Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0944420	02/20/2020
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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on surveyor review of patient work records, Manufacture Operator Manual (OM) and interview with the Clinical Consultant (CC), the laboratory failed to follow the OM for Hematology testing performed on the Beckman Coulter Act 2 from 5/16 /19 to the date of survey. The findings include: 1. The OM stated patient results with X flags (Aperture Alert. A problem was detected during counting that could compromise the integrity of the results.) The sample must be mixed thoroughly and rerun. 2. Four out of 50 patient work records reviewed had X flags but the laboratory did not rerun any samples. 3. The CC confirmed on 2/20/20 at 10:40 am the laboratory failed to follow the OM.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the

	laboratory's patient population. This STANDARD is not met as evidenced by: Based on surveyor review of the Quality Control (QC) records and interview with the Clinical Consultant (CC), the laboratory failed to take and document Corrective Action (CA) taken when Hematology calibration run on the Beckman Coulter Act 2 analyzer was unacceptable for 3/19/19 to 11/20/19. The findings include: 1. There was no documented evidence of CA taken when Hematology calibration run on 3/19/19 had ten out of ten White Blood Cell (WBC) results flagged "X" Aperture alert. 2. WBC calibration was adjusted based on inaccurate WBC results. 3. Approximately twenty patients were run per day. 4. The CC confirmed on 2/20/20 at 10:45 am that CA was not taken for flagged calibration results.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on an surveyors review of the laboratory's records, procedures and interview with the Clinical Consultant (CC), the Laboratory Director (LD) failed to provide overall management and direction to the laboratory to ensure that laboratory testing is performed satisfactorily and in compliance with the CLIA regulations from 3/19/19 to 11/20/19. 1. The LD failed to ensure the Manufacture Operator Manual was followed. Cross Refer to 5411 2. The LD failed to ensure that corrective action was taken for flagged calibration results. Cross Refer to 5781. 3. The LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for Hematology tests. Cross Refer to 6023
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) 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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on surveyor review of the Hematology records and interview with the Clinical Consultant (CC) the Laboratory Director (LD) failed to ensure the establishment and maintenance of acceptable levels of analytical performance for Hematology tests performed on the Beckman Coulter Act 2 from 3/19/19 until 11/20/19. The findings include: 1) There was no corrective action performed when White Blood Cell calibration results were flagged "X" (aperture alert.) 2) Calibration was adjusted based on inaccurate White Blood Cell results. 3) The laboratory failed to follow the Manufacture Operator Manual when patient results flagged "X" (aperture alert.) 4)

	The laboratory ran and reported approximately 20 patients per day. 5) The CC confirmed on 2/20/20 at 11:00 am the LD failed to ensure the establishment and maintenance of acceptable levels of analytical performance for Hematology tests.