

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1097486	(X3) Date Survey Completed 04/26/2023
Name of Provider or Supplier M & M Pediatrics	Street Address, City, State 4365 S Expressway 77/83 Suite 700, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
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 Instructions for Use for the BinaxNOW RSV card, a review of patient test records from October 2022 to February 2023, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions by ensuring the BinaxNOW RSV (Respiratory Syncytial Virus) test was run on patients five years of age or older for five of twenty patient test reports reviewed. Findings include: 1. A review of the Instructions for Use for the BinaxNOW RSV card test revealed the following: "ATTENTION Do not use the RSV test in patients 5 years or older." 2. A review of the laboratory's patient test records from October 2022 to February 2023 revealed the following 5 patient's samples were run using the BinaxNOW RSV card: Patient date of birth: 4/19/11 Patient age: 11 years Date tested: 10/10/22 Patient date of birth: 4/25/15 Patient age: 8 years Date tested: 10/14/22 Patient date of birth: 8/3/10 Patient age: 13 years Date tested: 12/9/22 Patient date of birth: 4/4/02 Patient age: 20 years Date tested: 1/21/23 Patient date of birth: 3/28/12 Patient age: 10 years Date tested: 2/11/23 3. An interview with the technical consultant (as indicated on the CMS 209 form) on 4/26/23 at 10:44 a.m. in the upstairs break room, after review of the records, confirmed the above findings.</p>

D3031

RETENTION REQUIREMENTS

CFR(s): 493.1105(a)(3)

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.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's Rotavirus Log Sheets for the SAS Rotavirus test and staff interview, it was revealed that the laboratory failed to retain the Rotavirus Log Sheets, containing quality control and patient test results, for 38 of 59 days from January 1, 2022 to February 28, 2022. Findings include: 1. A review of the laboratory's Rotavirus Log Sheets for the SAS Rotavirus test revealed the laboratory failed to retain the Rotavirus Log Sheets, containing quality control and patient test results, for 38 days from January 14, 2022 to February 22, 2022. 2. An interview with the technical consultant (as indicated on the CMS 209 form) on 4/26/23 at 10:05 a.m. in the upstairs break room, after review of the records, confirmed the above findings.

D5445

CONTROL PROCEDURES

CFR(s): 493.1256(d)(1)(2)(g)

Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on a review of the laboratory's IQCP (Individualized Quality Control Plan) for the SAS Rotavirus test, the laboratory's quality control records from 2022, the laboratory's patient test records, and staff interview, it was revealed that the laboratory failed to have documentation of running quality controls for the SAS Rotavirus test at the frequency established by the IQCP for one of twelve months from January to December 2022. Findings include: 1. A review of the laboratory's IQCP for the SAS Rotavirus test revealed the following: "QC for the SAS Rotavirus will consist of: Testing of Positive and Negative External Controls per each lot & shipment before placing these materials into service and monthly thereafter." 2. A review of the laboratory's quality control (QC) records from January to December 2022 revealed the laboratory failed to have documentation of running positive and negative controls in the month of July. 3. A review of the laboratory's patient test records revealed the laboratory ran the following SAS Rotavirus test in July: Patient: HG040621 Tested on: 7/6/22 4. An interview with the technical consultant (as indicated on the CMS 209 form) on 4/26/23 at 9:45 a.m. in the upstairs break room, after review of the records, confirmed the above findings.