

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2271506	(X3) Date Survey Completed 09/07/2023
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.
D5791	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, grossing report, test report, and interview, the laboratory failed to identify and correct an error in reporting gastrointestinal biopsy grossing specimens for one of ten cases reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled Quality Assurance Program, effective 11/01/2022, at Procedure under 3. Post-analytical stated, "3.1 QC slides (SOP Daily Routine in Histology) 3.2 Place slides in proper location in for distribution (SOP: Daily Routine in Histology) 3.3 File blocks and slides (SOP: Histology Daily Routine) 3.4 Block count analysis (SOP: Histology Daily Routine) 3.5 Pathologist Daily Review". B. Review of the Grossing Sheet for case LP23-0275 for specimen B from the colon, transverse, showed the specimen was received in 3 portions that were light-brown mucosal tissue measuring 5 mm to 2 mm, submitted in one cassette. C. Review of the Gastrointestinal Pathology Report for case LP23-0275 showed specimen B from the colon, transverse, stated, "It contains three portions of white brown mucosal tissue ranging from 0.5 cm to 0.2 cm in greatest dimension. The specimen is entirely submitted in one cassette." D. Interview with the histotechnologist on August 7, 2023 at 1540 hours confirmed the test report color description was incorrect.</p>