

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1097486	<b>(X3) Date Survey Completed</b>  05/13/2025
<b>Name of Provider or Supplier</b>  M & M Pediatrics	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5403</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable.</p> <p>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 procedures, random review of patient test results from April 1, 2025 to May 8, 2025, and interview with the staff it was determined the laboratory failed to have a procedure for addressing flagged Complete Blood Count (CBC) results according to manufacturer's instructions. The findings were: 1. Review of the manufacturer's user manual (Revised May 2014) for the</p>

Sysmex XP-300 hematology analyzer revealed: "Analysis of histogram allows use of the flagging system that suggests sample error or instrument error." And, WL: Relative frequency for LOWER discriminator (LD) exceeds the range. Probable cause is inclusion of numerous platelet agglutination, large platelets, and etc. AG: The particle count equal to or less than the LD exceeds a prescribed range. Probable cause is platelet agglutination, which does not alter WBC count but may result in decreased platelet count. 2. A review of the laboratory's procedures determined the facility did not have a procedure to resolve flagged results prior to reporting to the provider. 3. Random review of patient test results from April 1, 2025 to May 8, 2025 identified the following patients with flagged CBC results that were reported to provider: Date: 04/01/2025 ID: 102755 Flag: Platelet AG Date: 04/01/2025 ID: 126029 Flag: WBC WL LYM% WL MXD% WL NEUT% WL LYM# WL MXD# WL NEUT# WL Platelet AG Date: 04/28/2025 ID: 118449 Flag: Platelet AG Date: 05/08/2025 ID: 123949 Flag: WBC WL LYM% WL MXD% WL NEUT% WL LYM# WL MXD# WL NEUT# WL 4. The technical consultant confirmed the findings in an interview after her review of the records on 05/13/2025 at 1230 hours in the break room. Key: WBC- white blood cells LYM% - percent lymphocytes MXD% - percent mixed cells NEUT% - percent neutrophils LYM# - count WL MXD# WL NEUT# WL 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.

**D5813**

**TEST REPORT**  
CFR(s): 493.1291(g)

(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 records from May 1, 2025 to May 9, 2025, and staff interview, the laboratory failed to have documentation of the notification of 2 of 2 panic values. The findings included: 1. A review of the laboratory's policy titled "Reporting Panic Values" (approved 10/05/2009) determined it was the laboratory's policy to document who was notified, when the person was notified, and by whom for each patient panic value. 2. A review of the laboratory's policy titled "Panic Values" determined the laboratory defined the following panic values: a) White blood cell Less than 2 or greater than 20 3. A review of patient test records from May 1, 2025 to May 9, 2025 identified 2 panic values for which the laboratory failed to have documentation of panic value following its policy. They were: a) Date: 05/02/2025 Specimen ID: 125060 Test: White blood cell Value: 24.6 b) Date: 05/09/2025 Specimen ID: 118858 Test: White blood cell Value: 27.3 4. The technical consultant confirmed the findings in an interview conducted on 05/13/2025 at 1245 hours in the break room.