Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0966111	04/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Mehta Medical Group Pllc	1702 Fm 1960 Bypass Rd East, Humble, 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	An announced validation survey of the laboratory was conducted on 04/17/2025. The laboratory was found in compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories) for the specialties/subspecialties for which it was surveyed. STANDARD LEVEL DEFICIENCIES were cited.
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. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of laboratory's records, policies/procedures, test volumes and staff interview, the laboratory failed to retain documentation of quality control (QC), calibration and instrument maintenance/function checks for two of two test platforms used by the laboratory in 2023 and 2024, the Medonic M hematology and the Vitros 5600 chemistry analyzers. Findings included: 1. Review of laboratory's records revealed there was no documentation of 2023 and 2024 QC, maintenance/function checks or calibration for the Medonic M Series hematology analyzer. The Vitros 5600 analyzer's 2023 and 2024 maintenance/function checks and calibration records were also not available for review. 2. Review of laboratory's policies/procedures revealed there were no protocols in place for document retention requirements. 3. Review of laboratory's submitted test volumes revealed the laboratory performed approximately 10,000 hematology and 27,550 chemistry tests annually. 4. In an interview on 04/17/2025 at 1020 hours in the office, the laboratory's Testing Person number one (as indicated on submitted Form CMS 209) stated that the documents were discarded post accrediting agency's inspection, confirming the findings.

D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of laboratory's personnel records, policies/procedures and staff interview, the laboratory failed to document competency assessment for one of one technical consultant employed by the facility in 2023 and 2024. Findings included: 1. Review of laboratory's personnel records revealed there was no documentation of competency assessment for the laboratory's technical consultant. 2. Review of laboratory's policies/procedures revealed there were no protocols in place for assessment of competency of technical consultants. 3. In an interview on 04/17/2025 at 0955 hours in the office, the facility's Quality Director (as indicated on submitted Entrance/Exit Conference document) confirmed the findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of laboratory's instrument calibration records, policies/procedures, patient test records and staff interview, the laboratory failed to follow its own protocols for calibrating the instrument every 28 days for one of two analytes reviewed requiring 28-day calibrations, Vitamin D. Findings included: 1. Review of a sampling of calibration records for January and February 2025 for the Vitamin D analyte revealed the laboratory performed calibrations as follows: Calibrated: 01/06/2025 Nex calibrated: 02/06/2025 Elapsed time: 31 days 2. Review of laboratory's policy/procedure "Vitros 5600 25-OH Vitamin D" (policy number C-36, effective January, 2020) revealed: "When to calibrate: ... Calibrate every 28 days." 3. Review of patient test records revealed the laboratory performed approximately 18 Vitamin D tests between 02/03/25 and 02/05/2025, the days beyond the required calibration timeframe. 4. In an interview on 04/17/2025 at 1140 hours in the office, the laboratory's Testing Person number one (as indicated on submitted Form CMS 209) confirmed the findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

(b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

This STANDARD is not met as evidenced by:
Based on review of laboratory's calibration and calibration verification records for the Vitros 5600 chemistry analyzer, polices/procedures and staff interview, the laboratory failed to document calibration verification at least every six months for seven of seven analytes requiring calibration verifications in 2024. Findings included: 1. Review of laboratory's calibration records revealed the following seven analytes had two levels of calibrators analyzed at each calibration, requiring calibration verification every six months: Estradiol (E2) Follicle-stimulating hormone (FSH) Luteinizing hormone (LH) Prolactin Vitamin D Vitamin B12 Total Iron Binding Capacity (TIBC) 2. Review of laboratory's calibration verification records revealed calibration verifications were performed as follows: Analyte: E2 Calibration Verification on: 01/09/2024 Next Calibration Verification on: 09/10/2024 (time elapsed: 9 months) Next Calibration Verification on: 01/16/2025 Analyte: FSH Calibration Verification on: 01/09/2024 Next Calibration Verification on: 09/10/2024 (time elapsed: 9 months) Next Calibration Verification on: 01/16/2025 Analyte: LH Calibration Verification on: 01/09/2024 Next Calibration Verification on: 09/10/2024 (time elapsed: 9 months) Next Calibration Verification on: 01/16/2025 Analyte: Prolactin Calibration Verification on: 01/09/2024 Next Calibration Verification on: 09/10/2024 (time elapsed: 9 months) Next Calibration Verification on: 01/16/2025 Analyte: Vitamin D Calibration Verification not documented in 2024. There was no documentation of any calibration verification for this analyte. Analyte : Vitamin B12 Calibration Verification on: 01/09/2024 Next Calibration Verification not documented in 2024. Next Calibration Verification on: 01/16/2025 (time elapsed 12 months) Analyte : TIBC Calibration Verification on: 01/09/2024 Next Calibration Verification on: 09/10/2024 (time elapsed: 9 months) Next Calibration Verification on: 01/16/2025 3. Review of laboratory's policies/procedures for these analytes revealed there were no protocols in place for the analytes requiring calibration verification or calibration verification frequency/intervals. 4. In an interview on 04/17/2025 at 1140 hours in the office, the laboratory's Testing Person number one (as indicated on submitted Form CMS 209) confirmed the findings. Key: CMS - Centers for Medicare and Medicaid