Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D1100090	12/20/2023
Name of Provider or Supplier	**Street Address, City, State**	
Hematology Oncology Consultants Llc	2110 Oak Tree Road, Edison, 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
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. 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 review and evaluate results when they received an unacceptable score in Hematology/Coagulation tests performed with the American Proficiency Institute (API), for 2nd event 2022. The findings include: 1. The laboratory received an unacceptable score for Granulocytes sample HEM-06. 2. There was no documented evidence that the laboratory documented corrective action. 3. The TP confirmed on 12/20/23 at 12:20 pm that the laboratory did not review and document an evaluation of unacceptable PT results.
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 analyzer calibration records, review of the Manufacture Operator Manual (OM) and interview with the Testing Personnel (TP), the laboratory failed to follow the OM for Hematology testing performed on the Cell-Dyn Emerald in the calendar years 2022 and 2023. The findings include: 1. The OM Section 6 Calibration, Calibration Guidelines states "5. When a minimum of five successful runs

	are completed review data." 2. There was no documented evidence that calibration was run five times successfully every six months in the calendar years 2022 and 2023. 3. The OM appendix E, worksheet E.1, pre-calibration procedure checklist, states "7. Verify instrument precision." 4. There was no documented evidence that precision was verified prior to running calibration material in the calendar year 2022. 5. The TP confirmed on 12/20/23 at 11:40 am the laboratory failed to follow the OM.
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 surveyor review of the Procedure Manual (PM) and interview with Testing Personnel (TP) the laboratory failed to establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems from on the date of survey. The finding includes: 1. The laboratory failed to have a Quality Control Verification (QVC) procedure that stated how to verify new lots of controls before they were put in use. 2. The TP confirmed on 12/20/23 at 11:40 am that the laboratory failed to have the aforementioned procedure.