

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2119427	(X3) Date Survey Completed 11/18/2021
Name of Provider or Supplier Texas Digestive Specialists	Street Address, City, State 720 N 77 Sunshine Strip, Harlingen, 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, review of the laboratory's twice annual accuracy verification records for 2020 and 2021 and staff interview it was determined the laboratory failed to document twice annually verification of the Hematoxylin and Eosin stain. Findings included: 1. Review of the laboratory's procedures revealed the laboratory performed the following staining procedures: CD3 (immunohistochemical stain) AB/PAS (Alcian Blue/Periodic Acid-Schiff) H. pylori (Helicobacter pylori) H&E (Hematoxylin and Eosin) 2. Review of the laboratory's twice annual accuracy verification records for 2020 and 2021 revealed no documentation of verifying twice annually the accuracy of the Hematoxylin and Eosin stain used in the laboratory. 3. The laboratory was asked to provide documentation of</p>

twice annually verifying the accuracy of the Hematoxylin and Eosin stain and no such documentation was provided. 4. In an interview on 11/18/2021 at 1440 hours in the laboratory's anteroom the Laboratory Manager stated that the laboratory did not perform twice annual accuracy verification of the Hematoxylin and Eosin stain. This confirmed the findings.