

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2280547	<b>(X3) Date Survey Completed</b> 08/22/2025
<b>Name of Provider or Supplier</b> Gastrodoxs Pllc	<b>Street Address, City, State</b> 23920 Katy Freeway, Ste 560, Katy, 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>	The laboratory was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493 CLIA requirements. The conditions not met were: D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel;
<b>D5805</b>	<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 a random review of the laboratory's grossing logs from April to July 2025, patient's test reports, and staff interview, the laboratory failed to include the correct date that the patient's tissue was grossed for four of four patient's test reports reviewed. Findings include: 1. A random review of the laboratory's grossing logs from April to July 2025 revealed the laboratory grossed the following 4 patient's tissue specimens: Patient ID: BP-25-001634 grossed: 4/21/25 Patient ID: BP-25-001747 grossed: 5/3/25 Patient ID: BP-25-002062 grossed: 6/9/25 Patient ID: BP-25-002407 grossed: 7/15/25 2. A review of the patient's test reports revealed the laboratory failed to include the correct date that the patient's tissue was grossed for the 4 patients: Patient ID: BP-25-001634 grossed: 4/21/25 Test report indicated grossing was performed on 5/1/25 Patient ID: BP-25-001747 grossed: 5/3/25 Test report indicated</p>

	<p>grossing was performed on 5/15/25 Patient ID: BP-25-002062 grossed: 6/9/25 Test report indicated grossing was performed on 6/23/25 Patient ID: BP-25-002407 grossed: 7/15/25 Test report indicated grossing was performed on 8/4/25 3. In an interview on 8/22/25 at 11:05 a.m. in the office, after review of the records, the operations manager confirmed the above findings.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on a review of the laboratory's records, the laboratory's personnel records, and staff interview, the laboratory director failed to provide overall management of the laboratory for one of one high complexity test- grossing of patient's tissue specimens from April to August 2025. Findings include: 1. The laboratory director failed to ensure one of two testing personnel had 3 months of documented laboratory training prior to grossing patient's tissue specimens. (Refer to D6102)</p>
<p><b>D6102</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(12)</p> <p>(e)(12) 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;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory director failed to ensure one of two testing personnel had three months of documented laboratory training in histopathology prior to grossing patient's tissue specimens from April to August 2025. Findings include: 1. A review of the laboratory's submitted CMS 209 form and the laboratory's personnel records revealed the laboratory identified 2 testing personnel performing grossing on patient's tissue specimens. 2. Further review of the laboratory's personnel records revealed the laboratory failed to have 3 months of documented training in histopathology prior to grossing patient's tissue specimens in April 2025. 3. In an interview on 8/22/25 at 10:35 a.m. in the office, after review of the records, the operations manager confirmed the above findings.</p>
<p><b>D6168</b></p>	<p><b>TESTING PERSONNEL</b> CFR(s): 493.1487</p> <p>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.</p> <p>This CONDITION is not met as evidenced by:</p>

Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to have three months of documented laboratory training for one of two testing personnel to perform high complexity testing- grossing of patient's tissue specimens from April to August 2025. (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 (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 a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, the laboratory failed to ensure one of two testing personnel met the requirements to perform high complexity testing- grossing of patient's tissue specimens from April to August 2025. Findings include: 1. A review of the laboratory's submitted CMS-209 form listed 2 testing personnel performing high complexity testing- grossing of patient's tissue specimens. 2. A review of the laboratory's personnel records revealed the laboratory failed to have 3 months of documented laboratory training in histopathology for testing person #1. 3.

In an interview on 8/22/25 at 10:30 a.m. in the office, after review of the records, the operations manager confirmed the above findings.