

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0663100	(X3) Date Survey Completed 08/25/2022
Name of Provider or Supplier Vidalia Medical Associates	Street Address, City, State 200 Maple Drive, Vidalia, 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 August 25, 2022. 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:
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) the laboratory failed to successfully participate in the 3rd event of 2021, and the 1st event of 2022, for the Speciality Chemistry, Subspecialty Carbon Dioxide (CO2) for 2 out of 3 events. Refer to: D2096</p>

D2096

ROUTINE CHEMISTRY

CFR(s): 493.841(f)

Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents and staff interview, the laboratory failed to successfully participate in 2021, 3rd event and the 1st event of 2022, for the Speciality Chemistry, Subspecialty Carbon Dioxide (CO₂) for 2 out of 3 events. Findings: 1. Review of the API PT documents for the year 2021, 3rd event and 2022 1st event, for the Specialty Chemistry, subspecialty, Carbon Dioxide (CO₂), the laboratory failed to successfully participate with successful results. In 2021, 3rd event the laboratory scored 60% out of 100% . In 2022, 1st event the laboratory scored 0% out of 100%. 2. Interview with staff #2, 3 and 4, (CMS form 209) on August 25, 2022 at approximately 2pm in the conference room, confirmed the aforementioned statement.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) documents and staff interview, the laboratory Director (LD) failed to address the unsuccessful participation in 2021, 3rd event and the 1st event of 2022, for the Speciality Chemistry, Subspecialty Carbon Dioxide (CO₂) for 2 of 3 events. Findings: 1. Review of the API PT documents for the year 2021, 3rd event and 2022 1st event, for the Specialty Chemistry, subspecialty, Carbon Dioxide (CO₂), the laboratory failed to successfully participate with successful results. In 2021, 3rd event the laboratory scored 60% out of 100% and in 2022, 1st event the laboratory scored 0% out of 100%. 2. Interview with staff #2, 3 and 4, (CMS form 209) on August 25, 2022 at approximately 2pm in the conference room, confirmed the aforementioned statement.