

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1052653	(X3) Date Survey Completed 04/06/2022
Name of Provider or Supplier Marco Gutierrez Md And Associates	Street Address, City, State 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	The laboratory was surveyed on April 6, 2022 and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records for 2021 (events 1, 2, and 3) and 2022 (event 1), review of personnel files, and interview with laboratory personnel, the laboratory failed to ensure 1 of 2 testing personnel participated in proficiency testing for Hematology in 2021. The findings were: 1. Review of the laboratory's API Attestation records for Hematology 2021 (events 1, 2, and 3) found testing personnel #1 (as listed on Form CMS 209) performed testing each 3 of 3 events. 2. Review of the laboratory's personnel records found testing personnel #2 (as listed on Form CMS 209) has been testing since June 17, 2020. Therefore, testing personnel #2 should have participated in the 2021 proficiency testing events for Hematology. 3. The laboratory was asked to provide documentation that would exclude testing personnel #2 (as listed on Form CMS 209) from participating in any of the three Hematology testing events. No documentation was provided. 4. In an interview on April 6, 2021 at 09:51 hours in the break room with Testing Personnel #1 (as listed on Form CMS 209) 2021), he stated that he would try to do them as they came in so they did not get behind. This confirmed the findings.</p>
D5775	COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on review of laboratory instrument records, and interview with laboratory personnel, the laboratory failed to at least twice annually compare the relationship between 2 of 2 Siemens DCA Vantage analyzers used to perform Microalbumin and Creatinine in 2021. The findings included: 1. Review of the laboratory's twice annual instrument to instrument correlation records for 2020 and 2021 found the laboratory failed to compare the relationship between 2 of 2 DCA Vantage analyzers used to perform Microalbumin and Creatinine in 2021. a. 2020 records found the laboratory performed the instrument to instrument correlation studies in July 2020 and December 2020. 2. The laboratory was asked to provide documentation of performing the required instrument to instrument correlation studies at least twice annually in 2021. No documentation was provided. 3. In an interview on April 6, 2022 at 12:20 hours in the break room Testing Personnel #1 (as listed on Form CMS 209) stated he thought the technical consultant had told him he no longer had to do that. This confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services.