

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  14D1078862	<b>(X3) Date Survey Completed</b>  07/02/2024
<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>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 Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D, Individual Laboratory Profile and review of American Proficiency Institute (API) proficiency testing (PT) reports; the laboratory failed to participate in PT event 3 of 2023 for the routine chemistry analytes, including creatinine and creatine kinase, total (CK, total), and failed to achieve satisfactory performance for creatinine and CK, total in PT event 2 of 2024; resulting in unsuccessful PT performance (event three of 2023 and event two of 2024, see D2096).</p>

<p><b>D2096</b></p>	<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 consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D, Individual Laboratory Profile, and review of American Proficiency Institute (API) proficiency testing (PT) documentation; the laboratory failed to successfully participate in PT for the routine chemistry analytes creatinine and creatine kinase, total (CK, total) during event three of 2023 and event two of 2024, resulting in the unsuccessful PT performance for creatinine and CK, total. Findings include: 1. Review of the CASPER Report 0155D, ran on 07-01-2024, identified the initial unsuccessful PT performance in the specialty of chemistry for creatinine and CK, total. ROUTINE CHEMISTRY creatinine - Event 3, 2023 = 0% - Unsatisfactory creatinine - Event 2, 2024 = 40% - Unsatisfactory CK, total - Event 3, 2023 = 0% - Unsatisfactory CK, total - Event 2, 2024 = 0% - Unsatisfactory 2. Review of API PT documentation confirmed the unsuccessful PT performance for creatinine and CK, total during event three of 2023 and event two of 2024.</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D, Individual Laboratory Profile, 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 PT samples were tested as required (see D6089).</p>
<p><b>D6089</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D, Individual Laboratory Profile, and review of American Proficiency Institute (API) proficiency testing (PT) reports; the laboratory director failed to successfully participate in PT for the routine chemistry analytes creatinine and creatine kinase, total (CK, total) during event three of 2023 and event two of 2024, resulting in the unsuccessful PT performance for creatinine and CK, total (see D2096).</p>