Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D1079088	(X3) Date Survey Completed 04/03/2018
Name of Provider or Supplier Penn Medicine Hematology/Oncology Sewell	**Street Address, City, State** 239 Hurffville -Cross Keys Road, Sewell, 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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to maintain attestation statement for 2-2017 PT event with American Proficiency Institute at the time of survey. The TP # 3 listed on CMS form 209 confirmed on 4/3/18 at 10:45 am that all PT records were not maintained.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by:

	Based on the review Competency Assessment (CA) records and interview with the Technical Supervisor (TS), the laboratory failed to perform a CA on the TS for the calendar years 2016 and 2017 at the time of survey. The TS confirmed on 4/3/18 at 10: 05 am that the CA was not performed.
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 surveyor review of the Proficiency Testing (PT) records and interview with the Testing Personnel (TP), the laboratory failed to evaluate coded results obtained in 2016 and 2017 for Hematology/Coagulation events with the American Proficiency Institute (API) at the time of survey. The finding includes: 1) The laboratory did not evaluate Grade 6 (educational challenge) on sample BCI - 06 and 07 obtained from API for 1-2016 and three of three events in 2017. 2) The TP # 3 listed on CMS form 209 confirmed on 4/3/18 at 12:00 pm that the laboratory failed to evaluate coded results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) 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. This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to follow "Levey-Jennings Chart Policy"" procedure at the time of survey. The finding includes: 1. The PM stated to perform a "weekly check of the Sysmex quality control to make sure no shifts or trends are occurring" there was no documented evidence that it was performed. 2. The TP # 3 listed on CMS form 209 confirmed on 4/3/18 at 10:45 am that PM was not followed.
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 Testing Personnel (TP),), the laboratory failed to put new expiration dates on

	Hematology controls at the time of survey. The findings include. 1) The expiration date of control material shortens once opened. 2) The laboratory did not put open and new expiration dates on e-Check (XS) controls Lot# 80160804, 80160805, and 801060806 in use. 3) The TP # 3 listed on CMS form 209 confirmed on 4/3/18 at 11" 01 am the laboratory failed to put new expiration dates on the control material
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor review of the Calibration Verification records and interview with the Testing Personnel (TP), the Laboratory Director (LD) failed to ensure the Quality Control (QC) Program for Hematology tests performed on the Sysmex XS-1000i analyzer was maintained on 1/15/2018 at the time of survey. The finding includes: 1. Review of the Certificate of Calibration Verification (CCV) revealed there was no review to determine if results of the CCV were acceptable when performed on 1/15 /18. 2. The TP #3 listed on CMS form 209 confirmed on 4/3/18 at 10:00 am that the LD did not ensure the QC program was maintained.