

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D1078862	(X3) Date Survey Completed 05/05/2020
Name of Provider or Supplier Alpha Medical Llc	Street Address, City, State 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	<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 surveyor review of CASPER Report 155 Proficiency Testing (PT) records, and phone communication with the PT vendor American Association of Bioanalysts (AAB); it was confirmed that the laboratory fail to successfully participate in the testing of PT samples under the specialty of Hematology and Diagnostic Immunology. Findings include: 1. Review of PT CASPER Report 155 on May 04, 2020 at 8:0 AM revealed that the unsatisfactory PT performance were Initial and Subsequent PT failures that occurred during the 2019 and 2020 calendar years. See D2084 and D2130.</p>

D2084

GENERAL IMMUNOLOGY

CFR(s): 493.837(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 surveyor review of CASPER Report 155 Proficiency Testing (PT) records, and phone communication with the PT vendor American Association of Bioanalysts (AAB); it was confirmed that the laboratory fail to successfully participate in the testing of PT samples under the specialty of Diagnostic Immunology. Findings include: 1. Review of PT CASPER Report 155 on May 04, 2020 at 8:00 AM, revealed that the unsatisfactory PT performance was an Initial PT failure that occurred during calendar years 2019 and 2020 as listed below. INITIAL- PT Fail Performance DIAGNOSTIC IMMUNOLOGY Syphilis Serology Event-3, 2019 = 0% Event-1, 2020 = 0% Antinuclearantibody (ANA) Event-3, 2019 = 0% Event-1, 2020 = 0% 2. During PT Desk review on May 04, 2020 and phone communication with the PT vendor AAB at 11:10 AM, the Initial PT failing scores were confirmed.

D2130

HEMATOLOGY

CFR(s): 493.851(f)

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

This STANDARD is not met as evidenced by:

Based on surveyor review of CASPER Report 155 Proficiency Testing (PT) records, and phone communication with the PT vendor American Association of Bioanalysts (AAB); it was confirmed that the laboratory failed to successfully participate in the testing of PT samples under the specialty of Hematology. Findings include: 1. Review of PT CASPER Report 155 on May 04, 2020 at 8:00 AM, revealed that the unsatisfactory PT performance was a Subsequent and multiple Initial PT failure that occurred during calendar years 2019 and 2020 as listed below. SUBSEQUENT- PT Fail Performance Plateletes Event-2, 2019 = 60% Event-3, 2019 = 0% Event-1, 2020 = 0% INITIAL- PT- Fail Performance Hematology Event-3, 2019 = 0% Event-1, 2020 = 0% Cell ID/White Blood Cell (WBC) Differential Event-3, 2019 = 0% Event-1, 2020 = 0% Erythrocyte Count Red Blood Cells (RBC) Event-3, 2019 = 0% Event-1, 2020 = 0% Microhematocrit (HCT) Event-3, 2019 = 0% Event-1, 2020 = 0% Hemoglobin (HGB) Event-3, 2019 = 0% Event-1, 2020 = 0% Leucocyte Count (WBC) Event-3, 2019 = 0% Event-1, 2020 = 0% Fibrinogen PTT Event-3, 2019 = 0% Event-1, 2020 = 0% Prothrombin Time (PT) Event-3, 2019 = 0% Event-1, 2020 = 0% 2. During PT Desk review on May 04, 2020 and phone communication with the PT vendor AAB at 11:10 AM, the Subsequent and Initial PT failing scores were confirmed.