

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0271526	(X3) Date Survey Completed 08/24/2026
Name of Provider or Supplier Emerald Coast Oncology And Hematology	Street Address, City, State 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 08/21/2026-08/24/2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5200 493.1230 Condition: GENERAL LABORATORY SYSTEMS D6000 493.1403 Condition: MODERATE COMPLEXITY LABORATORY DIRECTOR
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on record review of Proficiency Testing (PT) and interview, the Laboratory Director (LD) failed to ensure attestation forms were signed for the specialty of Hematology in four of six (2025-1st, 2nd, 3rd, 2024-3rd) events reviewed, by Testing Personnel (TP). Findings Include: 1. Review of the CMS-209 Personnel Report listed 8 TP (TP #A, TP #B, TP #C, TP #D, TP #E, TP #F, TP #G, TP #F). 2. Review of Wisconsin State Laboratory Hygeine University of Wisconsin Madison (WLSH) Proficiency Testing records from 2024-2026 revealed the attached attestations to 2024 HemeReg 3rd Event, 2025 HemeReg 1st Event, 2025 HemeReg 2nd Event, 2025 HemeReg 3rd Event were missing signatures by TP or LD. 3. Interview with the Lab Manager (LM) on 08/21/2026 at 3:15 PM confirmed that the LD had failed to ensure attestation signatures.
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230

	Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review of Proficiency Testing (PT), and interview, the Laboratory Director (LD) failed to ensure PT evaluations were reviewed for the specialty of Hematology for three of six (2025-1st, 2nd, 3rd) events. (See D5211)
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on record review of Proficiency Testing (PT), and interview, the Laboratory Director (LD) failed to ensure PT evaluations were reviewed for the specialty of Hematology for three of six (2025-1st, 2nd, 3rd) events. This is a repeat deficiency from 05/22/2024 recertification survey. Findings Include: 1. In review of the submitted Plan of Correction signed by the Laboratory Director on 06/28/2024, it is stated that "From here on out the LD will sign and date all proficiency results...as well as ensure the review of Proficiency Testing." 2. Review of Wisconsin State Laboratory Hygiene University of Wisconsin Madison (WLSH) PT revealed the LD failed to ensure Proficiency Evaluations were completed for the specialty of Hematology for the 1st, 2nd, and 3rd Events in 2025. 3. Interview with the Lab Manager (LM) at 3:15 PM on 08/21/2026 confirmed the LD did not complete PT Evaluations for the three events in 2025.
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 record review of Proficiency Testing (PT), and interview, the Laboratory Director failed to monitor four of six (2024- 3rd , 2025- 1st, 2nd, 3rd) PT events reviewed. (See D6004)
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on record review of Proficiency Testing (PT), and interview, the Laboratory Director (LD) failed to monitor four of six (2024- 3rd , 2025- 1st, 2nd, 3rd) PT events reviewed. This is a repeat deficiency from recertification survey on 05/22/2024. Findings Include: 1. In review of the Plan of Correction submitted on 06/28/2024, it is stated, "From now on, the Lab Director will delegate management of Proficiency Testing to the General Supervisor, but will retain the responsibility of verifying all testing, reporting, and patient results in the clinical lab setting." No delegation was found during survey on 08/21/2026. 2. Review of Wisconsin State Laboratory Hygiene University of Wisconsin Madison (WLSH) PT revealed missing signatures for LD PT Evaluations for three of six (2025- 1st, 2nd, 3rd) events, Testing Personnel (TP) Attestation signatures for four of six (2024-3rd, 2025- 1st, 2nd, 3rd) events, Raw Data of PT materials missing for two of six (2024-3rd, 2025-3rd) events, and Submission of results for two of six (2024-3rd, 2025- 2nd) events reviewed. 3. Interview with the Laboratory Manager (LM) at 3:15 PM on 08/21/2026 confirmed missing signatures and documents.

D6005

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(c)

(c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that are part of the laboratory director responsibilities.

This STANDARD is not met as evidenced by:
Based on record review and and interview, the Laboratory Director (LD) failed to establish a policy to be onsite at least once every six months, with at least 4 months between the minimum two on-site visits and documenting the onsite visits during the year 2025 until 8/21/2026. Findings included: 1. Review of the procedure manual signed by the LD on 01/2/2026 revealed that it did not have policy to specify when the LD must be onsite and document the bi-annual visits. 2. During interview on 08/21 /2026 at approximately 3:15 PM, the Laboratory Manager confirmed there was no policy to monitor the LD visits to the laboratory.