

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2314241	<b>(X3) Date Survey Completed</b> 03/21/2025
<b>Name of Provider or Supplier</b> Gastroenterology Associates, Llc-Dr Zeid Karadsheh	<b>Street Address, City, State</b> 600 Kobayashi Rd Ste 114, Webster, TX	
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 initial onsite survey was performed completed on 03/18/2025. 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;
<b>D6079</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(a)(b)</p> <p>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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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.</p> <p>This STANDARD is not met as evidenced by: Based on the review of CMS Report 209 Laboratory Personnel Report, personnel records, and confirmed in an interview, the Laboratory director failed to ensure 1 of 2 testing personnel met the minimum education requirements for performing high complexity testing in histopathology. Refer to D6171.</p>
<b>D6127</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(9)</p> <p>(b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests</p>

patient specimens.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's CMS 209 Laboratory Personnel Report, testing personnel initial training records, grossing logs from 01/17/2025 to 03/17/2025, and confirmed in an interview, the Technical Supervisor failed to perform initial training for 1 of 1 testing personnel performing high complexity testing. The findings were: 1. Review of CMS 209 form Laboratory Personnel Report (CLIA) revealed the laboratory identified 1 testing person for high complexity testing. 2. Further review of CMS 209 form Laboratory Personnel Report (CLIA) revealed the laboratory director was also the technical supervisor. 3. Review of the laboratory's personnel records revealed the technical supervisor failed to perform initial training for 1 of 1 testing personnel performing high complexity testing. Testing personnel #1 hire date: 01/30/2025 4. Review the laboratory's grossing logs from 01/17/2025 to 03/17/2025 revealed total of 59 cases grossed by TP#1. 01/31/2025 TP#1 grossed 11 cases 03/10/2025 TP#1 grossed 16 cases 03/12/2025 TP#1 grossed 15 cases 03/17/2025 TP#1 grossed 17 cases 5. An interview on 03/08/2025 at 10:53 am in the lab, the operation manager confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services

**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 form 209, the laboratory's personnel records, and confirmed in an interview, the laboratory failed to provide qualifying documentation for 1 of 2 TP to perform high complexity testing. (Refer to 6171) Key: CMS=Center for Medicare and Medicaid Services TP=Testing Personnel

**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 from 01/17/2025 to 03/17/2025, and confirmed in an interview, the laboratory failed to provide documentation to qualify 1 of 2 testing personnel to perform high complexity testing. The findings were: 1. Review of the laboratory's submitted CMS 209, Laboratory Personnel Report (CLIA), signed by the Laboratory Director on 03/16/2025, 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 provide documentation to qualify 1 of 2 testing persons to perform high complexity testing. TP#2 Hired Date: 01/20/2025 3. Review of the laboratory's grossing logs from 01/17/2025 to 03/17/2025 revealed total of 174 cases grossed by TP#2. 01/17/2025 TP#2 grossed 9 cases 01/24/2025 TP#2 grossed 11 cases 01/28/2025 TP#2 grossed 14 cases 02/04/2025 TP#2 grossed 17 cases 02/07/2025 TP#2 grossed 13 cases 02/11/2025 TP#2 grossed 15 cases 02/14/2025 TP#2 grossed 18 cases 02/18/2025 TP#2 grossed 17 cases 02/21/2025 TP#2 grossed 18 cases 02/28/2025 TP#2 grossed 29 cases 03/07/2025 TP#2 grossed 13 cases 4. An interview on 03/18/2025 at 10:50 am in the lab, the Operations Manager confirmed the above findings. Key: CMS=Center of Medicare and Medicaid Services TP=Testing personnel