Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D1078862	03/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Alpha Medical Llc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (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. 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 alkaline phosphatase (ALK PHOS), resulting in unsatisfactory performance (see D2089). In addition, the laboratory failed to achieve successful performance for ALK PHOS in PT event 1 of 2024; resulting in two consecutive event failures (event three of 2023 and event one of 2024, see D2096).

D2089	ROUTINE CHEMISTRY CFR(s): 493.841(c) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3)The laboratory participated in the previous two proficiency testing events. 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 failed to participate in event three of 2023 for routine chemistry resulting in unsatisfactory analyte performance for 21 of 21 regulated chemistry analytes. Findings include: 1. Review API PT records for event three of 2023 identified the laboratory failed to participate in PT resulting in a score of 0% for the following regulated analytes: albumin, alkaline phosphatase, alanine transaminase, amylase, aspartate aminotransferase, bilirubin (total), calcium (total), chloride, cholesterol (high density lipoprotein), cholesterol (total), creatine kinase, creatinine, glucose, iron (total), lactate dehydrogenase, magnesium, potassium, sodium, total protein, triglycerides, urea nitrogen, and uric acid. 2. Review of the CASPER Report 0155D confirmed the unsatisfactory scores (0%) for the 21 routine chemistry analytes identified above.
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 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 analyte alkaline phosphatase during event three of 2023 and event one of 2024, resulting in the unsuccessful PT performance for alkaline phosphatase. Findings include: 1. Review of the CASPER Report 0155D, ran on 3-4-2024, identified the initial unsuccessful PT performance in the specialty of chemistry for alkaline phosphatase. ROUTINE CHEMISTRY alkaline phosphatase - Event 3, 2023 = 0% - Unsatisfactory alkaline phosphatase - Event 1, 2024 = 20% - Unsatisfactory 2. Review of API PT documentation confirmed the unsuccessful PT performance for alkaline phosphatase during event three of 2023 and event one of 2024.
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 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).
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. 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 (LD) failed to ensure the laboratory participated in event three of 2023 for routine chemistry resulting in unsatisfactory analyte performance for 21 of 21 regulated chemistry analytes (see D2089). The LD also failed to successfully participate in PT for the routine chemistry analyte alkaline phosphatase during event three of 2023 and event one of 2024, resulting in the unsuccessful PT performance for alkaline phosphatase (see D2096).