

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0271526	<b>(X3) Date Survey Completed</b>  05/22/2024
<b>Name of Provider or Supplier</b>  Emerald Coast Oncology And Hematology	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Emerald Coast Oncology and Hematology Associates PA on 5/22/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6000-Laboratory Director-493.1403 D6063-Testing Personnel -493.1421
<b>D5211</b>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of review of Proficiency Testing (PT) records, interview, the Laboratory Director failed to sign Proficiency Evaluation forms for PT for the speciality of Hematology for six of six ( 2022-2nd, 3rd, 2023-1st, 2nd, 3rd, and 2024-1st) events reviewed. Findings: Review of American Academy of Family Physicians (AAFP) records for 2022 and Wisconsin State Laboratory of Hygiene (WSLH) records for 2023-2024 showed there was no Proficiency Evaluation signed by the Laboratory Director. On 05/22/2024 at 11:30 AM, Testing Personnel C confirmed there were no Proficiency Evaluations reviewed by the Laboratory Director .</p>
<b>D6000</b>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on record review and interview, the Laboratory Director failed to provide overall management and direction of the laboratory for two of two years reviewed (2022-2024). Findings: The Laboratory Director failed to provide effective direction over the laboratory for two of two years reviewed (2022-2024). (See D6004) The Laboratory Director failed ensure Proficiency Evaluations were reviewed by him for PT for the speciality of Hematology for six of six ( 2022-2nd, 3rd, 2023-1st, 2nd, 3rd, and 2024-1st) events. (See D5211) The Laboratory Director (Technical Consultant ) failed to ensure evaluation of competency for testing personnel listed on the Laboratory Personnel Report for 6 of 7 testing personnel (B, C, D, E, F, and G) for two of two years reviewed (2022-2024). (See D6046) The Laboratory Director failed to ensure education qualifications were verified for 2 Testing Personnel (TP E and TP F) out of 7 Testing Personnel (TP A-TP-G). (See D6063)

**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 reappoints 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 and interview, the Laboratory Director failed to provide effective direction over the laboratory for two of two years reviewed (2022-2024). Findings: The Laboratory Director failed ensure Proficiency Evaluations were reviewed by him for PT for the speciality of Hematology for six of six ( 2022-2nd, 3rd, 2023-1st, 2nd, 3rd, and 2024-1st) events. (See D5211) The Laboratory Director (Technical Consultant ) failed to ensure evaluate competency of testing personnel listed on the Laboratory Personnel Report for 6 of 7 testing personnel (B, C, D, E, F, and G) for two of two years reviewed (2022-2024). (See D6046) The Laboratory Director failed to ensure education qualifications were verified for 2 Testing Personnel (TP E and TP F) out of 7 Testing Personnel (TP A-TP-G). (See D6063)

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

	<p>Based on record review and interview, the Laboratory Director failed to ensure Testing Personnel (TP) had education verified prior to reporting patient results for 2 (TP E and TP F) out of 7 Testing Personnel (A-G). Findings: See D6065.</p>
<p><b>D6046</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency evaluations, and interview, the Technical Consultant (Laboratory Director) failed to evaluate competency of testing personnel listed on the Laboratory Personnel Report for 6 of 7 testing personnel (B, C, D, E, F, and G) for two of two years reviewed (2022-2024). Findings: Review of the Laboratory Personnel Report signed by the Laboratory Director on 05/22/2024 showed there were 6 testing personnel other than himself. The Laboratory Director was also listed as Clinical Consultant and Technical Consultant. Review of initial, semi-annual, and annual competency evaluations for Testing Personnel B to G performed from 6/2022 to 5/2024 showed they were signed by Testing Personnel B or Testing Personnel C. On 05/22/2024 at 10:30 AM Testing Personnel B and C stated they performed and signed all competency evaluations from 6/2022 to 5/2024.</p>
<p><b>D6063</b></p>	<p><b>LABORATORY TESTING PERSONNEL</b> CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Laboratory Personnel Report, personal records, and interview, the laboratory failed to verify the education qualifications for 2 Testing Personnel (TP E and TP F) out of 7 Testing Personnel (TP A-TP-G). (See 6065)</p>
<p><b>D6065</b></p>	<p><b>TESTING PERSONNEL QUALIFICATIONS</b> CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p>

This STANDARD is not met as evidenced by:

Based on review of the Laboratory Personnel Report, personnel records and interview, the laboratory failed to verify the educational qualifications for 2 Testing Personnel (TP E and TP F) of 7 Testing Personnel (TP A-TP G). Findings: Review of the Laboratory Personnel Report, signed by the Laboratory Director 05/22/2024 showed there were 7 laboratory staff listed as moderate complexity testing personnel. Review of the laboratory personnel records showed there was no documentation of education for TP E and TP F available for review. On 05/22/2024 at 10:30 AM TP C confirmed there was no education available for review for TP E and TP F. On 05/22/2024 at 1:30 PM the Laboratory Director/Technical Consultant confirmed the lack of educational documentation for TP E and TP F.