

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2169720	(X3) Date Survey Completed 08/09/2025
Name of Provider or Supplier Arlington Gastroenterology Services	Street Address, City, State 2725 Matlock Road, Arlington, 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	The laboratory was found to be in substantial compliance with CLIA regulations 42 CFR Part 493. Standard level deficiencies were cited.
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e)(2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's standard operating procedures, patient reports, and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for four of five stains used in histopathology interpretations. Findings included: 1. Review of laboratory's standard operating procedure manual revealed the procedure failed to define the staining characteristics for intended reactivity for the following stains used by the laboratory for histopathology interpretations: Alcian Blue /Periodic Acid Schiff (AB/PAS) Trichrome Helicobacter Pylori (H. Pylori) CD3 2. A random review of patient reports revealed the following patients had histopathology interpretations where the facility failed to define the staining characteristics for intended reactivity: 06/05/2025 Patient Accession #: THS25-16228; stains: AB/PAS, CD3, H. Pylori 06/06/2025 Patient Accession #: THS25-16846; stains: Trichrome, CD3 06/16/2025 Patient Accession #: THS25-18464; stains: AB/PAS, CD3, H. Pylori, Trichrome 06/25/2025 Patient Accession #: 3347622-2025; stains: AB/PAS, H. Pylori, CD3 07/13/2025 Patient Accession #: THS25-21501; stains: Trichrome, CD3 07/17/2025 Patient Accession #: THS25-22055; stains: AB/PAS, CD3, H. Pylori 07/19/2025 Patient Accession #: THS25-22234; stains: AB/PAS, CD3, H. Pylori 07/25/2025 Patient Accession #: 3356314-2025; stains: Trichrome, CD3 3356309-2025; stains: AB/PAS, H. Pylori 3356298-2025; stains: AB/PAS, H. Pylori 07/29/2025</p>

Patient Accession #: 3357207-2025; stains: Trichrome, CD3 08/01/2025 Patient Accession #: THS25-23790; stains: AB/PAS, CD3, H. Pylori 08/02/2025 Patient Accession #: 3359207-2025; stains: AB/PAS, H. Pylori 3359352-2025; stain: CD3 3359354-2025; stain: CD3 08/08/2025 Patient Accession #: THS25-24611; stains: Trichrome, CD3 THS25-24609; stains: AB/PAS, H. Pylori 3. During an interview on 08/09/2025 at 1:32 p.m., the Laboratory Director, after review of records, confirmed the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for four of five stains used in histopathology interpretations.

D5805

TEST REPORT
CFR(s): 493.1291(c)

(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.

This STANDARD is not met as evidenced by:
Based on review of patient records and confirmed in interview, the laboratory failed to include the testing facility address on the final reports for 22 of 27 patients in 2025 (random review June-August). Findings included: 1. Review of patient records from 2025 (random sampling) revealed the following 22 final reports which did not include the testing facility address: 06/06/2025 Patient Accession #: THS25-16846 06/16/2025 Patient Accession #: THS25-18464 06/25/2025 Patient Accession #: 3347626-2025 3347622-2025 07/25/2025 Patient Accession #: 3356314-2025 3356309-2025 3356298-2025 07/29/2025 Patient Accession #: 3357207-2025 3357208-2025 3357210-2025 08/01/2025 Patient Accession #: THS25-23791 THS25-23790 08/02/2025 Patient Accession #: 3359207-2025 3358851-2025 3359352-2025 3359353-2025 3359354-2025 3359355-2025 3359361-2025 3359363-2025 08/08/2025 Patient Accession #: THS25-24611 THS25-24609 2. During an interview on 08/09/2025 at 1:32 p.m., the Laboratory Director, after a review of records, confirmed the laboratory failed to include the testing facility address on 22 of 27 patient final reports.