Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1097486	07/30/2019
Name of Provider or Supplier	**Street Address, City, State**	
M & M Pediatrics	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 representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, 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 recertification 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.
D2121	HEMATOLOGY CFR(s): 493.851(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's 2018 Hematology /Coagulation- 1st Event results and staff interview, it was revealed the laboratory failed to attain a score of at least 80% for the analyte Lymphocytes. Findings include: 1. A review of the laboratory's American Proficiency Institute's 2018 Hematology/ Coagulation- 1st Event results revealed the laboratory failed to attain a score of atleast 80% for the analyte Lymphocytes. The following results for Lymphocytes were submitted: Sample Reported Result Expected Result HSY-01 37.1 33.9-37.4 HSY-02 31.5 28.4-33.3 HSY-03 24.4 21.1-27.2 HSY-04 33.7 28.9-33.5 HSY-05 40.2 31.3-38.3 Two out of five results were unacceptable, resulting in a score of 60% for the

	Lymphocytes analyte. 2. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 7/30/19) on 7/30/19 at 09:40 in the upstairs break room, after review of the records, confirmed the above findings.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's 2018 Hematology /Coagulation- 1st Event results and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions for unacceptable results. Findings include: 1. A review of the laboratory's American Proficiency Institute's 2018 Hematology/Coagulation- 1st Event results revealed the laboratory failed to have documentation of performing corrective actions for unacceptable results for the analyte Lymphocytes. 2. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 7/30/19) on 7/30 /19 at 09:40 in the upstairs break room said, "for some reason they did not perform corrective action." This confirmed the above findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/2017
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) 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 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 the laboratory's policies, the laboratory's Temperature Logs from August 2018- September 2018, and staff interview, it was revealed the laboratory failed to ensure the laboratory's room temperature readings were within its acceptable range. Findings include: 1. A review of the laboratory's 'Daily Laboratory Duties' states the following: "Morning Startup: Read and record temperatures for all Laboratory Temperature Control devices (Incubators, Heat Blocks, Water Baths, Refrigerators, Freezers). Also note and record the room temperature. Compare temperature readings with the proper operating temperature of each device to ensure proper operation." 2. A review of the laboratory's Temperature Logs from August 2018-September 2018 revealed the Room Temperature Range between 70F- 77F. 3. Further review of the Temperature Logs from August 2018-September 2018 revealed the following days where the temperature exceeded the allowable range: 8/2/18 78F 8/4/18 78F 8/27/18 78F 8/28/18 78F 9/12/18 78F 4. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 7/30/19) on 7/30 /19 at 10:00 in the upstairs break room, after review of the records, confirmed the above findings.

D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test results from May 2019 - July 2019, and staff interview, it was revealed the laboratory failed to have documentation of following its policy for the notification of panic values. Findings include: 1. A review of the laboratory's policy titled 'Panic Values' states: "The Laboratory Personnel will immediately notify the requester or user about lab results in the 'Panic Range." White blood cell (WBC) Under 2000 Over 20,000 2. A review of the laboratory's policy titled 'Reporting Panic Values' states the following: "It is the policy of this laboratory to document the reporting of panic values. Document: 1)Who was notified 2)When was the person notified 3) By whom was the person notified 3. A review of patient test records from May 2019- July 2019 identified the following patients whose results met the laboratory's criteria as a 'panic value': Date ID Test 5/15 /19 115897-11M WBC: 21.5 6/18/19 116419 WBC: 25.1 6/18/19 116419 WBC: 25.4 7/12/19 104185-6Y WBC: 1.7 7/16/19 110825-14Y WBC: 23.3 4. The laboratory was asked to provide documentation of the notification of the provider as required by its policy. No documentation was provided. 5. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 7/30/19) on 7 /30/19 at 10:50 in the upstairs break room, after review of the patient records, confirmed the above findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/2017
D6025	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(7) Ensure that patient test results are reported only when the system is functioning properly. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of patient test records from August 2018- July 2019, and staff interview, it was revealed the laboratory director failed to ensure that patient results were reported only when the system was functioning properly. Findings include: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Code No. AU553517, May 2014) under the section titled "Analysis of Histogram" revealed: "Analysis of histogram allow use of the flagging system that suggests sample error or instrument error." 2. A review of patient test records from August 2018- July 2019 identified the following patient results which were reported to the provider without resolution of flags to ensure the instrument was working properly: Date ID Flag(s) 8/27/18 98894-15YR AG 9/12/18 114436-14YR AG 9/12/18 86231-11YR AG 5/10/19 111912-7YR AG 5/13/19 77897-17YR AG 5/16

	/19 115565-9M AG 5/21/19 107151-5Y AG 5/21/19 107151-5Y AG 5/29/19 88425-10YR AG 5/29/19 114629-16MO AG, T2 6/17/19 115721 AG 6/18/19 105301 AG, T2 6/18/19 105301-9Y AG, T2 6/20/19 114938-15MO AG, T2 6/21/19 111416-3Y AG 7/1/19 115586-10M F2, F3 3. An interview with the technical consultant (as indicated on the CMS 209 form, signed by the laboratory director on 7/30/19) on 7/30/19 at 11:00 in the upstairs break room, after review of the patient results, confirmed the above findings. NOTE: THIS IS A REPEAT DEFICIENCY FROM THE SURVEY CONDUCTED 04/2017