

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0265606	(X3) Date Survey Completed 06/04/2021
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 Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on June 4, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents, the laboratory failed to complete attestation statements for the PT testing performance in years 2019, 2020, and 2021. Findings: 1. Review of the APT PT testing documents for 2019, there were no attestation statements for the following events: Chemistry Core, events 1,2,3 Hematology/Coagulation, events 1,2,3 Microbiology, events 1,2 Immunology, events 1,2,3 Chemistry Misc, events 1,2 2. Review of the APT, PT testing documents for 2020, there was no attestation statements for the following events: Chemistry Core, events 1,2,3 Hematology /Coagulation, events 1,2,3 Microbiology, events 1,2 Immunology, events 1,2,3 Chemistry Misc, events 1,2 3, Review of the APT, PT testing documents for 2021 there was no attestation statements for the following events: Chemistry Core, events 1 Hematology/Coagulation, events 1 Microbiology, events 1 Immunology, events 1 Chemistry Misc, events 1 4. Interview with staff #2(CMS 209) on June 4, 2021 at approximately 2:30 pm, in the Conference Room, confirmed that there were no attestation statements for 2019, 2020, and 2021 for all specialties.</p>
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) provider documents, for the years 2019, 2020, 2021 the laboratory failed to document review of the PT scores for some of the events. Findings: 1. Review of the APT PT testing documents for 2019, the laboratory failed to show review for the following specialities: Chemistry Core, events 1 and 2 Hematology/Coagulation, events 1 and 2 Microbiology, events 1 and 2 Immunology, events 1 and 2 Chemistry Misc, events 1 and 2 2. Review of the API PT testing documents for 2020, the laboratory failed to show review for the following specialties: Chemistry Core, events 2 and 3 Hematology /Coagulation, events 2 Immunology, events 2 Chemistry Misc, events 1 and 3 3. Review of the APT PT testing documents for 2021, the laboratory failed to show review for the following specialties: Immunology, event 1 4. Interview with Staff #2 (CMS form 209), on June 4, 2023, at approximately 2:30 in the Conference Room, confirmed that there was no review documents for the above mentioned events for 2019, 2020, and 2021

D6018

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iii)

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. (e) The laboratory director must-- (e)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) provider documents, for the years 2019, 2020, 2021 the laboratory Director failed to ensure that all PT evaluation reports were reviewed for some of the events. Findings: 1. Review of the APT PT evaluation documents for 2019, the laboratory failed to show review for the following specialities: Chemistry Core, events 1 and 2 Hematology/Coagulation, events 1 and 2 Microbiology, events 1 and 2 Immunology, events 1 and 2 Chemistry Misc, events 1 and 2 2. Review of the API PT evaluation documents for 2020, the laboratory failed to show review for the following specialties: Chemistry Core, events 2 and 3 Hematology/Coagulation, events 2 Immunology, events 2 Chemistry Misc, events 1 and 3 3. Review of the APT PT evaluation documents for 2021, the laboratory failed to show review for the following specialties: Immunology, event 1 4. Interview with Staff #2 (CMS form 209), on June 4, 2023, at approximately 2:30 in the Conference Room, confirmed that there was no review of the evaluation documents for the above mentioned events for 2019, 2020, and 2021