Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2031405	11/28/2022
Name of Provider or Supplier	**Street Address, City, State**	
Emerald Coast Rheumatology	3890 Jenks Ave, Lynn Haven, 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 Rheumatology on November 28, 2022. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D6076 - Laboratory Director 493.1441 D6168 - Testing Personnel 493.1487
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to document Quality Assessment (QA) activities. Findings include: Record review on November 28, 2022 at 10:30 a.m., revealed no documented QA activities for 2020 and 2021. Interview with laboratory staff on November 28, 2022 at 11:00 a.m., confirmed QA activities had not been documented.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:

	Based on observation and interview, the laboratory failed to dispose of expired reagents from the laboratory refrigerator. Findings include: Observation on November 28, 2022 at 11:00 a.m., revealed expired reagents in the laboratory refrigerator: 1. Six unopened bottles of Chromogen - lot number 02193264 had an expiration date of 3/27 /2022. 2. One unopened bottle of Chromogen - lot number 05193465 had an expiration date of 2/28/2022. 3. Two unopened bottles of ANCA anti-IgG Conjugate - lot number 04214877 had an expiration date of 4/06/2022 and lot number 12204672 had an expiration date of 12/07/2021. Interview with laboratory staff on November 28, 2022 at 11:00 a.m., confirmed the reagents in the laboratory refrigerator were expired.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to provide overall management and direction by ensuring the testing personnel were qualified to perform high complexity testing. Refer to D6171 and D6101.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) The laboratory director must employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to employ testing personnel with the appropriate education and experience/training to perform high complexity testing. Refer to D6171
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of personnel records, the CMS-209 Personnel Report (CLIA), and interview with staff, the laboratory failed to employ testing personnel who meet the qualification requirements to perform high complexity testing. Refer to D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry 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; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

	This STANDARD is not met as evidenced by: Based on review of personnel records, the CMS-209 Personnel Report (CLIA), and interview with Testing Personnel (TP) #A, the laboratory failed to ensure 3 of 3 (#A, #B, #C) Testing Personnel were qualified to perform high complexity testing. Findings include: Review of personnel records on November 28, 2022 at 11:15 a.m., revealed: TP #A has a high school diploma and college transcripts listed 3 college credits in Human Biology, 1 college credit in Human Biology Lab, and 1 college credit in General Chemistry I Lab, which does not meet the requirements for high complexity testing. TP #B has a high school diploma. TP #C has a high school diploma. The CMS-209 Personnel Report (CLIA) signed and dated by the Laboratory Director on October 25, 2022 listed 3 Testing Personnel for high complexity testing. Review of the Clinical Laboratory Improvement Amendments (CLIA) Application for Certification signed and dated by the Laboratory Director on October 25, 2022, showed an estimated annual test volume of 10,000. The tests performed were Rheumatoid Factor (RF3), Anti-Citrullinated Cyclic Peptide (CCP), Anti-Thyroid Peroxidase Antibodies (TPO), Anti-Thyroglobulin Antibodies (Thyg Ab), Anti-Myeloperoxidase (MPO), Anti-Proteinase - 3 Antibodies (PR3), Beta-2 Glycoprotein, Anti-Cardiolipin Antibodies (ACL), Anti-Nuclear Antibodies (ANA 10), Vitamin D, and Mycobacterium (TBGP). Interview on November 28, 2022 at 9:15 a.m., TP #A stated, "I do not have an Associates Degree. When the previous qualified TP left the laboratory, the Laboratory Director asked if she wanted to run the lab for him." Interview with TP #A on November 28, 2022 at 11:15 a.m., confirmed the 3 TP were not qualified to perform high complexity testing.