

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2310026	(X3) Date Survey Completed 01/06/2025
Name of Provider or Supplier Coastal Gastroenterology Associates	Street Address, City, State 1015 W Medical Center Blvd, Ste 1400, Webster, TX	
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 initial onsite survey was performed completed on 01/06/2025. The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the laboratory's Grossing logs, patient final reports, and confirmed in an interview, the laboratory failed to include the address of the laboratory where patient samples were grossed in 3 of 3 patient final reports reviewed. The findings were: 1. Random review of the laboratory's Grossing logs revealed 3 patient samples were grossed by the testing personnel#1 at the address of the laboratory. 2. Review of the laboratory's patient final reports revealed the laboratory failed to include the address of the laboratory where patient samples were grossed in 3 of 3 patient final reports reviewed. 12/11/2024 Accession#: AM24-767 12/11/2024 Accession#: AM24-768 12/11/2024 Accession#: AM24-769 3. An interview on 01/06/2025 at 1:13 pm in the lab, the Operations Manager confirmed the above findings.</p>

D6143

GENERAL SUPERVISOR QUALIFICATIONS

CFR(s): 493.1461

(a) The general supervisor must possess a current license issued by the State in which the laboratory is located, if such licensing is required; and (b) The general supervisor must be qualified as a-- (b)(1) Laboratory director under 493.1443; or (b)(2) Technical supervisor under 493.1449. (c) If the requirements of paragraph (b)(1) or (2) of this section are not met, the individual functioning as the general supervisor must-- (c)(1)(i) 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, biological, clinical or medical laboratory science, or medical technology from an accredited institution; and (c)(1)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing; or (c)(2)(i) Qualify as testing personnel under 493.1489(b)(3); and (c)(2)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing; or (c)(3) Meet the requirements at 493.1443(b)(3) or 493.1449(c)(4) or (5); or (c)(4) Notwithstanding any other provision of this section, an individual is considered qualified as a general supervisor under this section if they were qualified and serving as a general supervisor in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (d) For blood gas analysis, the individual providing general supervision must-- (d)(1) Be qualified under 493.1461(b)(1) or (2), or 493.1461(c); or (d)(2)(i) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; and (d)(2)(ii) Have at least one year of laboratory training or experience, or both, in blood gas analysis; or (d)(3) (i) Have earned an associate degree related to pulmonary function from an accredited institution; and (d)(3)(ii) Have at least two years of training or experience, or both in blood gas analysis. (e) The general supervisor requirement is met in histopathology, oral pathology, dermatopathology, and ophthalmic pathology because all tests and examinations, must be performed: (e)(1) In histopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (f)(1); (e)(2) In dermatopathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(2); (e)(3) In ophthalmic pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or 493.1449(f)(3); and (e)(4) In oral pathology, by an individual who is qualified as a technical supervisor under 493.1449(b) or (g).

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's CMS 209, the laboratory's records, and confirmed in an interview, the laboratory failed to document the TS review within 24 hours for all physical examinations/description, including color, weight, measurement and other characteristics of the tissues; or other mechanical procedures for 3 of 3 patient final reports reviewed. The findings were: 1. An interview on 01/06/2025 at 1: 10 pm in the lab, the Operations Manager confirmed the testing personnel performed grossing including inking. 2. Review of CMS 209 Laboratory Personnel Report (CLIA), provided by the laboratory on 01/06/2025, revealed TP#1 is not qualified as a TS. 3. Review of the laboratory's records revealed no documentation of TS review of grossing within 24 hours. 4. An interview on 01/06/2025 at 1:13 pm in the lab, the Operations Manager confirmed the above findings. Key: TS=Technical supervisor TP=Testing personnel CMS=Centers for Medicare and Medicaid

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 the review of the laboratory's submitted CMS 209, testing personnel credential records, and confirmed in an interview, the laboratory failed to have documentation of qualification for 1 of 2 TP performing high complexity testing. (Refer to 6171)

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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's submitted CMS 209, testing personnel

credential records, the laboratory's grossing logs, and confirmed in an interview, the laboratory failed to meet TP requirements or qualifications for 1 of 2 TP performing high complexity testing. The findings were: 1. Review of the laboratory's submitted CMS 209, Laboratory Personnel Report (CLIA), provided by the Laboratory on 01/06/2025, revealed the laboratory identified 2 TP who performed high complexity testing. 2. Review of the laboratory's TP educational credential records revealed the laboratory failed to meet TP requirements or qualifications for 1 of 2 TP performing high complexity testing. TP#2 Hired Date: 12/23/2024 3. Review of the laboratory's grossing logs revealed TP#2 grossed 13 patient samples on 12/20/2024. 12/20/2024 Accession#: AM24-00783 12/20/2024 Accession#: AM24-00785 12/20/2024 Accession#: AM24-00786 12/20/2024 Accession#: AM24-00787 12/20/2024 Accession#: AM24-00788 12/20/2024 Accession#: AM24-00789 12/20/2024 Accession#: AM24-00791 12/20/2024 Accession#: AM24-00792 12/20/2024 Accession#: AM24-00793 12/20/2024 Accession#: AM24-00794 12/20/2024 Accession#: AM24-00796 12/20/2024 Accession#: AM24-00797 12/20/2024 Accession#: AM24-00782 3. An interview on 01/06/2025 at 12:54 pm in the lab, the Operations Manager confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TP=Testing personnel