

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2047881	(X3) Date Survey Completed 09/13/2022
Name of Provider or Supplier Mcallen Gastroenterology Clinic Lp	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5785	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (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 laboratory environmental records and confirmed in interview of laboratory personnel, the laboratory failed to provide documentation of performing corrective action when the laboratory documented room temperatures out of range for 16 of 73 testing days from June 1, 2022 to September 13, 2022. The findings included: 1. Review of the laboratory's environmental records found the laboratory's established room temperature range was 68 to 77 degrees Fahrenheit. 2. Review of the laboratory's room temperature environmental logs found the following 16 of 73 testing days from June 1, 2022 to September 13, 2022 when the laboratory documented the room temperature below the established acceptable range: June 6, 2022 64F June 7, 2022 67F June 8, 2022 67F June 9, 2022 63F June 15, 2022 66F June 16, 2022 66F August 17, 2022 66F August 18, 2022 66F August 19, 2022 66F August 23, 2022 66F August 24, 2022 66F August 26, 2022 66F August 29, 2022 66F August 30, 2022 66F August 31, 2022 66F September 8, 2022 52F 3. The laboratory was asked to provide documentation of corrective action for the days when the temperature was documented below the laboratory's established acceptable range. No documentation was provided. 4. The findings were confirmed with testing personnel #1 (as listed on Form CMS 209) on September 13, 2022 at 11:15 hours in the break room. Key: CMS - Centers for Medicare and Medicaid Services</p>