

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2119427	(X3) Date Survey Completed 11/05/2019
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	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was 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 to be 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 the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5219	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, a review of the laboratory's twice annual accuracy assessments for 2018 and staff interview, it was revealed the laboratory failed to verify the accuracy of each non-regulated test performed by the facility. Findings include: 1. A review of the laboratory's test menu revealed the laboratory performs the following tests: H & E stain AB/PAS (Alcian Blue/Periodic acid-Schiff) FE (Iron) H.Pylori (Helicobacter Pylori) PAS (Periodic acid-Schiff) Trichrome Grossing 2. A review of the laboratory's twice annual accuracy assessments for 2018 revealed the laboratory failed to have records of performing the assessments on the following analytes: H & E stain AB/PAS (Alcian Blue/Periodic</p>

acid-Schiff) FE (Iron) H. pylori (Helicobacter Pylori) PAS (Periodic acid-Schiff) Trichrome Grossing 3. An interview with Testing Personnel #1 (as listed on Form CMS-209) on November 5, 2019 at 15:45 hours in the laboratory confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services

D6107

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(15)

The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory's submitted CMS Form-209, review of personnel records, and confirmed in interview of facility personnel, the laboratory director failed to specify in writing the responsibilities of each consultant and testing person. The findings were: 1. Review of the laboratory's submitted Form CMS-209, approved by the laboratory director on November 5, 2019 revealed the laboratory had designated 1 clinical consultant, 1, technical supervisor, 1 general supervisor, and 8 testing persons. 2. Review of laboratory records revealed no job descriptions available for review for each consultant and testing person. 3. The findings were confirmed in interview with Testing Personnel #1 (as listed on Form CMS-209) on November 5, 2019 in the laboratory. Key: Centers for Medicare and Medicaid Services

D6128

TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of laboratory personnel records, and confirmed in interview of facility personnel, the technical supervisor failed to perform an annual competency for Testing Personnel #3 (as listed on Form CMS-209) in 2018. The findings were: 1. Review of personnel records for Testing Personnel #3 (as listed on Form CMS-209) revealed no records of an annual competency assessment in 2018 performed by the Technical Supervisor. 2. The findings were confirmed in interview with Testing Personnel #1 (as listed on Form CMS-209) on November 5, 2019 at 16:00 hours in the laboratory. Key: CMS - Centers for Medicare and Medicaid Services