

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2309681	<b>(X3) Date Survey Completed</b> 03/20/2025
<b>Name of Provider or Supplier</b> Houston Gastroenterology Associates	<b>Street Address, City, State</b> 21316 Provincial Blvd, 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>	An announced survey of the laboratory was conducted on 03/20/2025. The laboratory was found out of compliance with the CLIA regulations (42 CFR Part 493, Requirements for Laboratories). 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>D5407</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's policies/procedures, patient test records and staff interview, the laboratory failed to ensure its policies/procedures were approved, signed and dated by the laboratory director prior to being placed into use for one of one test performed by the laboratory in 2024 and 2025, grossing of histology samples. Findings included: 1. Review of laboratory's policies/procedures revealed the "Standard Operating Procedure Manual" was signed and approved by laboratory director on 02/21/2025. 2. Review of laboratory's patient test records revealed patient testing started on 11/12/2024. 3. In an interview on 03/20/2021 at 1100 hours in the laboratory, the laboratory's Operations Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.</p>
<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</p>

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.

This STANDARD is not met as evidenced by:  
Based on review of laboratory's patient test reports and staff interview, the laboratory failed to ensure the name and address of the testing laboratory was included on the patient's final report for eleven of eleven final reports reviewed for the one test performed by the laboratory in 2024 and 2025, grossing of histology samples. Findings included: 1. Review of eleven random patient test reports from November 2024 and February 2025 revealed the laboratory's final reports did not include the name or address of the testing facility where grossing of histology samples was performed. Reviewed reports included reports for the following patients: Date tested: 11/12/2024 Patient MRN: 191708 188539 191710 191707 191715 82657 35751 82647 Date tested: 02/21/2025 Patient MRN: 194373 194158 194375 2. In an interview on 03/20/2021 at 1205 hours in the laboratory, the laboratory's Operations Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings. Key: MRN = Medical Record Number

**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 review of laboratory's personnel records, policies/procedures, patient test records and staff interview, the Laboratory Director failed to provide overall direction of the laboratory for one of one test performed by the laboratory in 2024 and 2025, grossing of histology samples. Findings included: 1. Laboratory Director failed to ensure the General Supervisor is on site during testing. Refer to D6100. 2. Laboratory Director failed to ensure prior to patient testing laboratory personnel had the appropriate education to qualify for high complexity testing. Refer to D6102A. 3. Laboratory Director failed to ensure prior to start of patient testing laboratory personnel had the appropriate training documented. Refer to D6102B. 4. Laboratory Director failed to ensure approved policies/procedures' manual was available to personnel prior to start of patient testing. Refer to D6106.

**D6100**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(10)

(e)(10) Ensure that a general supervisor provides on-site supervision of high complexity test performance by testing personnel qualified under 493.1489(b)(5);

This STANDARD is not met as evidenced by:  
Based on review of laboratory's submitted Form CMS 209 (Laboratory Personnel

Report), patient test records, policies/procedures and staff interview, the Laboratory Director failed to ensure General Supervisor provided on-site supervision of high complexity test performance by testing personnel for one of one test performed by the laboratory in 2024 and 2025, grossing of histology samples. Findings included: 1. Review of laboratory's submitted Form CMS 209 revealed the Laboratory Director also held the position of the laboratory's General Supervisor. 2. Review of patient test records revealed Testing Person number 2 (TP2) performed testing on 11/12/2024 but had initial competency assessed on 11/28/2024. There was no documentation of whether TP2 was testing under supervision. 3. Review of laboratory's policies /procedures revealed the laboratory's policies did not define TS/GS responsibilities for onsite supervision of grossing, a high complexity test performance. 4. In an interview on 03/20/2025 at 1030 hours in the laboratory, Testing Person number 3 (as indicated on submitted Form CMS 209) when asked, stated that the laboratory director/general supervisor was not always onsite during testing. This confirmed the findings.

**D6102**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(12)

(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;

This STANDARD is not met as evidenced by:  
A. Based on review of laboratory's submitted Form CMS 209 (Laboratory Personnel Report), laboratory's personnel records and staff interview, the Laboratory Director failed to ensure prior to patient testing laboratory personnel had the appropriate education to qualify for high complexity testing for four of six testing personnel that performed grossing of histology samples in 2024 and 2025. Refer to D6171. B. Based on review of laboratory's submitted Form CMS 209 (Laboratory Personnel Report), patient test records, policies/procedures, personnel records and staff interview, the Laboratory Director failed to ensure prior to patient testing laboratory personnel had documentation of training for grossing of histology samples for five of six testing personnel (TP) that performed grossing in 2024 and 2025. Findings included: 1. Review of laboratory's submitted Form CMS 209 revealed the laboratory had six testing personnel (including the laboratory director) that performed grossing of histology samples in 2024 and 2025. 2. Review of patient test records revealed the laboratory started testing patient samples on 11/12/2024. 3. Review of laboratory's "Personnel Qualifications and Training" policy (approved 02/21/2025) revealed: "Every new employee must complete an onboarding training program that includes: ... Grossing Procedures: detailed instructions on proper specimen handling, description, dissection, and sample submission for histology processing." And, "All training activities including completion of each module and competency evaluations, will be documented in personnel records." 4. Review of laboratory's personnel records revealed the following five of the laboratory's six TPs did not give documentation of training for grossing of histology samples prior to patient testing: TP#(number) 1 TP#2 TP#3 TP#4 TP#5 5. In an interview on 03/20/2021 at 1030 hours in the laboratory, the laboratory's Operations Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.

**D6106**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(14)

(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and

This STANDARD is not met as evidenced by:

Based on review of laboratory's policies/procedures, patient test records and staff interview, the laboratory director failed to ensure an approved procedure manual was available to personnel prior to patient testing for one of one test performed by the laboratory in 2024 and 2025, grossing of histology samples. Refer to D5407.

**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 laboratory's submitted Form CMS 209 (Laboratory Personnel Report), laboratory's personnel records and staff interview, the laboratory failed to ensure prior to patient testing laboratory personnel had the required education to qualify for high complexity testing for three of six testing personnel that performed grossing of histology samples in 2024 and 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 review of laboratory's submitted Form CMS 209 (Laboratory Personnel Report), laboratory's personnel records and staff interview, the laboratory failed to ensure prior to patient testing laboratory personnel had the appropriate education to qualify for high complexity testing for three of six testing personnel that performed grossing of histology samples in 2024 and 2025. Findings included: 1. Review of laboratory's submitted Form CMS 209 revealed the laboratory had six testing personnel (TP), including the laboratory director, that performed grossing of histology samples in 2024 and 2025. 2. Review of laboratory's personnel records revealed the following three of six testing personnel did not have documentation of education required to qualify for the laboratory's high complexity testing: TP2 (testing person number two): Signed off for testing: 11/28/2024 Documentation of: Associates Degree in Biology - Biology Majors and Pre-Medical Programs. TP3: Signed off for testing: 01/15/2025 Documentation of: Foreign diploma with equivalency in Bachelors of Science in Chemical Engineering There was no documentation of completion of twenty-four semester credit hours of science courses that included six credit hours of chemistry, six credit hours of biology and twelve credit hours of chemistry, biology or medical laboratory science. TP5: Signed off for testing: 01/18/2025 Documentation of: Foreign diploma equivalency in Doctor of Pharmacy There was no documentation of at least 16 semester hours of doctoral level coursework in biology, chemistry, Medical Technology (MT), Clinical Laboratory Science (CLS) or Medical Laboratory Science (MLS), or an approved thesis or research project in biology, chemistry, MT, CLS or MLS. 3. In an interview on 03/20/2021 at 1030 hours in the laboratory, the laboratory's Operations Manager (as indicated on submitted Survey Entrance/Exit Conference document) confirmed the findings.