

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1003540	(X3) Date Survey Completed 09/30/2026
Name of Provider or Supplier Marco Gutierrez Md And Associates	Street Address, City, State 401 S Alamo, Alamo, 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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of the laboratory's instrumentation, review of the laboratory's existing Individualized Quality Control Plans, and staff interview, the laboratory failed to have documentation of developing new Individualized Quality Control Plans for 2 of 2 new analyzers. The findings included: 1. A review of the laboratory's instrumentation identified 2 new DCA Vantage analyzers were placed into use: Serial number: S093891 In use: 3/14/2025 Serial number: S097198 In use: 1/23/2026 2. A review of the laboratory's IQCP for the DCA Vantage determined the laboratory failed to perform studies including the new analyzers. 3. The technical consultant confirmed the finding in an interview conducted on 09/30/2026 at 1100 hours in the X ray room.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's

verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b) (1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's policies, review of patient test records from August 2026, and staff interview, the laboratory failed to perform corrective actions for 1 of 1 patient results which were less than the linearity of the Medonic M-series hematology analyzer. The findings included: 1. The laboratory's policy titled "Actions to be Taken when Results are Outside of Reportable Range" stated: "Out-of -linear range indicators (WBC, HGB, RBC, PLT) AL - Result is above linearity -- The results is above linear range. The sample can be diluted and rerun, and then the dilution factor can be multiplied with the result to calculate the correct value. BL - Result is below linearity. The results is below linear range. Re-analyze sample. NOTE: For this Laboratory the recommended ACTION to be taken when these flags appear is to send the specimen to REFERENCE LAB. Document on the report that flagged Results are INVALID due to being out of RANGE and specimen is to be sent out to Reference lab for accurate testing. Make sure that provider gets the accurate patient report for Reference lab and scan into EMR." 2. A review of patient test records from August 2026 identified the following results flagged as below the linearity of the analyzer: Date: 08/07/2026 ID: 70936 Test: PLT Result: 24 Flag: BL 3. The laboratory provided the flagged result to the provider without performing corrective actions as stated in its policy. 4. The technical consultant confirmed the findings in an interview conducted on 09/30/2026 at 1045 hours in the X ray room.

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 August 2026 and September 2026, and staff interview, the laboratory failed to have documentation of the notification of 3 of 3 panic values. The findings included: 1. The laboratory's policy titled "Repeat and Panic Value Policy" stated: "When a critical value is noted it will be verified by repeating the test and the result will be called or given to the Physician within 15-30 minutes. Document on the patient's report the date, time and provider receiving the panic value. This report will be scanned into the patient's record." 2. The policy then defined the following panic values: a) Ages 9 yrs - Adult White blood cell less than 2 greater than 20 Hemoglobin less than 7 greater than 20 Hematocrit less than 21 greater than 60 Platelet less than 37 greater than 900 3. A review of patient test results from August 2026 and September 2026 identified the following 3 panic values: a) Date: August 7, 2026 ID: 6726 Test: Platelet Value: 24 b) Date: August 31, 2026 ID: 7074 Test: Hemoglobin Value: 6.8 c) Date: September 18, 2026 ID: 7366 Test: Hematocrit Value: 20.6 4. The laboratory failed to

have documentation of the notification of the 3 panic values. 5. The technical consultant confirmed the findings in an interview conducted on September 30, 2026 at 1045 hours in the X ray room.