Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1003540	07/26/2022
Name of Provider or Supplier	**Street Address, City, State**	
Marco Gutierrez Md And Associates	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
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policies, and interview with laboratory personnel, the laboratory failed to follow its infection control policy for one of one observed events occurring on July 26,2022. The findings included: 1. Surveyor observation on July 26, 2022 at 09:10 hours in the laboratory found 2 personal drinking items, one located next to the computer and one located on top of a laboratory refrigerator. 2. Review of the laboratory's policy title 'Infection Control Policy' approved by the laboratory director on September 1, 2016 stated, "Infection Control Policy is to ensure the avoidance of spreading infectious disease. Universal Precautions apply to blood and other body fluids containing blood..." 3. The findings were confirmed in interview with the technical consultant on July 26, 2022 at 11:30 hours in the radiology room.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's verification studies performed on the Medonic M hematology analyzer, and confirmed in staff interviews, laboratory failed to have documentation of completing verification studies on 1 of 1 new analyzers implemented in November 2021. The findings included: 1. A review of the laboratory's verification studies performed on the Medonic M Series hematology analyzer in November 2021 found the laboratory failed to have documentation of verification of patient normal ranges. As of July 22, 2022, the day of the survey, patient normal ranges had not been verified. 2. The laboratory was asked to provide documentation of the missing studies. No documentation was provided. 3. An interviews with the technical consultant on July 26, 2022 at 11:30 hours in the radiology room confirmed the findings.