

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1097486	(X3) Date Survey Completed 09/23/2021
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	<p>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 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 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>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in</p>

the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.
(14) Description of the course of action to take if a test system becomes inoperable.

This STANDARD is not met as evidenced by:

Based on review of the manufacturer's user manual for the Sysmex XP-300 hematology analyzer, review of the laboratory's policies, random review of patient test results for July to September of 2021 and interview with the staff it was determined the laboratory failed to establish and follow protocols for flagged Complete Blood Count (CBC) results according to manufacturer's instructions. The findings were: 1. Review of the manufacturer's user manual (Revised July 2012) for the Sysmex XP-300 hematology analyzer revealed: "When the histogram flags are displayed perform analysis again. If afterwards the flags are still displayed, the sample is considered to correspond to one of the following." And, "Flag: [AG] Probable sample cause: presence of nucleated red blood cells, effects of fragmented red blood cells, increase of large platelets, platelet aggregation or agglutination, precipitation of fibrin, etc. Correction (reference): Check smear, etc." 2. Random review of patient test results from July to September 2021 identified the following patients with flagged CBC results that were reported to provider: Sample from 07/27/2021 Tested at 11:34; repeated at 11:36 PLT result: AG (flag) Sample from 08/14/2021 Tested at 10:44; repeated at 10:50 PLT result: AG (flag) Sample from 08/16/2021 Tested at 17:31; repeated at 17:36 PLT result: AG (flag) Sample from 08/19/2021 Tested at 17:52; repeated at 17:56 PLT result: AG (flag) Sample from 08/19/2021 Tested at 19:10; repeated at 19:16 PLT result: AG (flag) Sample from 09/11/2021 Tested at 13:16; repeated at 13:19 PLT result: AG (flag) Sample from 09/11/2021 Tested at 13:42; repeated at 13:43 PLT result: AG (flag) Sample from 09/12/2021 Tested at 13:38; repeated at 13:42 PLT result: AG (flag) Note: Please refer to the alias list attached. Key: PLT- Platelets 3. In an interview on 09/23/2021 at 1130 hours in the upstairs break room the Technical Consultant (as stated in the Form 209 signed by the laboratory director on 09/23/2021) stated that repeat flagged results are not to be reported and the sample is to be sent for review to a reference laboratory. This confirmed the findings.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's Sysmex XP-300 hematology analyzer manufacturer's manual (January 2012), review of the laboratory's Sysmex XP-300 maintenance records from August of 2019 to May of 2021 and interview with the staff it was determined the laboratory failed to document weekly maintenance as required. The findings were: 1. Review of the laboratory's Sysmex XP-300 hematology analyzer manufacturer's manual under section 12.1 Maintenance Schedule revealed: "Weekly "Clean SRV tray (see 12.5)" 2. Review of the laboratory's maintenance records for Sysmex XP-300 hematology analyzer from August of 2019 to May of 2021 revealed missing documentation of weekly maintenance for the following: a) August 2019 (2 of 4 weeks missing documentation) 08/19/2019 09/29/2019 b)

January 2020 (2 of 4 weeks missing documentation) 01/20/2020 01/28/2020 c)
February 2020 (3 of 4 weeks missing documentation) 02/03/2020 02/10/2020 02/24/2020 d) September 2020 (2 of 4 weeks missing documentation) 09/14/2020 09/21/2020 e) May 2021 (2 of 4 weeks missing documentation) 05/21/2021 05/28/2021 3.
In an interview on 09/23/2021 at 1015 hours in the upstairs break room the Technical Consultant (as described on CMS Form 209 signed by the laboratory director on 09/23/2021) confirmed the findings after review of the Sysmex XP-300 maintenance records.

D5785

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(3)

(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.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies for definition of humidity range, review of the laboratory's humidity records for July to September 2021 and interview with the staff it was determined the laboratory failed to document corrective action when humidity was out of laboratory defined range for 5 of 5 instances corrective action was required. The findings were: 1. Review of the laboratory's policies for definition of humidity range revealed humidity range was defined as 35-60%. 2. Review of the laboratory's humidity records revealed humidity was out of laboratory defined range as follows: 07/10/2021 - 66% 07/31/2021 - 63% 09/15(sic)/2021- 64% 09/17/2021 - 62% 09/18/2021 - 62% Note: There were 2 days on the forms designated as the 15th day of the month, and no day 16th of the month. The above 09/15(sic)/2021 was the second day designated as the 15th of the moth. 3. In an interview on 09/23/2021 at 1030 hours in the upstairs break room the Technical Consultant (as described on CMS Form 209 signed by the laboratory director on 09/23/2021) confirmed the findings after review of the humidity records.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's Quality Assurance (QA) policies, review of the QA records from August 2019 to June 2021 and interview with the staff it was determined the laboratory director failed to maintain QA for 5 of 22 intervals reviewed. The findings were: 1. Review of the laboratory's Quality Assurance Plan (signed into effect by laboratory director on 10/5/09) revealed: "We will perform a quality review at least monthly and review the results with the laboratory director or technical consultant for their approval." And, "The record of our quality assurance reviews are filed with this plan and are available for review by the director,

consultant, staff, and laboratory surveyors." 2. Review of the laboratory's QA records from August 2019 to June 2021 revealed missing documentation of QA review for: August of 2019 February of 2020 March of 2020 May of 2020 April of 2021 3. In an interview on 09/23/2021 at 1030 hours in the upstairs break room the Technical Consultant (as described on CMS Form 209 signed by the laboratory director on 09/23/2021) stated that the QA review should have been done monthly. This confirmed the findings.