Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1052653	06/02/2026
Name of Provider or Supplier	**Street Address, City, State**	
Marco Gutierrez Md And Associates	5148 N 10th St, Mcallen, 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
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records for the DCA Vantage microalbumin/creatinine assay from June 2024 to June 2026, and staff interview, the laboratory failed to have documentation of monitoring quality control values over time for 3 of 3 lots. The findings included: 1. A review of the laboratory's DCA Vantage control records from June 2024 to June 2026 identified the laboratory utilized the following 3 lots: 0063 0064 0066 2. The laboratory failed to have documentation of monitoring control values over time to detect shifts and trends from June 2024 to June 2026. 3. The technical consultant confirmed the findings in an interview conducted on 06/02/2026 at 1130 hours in the conference room.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number

	of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on review of the laboratory's Medonic M-series hematology quality control records from September 2025 to March 2026, and staff interview, the laboratory failed to have documentation of verifying 2 of 3 new lots of control material prior to placing them into use. The findings included: 1. A review of the laboratory's quality control records for the Medonic M-series hematology analyzer from September 2025 to March 2026 determined the the laboratory failed to have documentation of verifying the following 2 of 3 lots of control material prior to placing them into use: Lot: 22508 Lot: 22511 2. The technical consultant confirmed the findings in an interview conducted on 06/02/2026 at 1045 hours in the conference room.
D5785	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(3) (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 temperature records from May 2025 to May 2026, and staff interview, the laboratory failed to have documentation of performing corrective actions on 20 of 24 days when temperatures were documented outside the laboratory acceptable ranges. The findings included: 1. A review of the laboratory's temperature records from May 2025 to May 2026 identified the laboratory listed the following acceptable temperature ranges: Room Temperature: 68 - 77 F Refrigerator Temperature: 36 - 46 F 2. Further review of the records identified the following days when the documented temperature was outside the laboratory's acceptable range, but the laboratory failed to identify and perform corrective actions: a) May 2025 Room Temperature 06/19 60.3 F 06/20 60.5 F 06/21 60.2 F 06/22 60.7 F 06/23 63.7 F 06/27 63.1 F 06/28 65.1 F 06/29 63.2 F 06/30 65.8 F b) October 2025 Refrigerator Temperature 10/17 35.4 F c) November 2025 Refrigerator Temperature 11/26 35.2 F d) December 2025 Refrigerator Temperature 12/24 46.4 F e) January 2026 Room Temperature 01/12 78.3 F 01/26 78.3 F 01/27 78.3 F f) May 2026 Room Temperature 05/18 61.4 F 05/19 61.4 F 05/20 62.5 F 05/21 64.8 F 05/22 64.7 F 3. The technical consultant confirmed the findings in an interview conducted on 06/02/2026 at 1045 hours in the conference room
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

	This STANDARD is not met as evidenced by: Based on review of the laboratory's records, and staff interview, the laboratory director failed to ensure a quality assessment policy was established and followed. The findings included: 1. A review of the laboratory's records identified the laboratory failed to have a policy for and documentation of performing quality assessments from January 2025 to May 2026. 2. In an interview conducted on 06/02/2026 at 1126 hours in the conference room, the technical consultant stated she used to perform the quality assessments monthly but had stopped and not performed in 2025 and 2026. This confirmed the findings.