Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0265606	(X3) Date Survey Completed 04/13/2023
Name of Provider or Supplier Valdosta Family Medicine Associates	**Street Address, City, State** 2418 North Oak Street, Valdosta, GA	
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	A recertification survey was performed on April 13, 2023 An entrance conference was held with the laboratory representatives. The survey process was discussed, along with review of the survey forms that was sent to the facility, previous to the survey. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficencies, but none were provided. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents and staff interview, in 2022, for the Speciality Immunology, the laboratory failed to verify the accuracy of the test kit for H pylori by successfully passing two PT events for the year. Findings: 1. Review of the API PT documents for 2022, Specialty Immunology, the laboratory received a score of 50% for event 1 for H pylori, and 50% for event 3 for H pylori. 2. Interview with the lab manager, on April 13, 2023 at approximately 3pm, in the facility conference room, confirmed the aforementioned statement.
D6005	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(c) The laboratory director is responsible for the overall operation and administration of

	the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (c) The laboratory director must be accessible to the laboratory to provide onsite, telephone or electronic consultation as needed. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents for 2022, and staff interview, the laboratory failed to verify the Specialty Immunology, analyte H pylori, by receiving unsuccessful scores for event 1 and event 3 for the year. The Laboratory Director is responsible for the overall operation and administration of the laboratory. Findings: 1. Review of the API PT documents for 2022, Specialty Immunology, the laboratory received a score of 50% for event 1 for H pylori, and 50% for event 3 for H pylori. 2. Interview with the lab manager on April 13, 2023 at approximately 3pm in the facility conference room, confirmed the aforementioned statement.