Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1052653	12/09/2020
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory records and confirmed in interview of facility personnel, the laboratory failed to retain the Alere Triage instrument verification records for the life of the instrument but no less than two years. The findings were: 1. Direct observation on December 9, 2020 at 09:20 hours in the laboratory revealed the Alere Triage instrument was in use on the day of the survey. The laboratory performs the following moderate complexity testing on the Alere Triage: Troponin CK-MB 2. Review of Alere Triage instrument records found the laboratory did not retain the instrument verification records for the instrument currently in use. 3. Interview with testing personnel one (as listed on Form CMS 209)

	on December 9, 2020 at 11:28 hours revealed he could not located the verification records. He went on to say that those records would have been done prior to his employment. Key: CMS - Centers for Medicare and Medicaid Services
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. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records from January 2019 to October 2020 and staff interview, it was revealed the laboratory failed to have documentation of monitoring quality control results over time for the Alere Triage meter (used to test CK-MB and Troponin). The findings were: 1. A review of the laboratory's quality control records from January 2019 to October 2020 revealed the laboratory tested two levels of quality control material once each month and with each new lot and new shipment for CK-MB an Troponin. The previous two lot numbers in use are C3548AN and C3552AN. 2. Review of laboratory records revealed the laboratory did not have a policy to ensure the laboratory had a mechanism in place to evaluate control material over time. 3. The laboratory was asked to provide documentation of having mechanism is place to monitor quality control values over time. No documentation was provided. 4. Interview of the technical consultant conducted on December 9, 2020 at 12:00 hours in the break room confirmed the findings. She confirmed that the laboratory did not monitor quality control statistics for the Alere Triage meter over time as required.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of patient final reports, and confirmed in interview of facility personnel, the laboratory failed to run at least two levels of quantitative quality control material at least once per day of patient testing for 8 patient testing days from July 25, 2020 to August 26, 2020. The findings were: Note: The laboratory did not develop an Individualized Quality Control Plan (IQCP) for Myoglobin. Therefore, the laboratory must perform at least two levels of

	quantitative quality control materials each day of patient testing. 1. Review of the manufacturer's instructions for the Alere Triage Cardiac Panel Product Insert (PN: 2633en Rev. B, 2014/04) it stated, " ...Good laboratory practice suggests that external controls should be tested with each new lot or shipment of test materials, or every 30 days, as otherwise required by your laboratory's standard quality control procedures ..." and; "Users should follow government guidelines (for example, federal, state or local) and/or accreditation requirements for quality control." 2. Review of patient final reports from July 25, 2020 to August 26, 2020 found the following patients were tested when quality control testing was not performed: Specimen ID: ---N0003 Tested on: 07-25-2020 Myoglobin Result: 387 ng/mL (Patient Result Abnormal) Specimen ID: ---R0006 Tested on: 08-02-2020 Myoglobin Result: 89.2 ng/mL Specimen ID: ---L1001 Tested on: 08-07-2020 Myoglobin Result: 26.1 ng/mL Specimen ID: ---A0001 Tested on: 08-07-2020 Myoglobin Result: 74.7 ng/mL Specimen ID: ---A0001 Tested on: 08-20-2020 Myoglobin Result: 175 ng/mL (patient result abnormal) Specimen ID: ---I0001 Tested on: 08-22-2020 Myoglobin Result: 66.5 ng/mL Specimen ID: ---N0001 Tested on: 08-23-2020 Myoglobin Result: 27.4 ng/mL Specimen ID: ---O002 Tested on: 08-23-2020 Myoglobin Result: 376 ng/mL (patient result abnormal) 3. The laboratory was asked to provide documentation of performing at least two levels of quantitative quality control each day of patient testing for Myglobin from July 25, 2020 to August 23, 2020. No documentation was provided. 4. The findings were confirmed in interview with the Technical Consultant on December 9, 2020 at 12:00 hours. She revealed that the laboratory does not routinely test Myoglobin and that the manufacturer