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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 45D2119427 | (X3) Date Survey Completed 09/24/2025 |
| 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 |
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| 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 test menu, review of the laboratory's records, and staff interview, the laboratory failed to have documentation of performing twice annual accuracy assessments for 23 of 23 tests in 2023 and 2024. The findings included: 1. A review of the laboratory's test menu identified the laboratory performed testing utilizing the following 22 stains: H&E CD 3 CD 20 CK OSCAR KI-67 MLH-1 PMS2 MSH-6 CMV P53 Chromogranin Synaptophysin H-pylori Gastrin MSH2 SMA Trichrome Iron AFB PAS Aician Blue PAS Fungus PAS D 2. The laboratory also performed grossing the samples. 3. A review of the laboratory's records determined the facility failed to have documentation of performing twice annual accuracy assessments for each of the identified tests in 2023 and 2024. 4. The pathology manager confirmed the findings in an interview conducted on 09/24/2025 at 1000 in the laboratory.</p> |
| D5785 | <p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b)(3) The criteria for proper storage of reagents and specimens, as specified under 493.1252(b), are not met.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's refrigerator temperature records from January 2025 to August 2025, review of the laboratory's room humidity records from October</p> |

2024 to December 2024, and staff interview, the laboratory failed to have documentation of performing corrective actions when the documented refrigerator temperature and room humidity were outside the laboratory's acceptable range. The findings included: 1. A review of the laboratory's refrigerator temperature records from January 2025 to August 2025 determined the laboratory's acceptable range for the refrigerator temperature was 2 - 10 C. 2. Further review of the records determined the following days when the documented temperature was outside the laboratory acceptable range, however the laboratory failed to have documentation of performing corrective actions: Date Temperature 1/5/25 11.5 C 2/2/25 10.9 C 3/2/25 12.1 C 5/1/25 10.5 C 5/14/25 10.7 C 7/6/25 13 C 7/20/25 13 C 7/27/25 13 C 8/16/25 1.9 C 8/17/25 10.6 C 3. A review of the laboratory's room humidity records from October 2024 to December 2024 determined the laboratory's acceptable range for room humidity was 45% - 60%. 4. Further review of the records determined the following days when the documented room humidity level was outside the laboratory's acceptable range, however the laboratory failed to have documentation of performing corrective actions: Date Humidity 10/1/24 43% 10/2/24 44% 10/5/24 43% 10/6/24 43% 10/7/24 43% 10/8/24 44% 10/14/24 43% 10/17/24 44% 10/18/24 44% 10/19/24 44% 10/20/24 44% 10/25/24 41% 11/5/24 41% 11/6/24 41% 11/8/24 42% 11/10/24 44% 11/12/24 41% 11/13/24 44% 11/19/24 42% 11/20/24 41% 11/23/24 41% 11/24/24 41% 11/25/24 41% 12/3/24 44% 12/11/24 44% 12/13/24 40% 5. The pathology manager confirmed the findings in an interview conducted on 09/24/2025 at 1130 hours in his office.