Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0944420	03/05/2018
Name of Provider or Supplier	**Street Address, City, State**	
Oncology & Hematology Specialists Pa	100 Madison Avenue Suite C3402, Morristown, 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	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 surveyor review of the Competency Assessment (CA) records and interview with the Nurse Manager (NM), the laboratory failed to perform CA correctly on nine out of nine Testing Personnel (TP) from 2/29/16 to the date of survey. The findings include: 1. The laboratory did not document when testing personnel were observed, what records were reviewed and how assessment was done. 2. Assessment of problem solving skills was not documented on CA for nine out of nine TP. 3. The NM confirmed on 3/5/18 at 10:20 am that the CA procedure was not performed correctly.
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 Nurse Manager (NM), the laboratory failed to follow its calibration procedure for the Beckman Act 2 Diff in the calendar year 2017. The finding includes: 1. The PM stated calibration must be done every six months but the laboratory had no documentation of

	calibration after March 3, 2017 in the calendar year 2017. 2. The NM confirmed on 3/5 /18 at 11:00 am that the PM was not followed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Final Report, Performance Specification records and interview with the Nurse Manager (NM), the laboratory failed to report patient test results accurately when test results were above the assay detectable limit for platelet tests performed on the Beckman Act 2 Diff from 2/29/16 to the date of survey. The findings include: 1. The laboratory reported a platelet value of 1291 on 2/15/18 and the FR also had 1221 (previous result) which were above the laboratory's linearity limit of 999. 2. The laboratory routinely reported values above or below the linearity limit when applicable. 2. The NM confirmed on 3/5/18 at 11:50 am that the laboratory reported values above the linearity limit.