

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1033622	(X3) Date Survey Completed 07/13/2022
Name of Provider or Supplier M & M Pediatrics Pllc	Street Address, City, State 3354 International Blvd, Brownsville, 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
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, patient records, and confirmed in interview of laboratory personnel, the laboratory failed to retain patient and quality control records for Rotavirus from June 2, 2021 to October 31, 2021. The findings included: 1. Review of the laboratory's Rotavirus quality control records from June 2, 2021 to June 30, 2022 found no records could be recovered to ensure the laboratory performed quality control according to its IQCP from June 2, 2021 to October 31, 2021. a. The laboratory failed to retain Rotavirus quality control records from June 2, 2021 to October 31, 2021 for a minimum of two years. 2. Review of the laboratory's patient test records from June 2, 2021 to June 30, 2022 found no records could be recovered from June 2, 2021 to October 31, 2021. The laboratory failed to retain patient test records for a minimum of two years. 3. The laboratory was asked to provide documentation of retaining patient and quality control records for a minimum of two years. No documentation was provided. 4. The findings were confirmed in interview with the technical consultant on July 13, 2022 at 11:00 hours in the break room. Key: IQCP - Individualized Quality Control Plan</p>