

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1033622	(X3) Date Survey Completed 06/10/2021
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
D0000	<p>Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, 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 certification 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.</p>
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Alere i RSV test kit, surveyor observation, review of patient test records, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for not using expired test kits. The findings were: 1. Based on review of the manufacturer's instructions for the Alere i RSV test kit (IN430002 v. 14.0) under the section titled "Precautions" revealed: "Do not use kit past its expiration date." 2. Surveyor observation of test kits currently in use in the laboratory on 06/10/2021 at 09:55 am identified the following RSV kit: Lot: M115700 Expiration date: 2021-04-16 Thus the kit had been expired for 55 days 3. A review of patient test records from April, May</p>

and June 2021 identified two patients whose samples were testing using the expired kit: 04/21/2021 Patient ID: 120389 05/13/2021 Patient ID: 120033 4. An interview with the technical consultant on 06/10/2021 at 0955 hours in the laboratory - after her review of the records- confirmed the findings.