Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0271526	04/01/2022
Name of Provider or Supplier	**Street Address, City, State**	
Emerald Coast Oncology And Hematology	1024 Mar Walt Dr, Fort Walton Beach, FL	

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
D0000	A recertification survey was conducted on March 8, 2022 and continued through April 1, 2022 to gather additional documentation. Emerald Coast Oncology and Hematology, a clinical laboratory, was not in compliance with 42 CFR 493, Requirements for Laboratories.
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 record review and interview with Testing Personnel (TP) #A, the laboratory failed to have the proficiency testing attestation sheet signed by the laboratory director and testing personnel for the first testing event of 2020. Findings included: Record review of attestation sheets revealed the form for the first testing event in 2020 had not been signed by the laboratory director or the testing personnel. Interview on 3/08 /2022 at 1530 with TP #A confirmed the attestation sheet had not been signed by the laboratory director or the testing personnel.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(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 general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel (TP) #A, the laboratory failed to establish and follow a written quality assessment policy. Findings included: Review of laboratory records revealed there was no quality assessment policy. Interview with TP #A on 3/08/2022 at 1530 confirmed the laboratory did not have a quality assessment policy in place.