

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2047881	<b>(X3) Date Survey Completed</b>  11/27/2018
<b>Name of Provider or Supplier</b>  Mcallen Gastroenterology Clinic Lp	<b>Street Address, City, State</b>  1900 South Jackson Ste 11, Mcallen, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor observations, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow manufacturer's instructions for storage of laboratory reagents. The findings were: 1. Surveyor observations on November 27, 2018 at 10:05 hours in the histotechnologist's office during the initial tour of the facility revealed the following reagents stored in the refrigerator: TBS Autowash (Lot 101718) - quantity of 2 Reveal Decloaker (Lot 081018) - quantity of 1 Automation Tween 20, 20X (Lot 092518) - quantity of 2 2. Review of the manufacturer's instructions located on the package labeling revealed the reagents were to be stored as follows: TBS Autowash (Lot 101718) - "20-25 degrees Celsius" Reveal Decloaker (Lot 081018) - "20-25 degrees Celsius" Automation Tween 20, 20X (Lot 092518) - "20-25 degrees Celsius" 3. Interview of the histotechnologist on November 27, 2018 at 10:23 hours in the laboratory confirmed the findings. He stated that the manufacturer shipped the reagents on ice, but after the reagents are opened, they were stored at room temperature.</p>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's</p>

instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on surveyor observations, review of manufacturer instructions, and confirmed in interview of facility personnel, the laboratory failed to monitor the room temperature where laboratory reagents were stored. The findings were: 1. Surveyor observations on November 27, 2018 at 10:05 hours in the histotechnologist's office revealed no means to monitor room temperature. 2. Further observations on November 27, 2018 at 10:05 hours revealed the following items stored in the office: Phosphomolybdic Phosphotungstic Acid Solution (Lot 1819012) Ailine Blue Stain (Lot 1823906) Acetic Acid (Lot 1812113) 3. Review of manufacturer's instructions found on the manufacturer labeling revealed the following reagents should be stored as follows: Phosphomolybdic Phosphotungstic Acid Solution (Lot 1819012) - "15-30 degrees Celsius" Ailine Blue Stain (Lot 1823906) - "15-30 degrees Celsius" Acetic Acid (Lot 1812113) - "15-30 degrees Celsius" 4. Interview of testing personnel three (as listed on Form CMS 209) at 10:08 hours in the histotechnologist's office confirmed the findings. When asked if the room temperature was being monitored in the office where laboratory reagents were stored, he stated, "No, just in the other room." Key: CMS - Centers for Medicare and Medicaid Services

**D5793**

**ANALYTIC SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1289(b)(c)

(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.

This STANDARD is not met as evidenced by:  
Based on laboratory policy, review of quality assurance records, and confirmed in interview of facility personnel, the laboratory's quality assurance program failed to identify that twice annual accuracy assessments for each test performed by the laboratory were performed in 2017. The findings were: 1. Review of the laboratory's test menu revealed the laboratory performs the following tests: Tissue Grossing H & E (Hematoxylin & Eosin) ALB/PAS Trichrome PAS-F (Periodic Acid Schiff) GMS (Gomori Methenamine-Silver) Iron AFB (Acid Fast Bacilli) H. pylori (Helicobacter) AE1/AE3 Synaptophysin Chromogranin CD-20 CMV (Cytomegalovirus) S-100 Actin DOG-1 BCL-2 Gastrin KI-67 2. Review of the laboratory's policy titled, "Quality Assessment Plan" signed by the laboratory director on October 10, 2017 stated, "The process of quality assessment consists of four main areas: 1. Planned review of all policies and procedures for their effectiveness. 2. Identification of any problems through this review process. 3. Corrective action taken to prevent future problems. 4. Follow-up review of the effectiveness of corrective actions." 3. The laboratory's quality assurance program did not identify and correct that twice annual accuracy assessments were not performed in 2017. 4. An interview with testing personnel three (as listed on Form CMS 209) in the break room at 10:55 hours confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services