.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Final Report (FR) and interview with the Technical Supervisor (TS), the laboratory failed to ensure that the Test Report Date (TRD) was indicated on the FR from the initiation of electronic medical records to the date of survey. The TS confirmed on 6/27/18 at 1:30 pm that the TRD was not on the FR.

D5891

POSTANALYTIC SYSTEMS QUALITY ASSESSMENT
CFR(s): 493.1299(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.

This STANDARD is not met as evidenced by:
Based on surveyor review of the Procedure Manual (PM) and interview with the Technical Supervisor (TS), the laboratory failed to have a procedure to verify manually entered results into electronic medical records at the time of survey. The TS confirmed on 7/27/18 at 1:15 pm that the laboratory did not have the procedure mention above.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on surveyor review of the Personnel Files and interview with the Technical Supervisor (TS), the Laboratory Director failed to specify in writing the list of job responsibilities for TS on the day of survey. The TS confirmed on 7/27/18 at 11:30 am that TS job duties and responsibilities were not documented.