

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2271506	(X3) Date Survey Completed 06/04/2025
Name of Provider or Supplier Lonestar Gastroenterology, Pa	Street Address, City, State 9312 Brodie Lane, Austin, 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 surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended. Standard level deficiencies were cited.
D3011	<p>FACILITIES CFR(s): 493.1101(d)</p> <p>Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, observation, formaldehyde badge test, interview, and pre-survey paperwork, the laboratory failed to monitor the formaldehyde exposure monitoring test for two of two years reviewed in 2023 and 2024. Findings follow. A. Review of the laboratory's policy and procedure titled Laboratory Standard (Occupational Exposure to Hazardous Chemicals in Laboratories Standard) under Procedure stated, "Permissible Exposure Limits 1.1 The laboratory shall assure the employees' exposures to OSHA regulated substances do not exceed the Permissible Exposure Limit (PEL). 2. Initial monitoring 2.1 The laboratory shall initially measure the employee's exposure to any substance regulated by an OSHA standard (i.e. formaldehyde) which requires monitoring if there is reason to believe that exposure levels for that substance ever exceeds the Short-Term Exposure Limit (STEL), action level, or in the absence of an action level, the PEL. 3. Periodic Monitoring 3.1 If the levels of these substances fall below the action level and STEL the substance shall continue to be monitored on an annual schedule. If the action level or STEL is exceeded corrective action must be taken and the level shall be monitored every six (6) months until levels fall below the acceptable levels. 4. Employee Notification of Monitoring 4.1 Within fifteen (15) days after receipt of any monitoring results the laboratory shall notify employees of results in</p>

writing either individually or by posting results in an appropriate location accessible to all employees." During a tour of the laboratory on June 4, 2025 at 1320 hours the surveyor observed a strong odor of formaldehyde in the laboratory. B. The 2023 and 2024 results of the Formaldehyde and Organic Vapors Personal Monitoring Badges were requested on June 4, 2025 at 1330 hours but not provided. C. Interview with the general supervisor/testing personnel on June 4, 2025 at 1320 hours in the laboratory confirmed the badge test results had not been received from the analytical laboratory for 2024 and they were submitted "a while back". He did not have results from 2023 either. D. Review of the CMS Form 116 showed an estimated annual volume of 8000 blocks.

D3031

RETENTION REQUIREMENTS
CFR(s): 493.1105(a)(3)

Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:

This STANDARD is not met as evidenced by:
Based on review of the reagent log, interview, and presurvey paperwork, the laboratory failed to retain the chemical name and concentration (if applicable), manufacturer, lot number, expiration date, received date, and open date of the chemicals and stains used in the laboratory for the Hematoxylin and Eosin (H&E) stain, Helicobacter pylori (H. pylori) stain, and Alcian Blue Periodic Acid-Schiff (AB PAS) stains used in gastrointestinal histopathology biopsy specimens for 20 of 22 months reviewed. Findings follow. A. Review of the reagent log from August 2023 - May 2025 was missing the documentation of the chemicals and stains (Vintage Hematoxylin, Mayer's Hematoxylin, Eosin, Alcian Blue, Periodic Acid, Schiff's, Bluing, 100% Reagent Alcohol, Xylene, etc.) from September 2023 - April 2025 (elapsed time 20 months). B. Interview with the general supervisor/testing personnel on June 4, 2025 at 1515 hours in the breakroom confirmed the findings C. Review of the CMS Form 116 showed an estimated annual volume of 8000 blocks.

D5217

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policy and procedure, accuracy assessments, interview, and pre-survey paperwork, the laboratory failed to verify the accuracy of grossing gastrointestinal histopathology biopsy specimens at least twice annually for 2 of 2 years reviewed in 2023 and 2024. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Improvement Review Method Accuracy Verification, implemented 11/01/2022, under Purpose stated, "each technical employee in Histology will be evaluated by the Medical Director to ensure that each employee understands and follows all procedures for grossing and slide preparation. Every quarter or biannual the laboratory staff will pick 5 random cases to review all aspects of grossing, processing, staining and microtomy." B. Accuracy assessments

from 2023 and 2024 for grossing gastroenterology histopathology were requested on June 4, 2025 at 1430 hours but not provided. C. Interview with the general supervisor /testing personnel on June 4, 2025 at 1515 hours in the breakroom confirmed the findings. D. Review of the CMS Form 116 showed an estimated annual volume of 8000 blocks.

D5801

TEST REPORT

CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of the grossing report, test report, interview, and pre-survey paperwork, the laboratory failed to ensure the test result was manually entered into the LIS correctly for its gastrointestinal histopathology biopsy grossing specimens for one of 11 cases reviewed. Findings follow. A. Review of 11 cases from 10/25/2023 - 04/22/2025 showed one case, LP24-1358, collected 12/16/2024, had an incorrect test report. Review of the Grossing Sheet for case LP24-1358 for specimen D from the colon, sigmoid, showed the specimen was received in 2 portions that were tan-brown mucosal tissue measuring 3 mm to 2 mm, submitted in one cassette. Review of the Gastrointestinal Pathology Report for case LP24-1358 showed specimen D from the colon, sigmoid, stated, "It contains two portions of light brown mucosal tissue ranging from 0.3 cm to 0.2 cm in greatest dimension. The specimen is entirely submitted in one cassette." B. Interview with the general supervisor/testing personnel on June 4, 2025 at 1445 hours in the breakroom confirmed the color had been transcribed incorrectly on the test report. C. Review of the CMS Form 116 showed an estimated annual volume of 8000 blocks.