Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0115429	(X3) Date Survey Completed 02/13/2018
Name of Provider or Supplier Oncology & Hematology Specialists Pa	**Street Address, City, State** 333 Route 46 West, Mountain Lakes, 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 Laboratory Director (LD), the laboratory failed to perform CA correctly on six out of six Testing Personnel (TP) from 1/6/16 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 six out of six TP. 3. The TP #6 listed on CMS form 209 performing Flow Cytometry did not have a CA performed. 4. The LD confirmed on 2/13/18 at 12:50 pm that the CA procedure was not performed correctly.
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 Performance Specifications (PS) records and interview with the Laboratory Director (LD), the laboratory failed to verify accuracy and precision on Hematology tests performed on the Beckman AcT 5 Differential (Diff) analyzer before reporting patient test results from June 2017 to the date of survey. The LD confirmed on 2/13/18 at 1:50 pm PS were not done.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on lack of Maintenance Records (MR) and interview with the Laboratory Director (LD), the laboratory failed to establish a maintenance protocol for the Rotonta 460 Centrifuge from 8/20/15 to the date of survey. The LD confirmed on 2/13 /18 at 1:00 pm that a Centrifuge maintenance protocol was not established.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on surveyor review of the Laboratory Records and interview with the Laboratory Director (LD), the laboratory failed to perform Correlation studies for Complete Blood Count (CBC) performed on the Beckman AcT 5 Differential (Diff) analyzers twice per year in the calendar year 2017. The finding includes: 1. Instrument Correlation was performed on 6/28/17 but there was no documented evidence it was performed again at the time of the survey. 2. The LD confirmed on 2 /13/18 at 2:40 pm that the laboratory did not perform a Correlation study twice a year.
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 Laboratory Director (LD), the laboratory failed to ensure that the location of the laboratory where tests were performed was on the FR from June 2017 to the date of survey. The LD confirmed 2/13/18 at 2:20 pm that the FR did not indicate the laboratory location.
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 Final Report (FR), Panic Values (PV) found in the procedure manual and interview with the Laboratory Director (LD) the laboratory failed to correct problems in the postanalytic system when the test results were flagged as a PV but the result did not agree with established PV from 1/6/16 to the date of the survey. The findings include: 1. The FR revealed that White Blood Cell Count and Lymphocyte number were reported out as a PV but the laboratory did not define a PV for the above parameters. 2. The LD confirmed on 2/13/18 at 2:00 pm that PV flagging was incorrect on the TR. This was cited on previous survey performed on 1/6/16.