Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0271526	04/03/2020
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	An announced CLIA recertification survey was conducted at Emerald Coast Oncology And Hematology Associates PA on April 3, 2020. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of CMS 209- Laboratory Personnel Report, review of American Academy of Family Physicians (AAFP) proficiency testing, and interview with the Laboratory Staff, the laboratory failed to have all testing people to rotate through the testing of proficiency testing for 1 of 1 year (2019) reviewed. Findings Included: Review of the CMS 209 (signed and dated by the Laboratory Director 03/30/20) had 8 testing people listed (#2 - #9). Review of AAFP proficiency testing found that Testing Person #2 was the only person who performed the proficiency testing in 2019. Interview with the Laboratory Manager on 04/03/20 at 11:00 AM confirmed that Testing Person #2 was the only person performing proficiency testing even though Testing Person #2 - #9 all performed patient testing.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's

	instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory failed to monitor the room temperature and humidity of the laboratory for 2 of 2 years (2018-2020) reviewed. Findings included: Review of the maintenance logs showed no room temperature and humidity were recorded from 2018 through 2020. Review of the instrument manual of the Complete Blood Count (CBC) Analyzer, Coulter Act Diff revealed that the environmental conditions of the equipment needed a maintenance of a room temperature between 16 degrees Celsius to 35 degrees Celsius and a humidity no higher than 85 %. Interview with Laboratory Manager at 1:00 PM confirmed that the room temperature and humidity of the laboratory were not documented.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory staff, the laboratory director failed to approve and sign the Policies and Procedures of the laboratory for 2 of 2 years (2018-2020) reviewed. Findings included: Review of the Policies and Procedures of the laboratory showed that signature and approval of the laboratory director were missing from 2018 through 2020. Interview with Laboratory Manager at 11:30 AM confirmed that the laboratory director did not approve and sign the Policies and Procedures of the laboratory.