

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1033622	(X3) Date Survey Completed 08/11/2026
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
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (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. 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 July 2026 and August 2026, review of the laboratory's procedure manual, and staff interview, the laboratory failed to have a procedure for how to deal with flagged CBC (complete blood count) results. The findings included: 1. The manufacturer's instructions for the Sysmex XP-300 hematology analyzer (Revision 2, June 2014) under the section titled "Histogram Flags" stated: "AG - The particle count equal to or less than the LD exceeds a

	prescribed range. Probable cause is platelet agglutination, which does not alter the WBC count, but may result in decrease platelet count." 2. A review of patient test records from July 2026 to August 2026 identified 2 of 6 flagged platelet results which were reported to the provider without verification of flagged results. They were: a) Patient 127995 tested: 08/03/2026 Flag: AG b) 124360 tested: 08/09/2026 Flag: AG 3. The laboratory failed to have a procedure available to staff to address flagged histogram results. 4. The technical consultant confirmed the findings in an interview conducted on 08/11/2026 at 1027 hours in the laboratory.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) 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 manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of the laboratory's hematology maintenance records from June 2025 to June 2026, and staff interview , the laboratory failed to have documentation of performing weekly maintenance for 4 of 56 weeks. The findings included: 1. A review of the manufacturer's instructions for the Sysmex XP-300 hematology analyzer determined the manufacturer required the following maintenance be performed weekly: Clean SRV Tray 2. A review of the laboratory's hematology maintenance records from June 2025 to June 2026 identified the laboratory failed to document weekly maintenance for 4 of 56 weeks. The weeks missing documentation were: August 29, 2025 October 31, 2025 January 30, 2026 July 24, 2026 3. The technical consultant confirmed the findings in an interview conducted on 08/11/2026 at 0915 hours in the break room.