

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D1078862	<b>(X3) Date Survey Completed</b>  11/02/2023
<b>Name of Provider or Supplier</b>  Alpha Medical Llc	<b>Street Address, City, State</b>  8635 Lemont Rd, Downers Grove, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D2016</b>	<p><b>SUCCESSFUL PARTICIPATION</b> 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 CASPER Report 0155D and American Proficiency Institute (API) proficiency testing (PT) documentation the laboratory failed to successfully participate in PT for the routine chemistry analyte total cholesterol during events one and three of 2023. See D2096.</p>
<b>D2096</b>	<p><b>ROUTINE CHEMISTRY</b> CFR(s): 493.841(f)</p> <p>Failure to achieve satisfactory performance for the same analyte or test in two</p>

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 CASPER Report 0155D and review of American Proficiency Institute (API) proficiency testing (PT) documentation the laboratory failed to successfully participate in PT for the routine chemistry analyte total cholesterol during events one and three of 2023, resulting in the unsuccessful PT performance for total cholesterol. Findings include: 1. Review of the CASPER Report 0155D ran on 11-01-2023 identified the initial unsuccessful PT performance for the chemistry analyte total cholesterol. ROUTINE CHEMISTRY Cholesterol, total - EVENT-1, 2023 = 40% - Unsatisfactory Cholesterol, total - EVENT-3, 2023 = 0% - Unsatisfactory 2. Review of API PT documentation confirmed the unsuccessful PT performance for total cholesterol during events one and three of 2023.

**D6076**

**LABORATORY DIRECTOR**  
CFR(s): 493.1441

The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

This CONDITION is not met as evidenced by:

Based on review of the CASPER Report 0155D and review of American Proficiency Institute (API) proficiency testing (PT) reports the laboratory director failed to meet the requirements of this condition. The laboratory director failed to ensure test methods were performed as required to provide accurate and reliable results for the specialty of chemistry analyte total cholesterol in 2023. See D6087.

**D6087**

**LABORATORY DIRECTOR RESPONSIBILITIES**  
CFR(s): 493.1445(e)(3)(iii)

The laboratory director must ensure that laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:

Based on review of the CASPER Report 0155D and review of American Proficiency Institute (API) proficiency testing (PT) reports the laboratory director failed to ensure test methods were performed as required to provide accurate and reliable results for the specialty of chemistry analyte total cholesterol in 2023. Findings Include: 1. The laboratory failed to ensure successful participation in proficiency testing for the chemistry analyte total cholesterol during events one and three of 2023. See D2096.