

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0999149	(X3) Date Survey Completed 02/03/2026
Name of Provider or Supplier Alpha Clinical Laboratory, Inc	Street Address, City, State 3021 N San Fernando Blvd Ste C, Burbank, CA	
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
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and interview with the testing personnel (TP), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for the Carbon Dioxide (CO2), Alanine Aminotransferase (ALT), Phosphorus, and Cholesterol analytes. The findings include: 1. The surveyor reviewed the PT records wherein AAB-MLE reported unsatisfactory scores of the following analytes: a. 20% CO2 during the third event in 2023 (Q3-2023) Sample Result Expected 11 *26 28.0 - 41.0 12 *18 19.0 - 41.0 13 *24 25.0 - 37.0 14 24 23.0 - 35.0 15 *19 22.0 - 33.0 b. 60% ALT during the first event in 2024 (Q1-2024) Sample Result Expected 1 *24 12.0 - 18.0 2 209 169.0 - 254.0 3 157 125.0 - 187.0 4 *25 14.0 - 22.0 5 289 234.0 - 351.0 c. 60% Phosphorus during the second event in 2024 (Q2-2024) Sample Result Expected 6 5.0 4.6 - 5.7 7 3.2 3.1 - 3.8 8 *1.3 1.4 - 2.0 9 2.7 2.7 - 3.3 10 *1.8 1.9 - 2.5 d. 60% Cholesterol during the first event in 2025 (Q1-2025) Sample Result Expected 1 114 106 - 130 2 *53 54 - 66 3 *77 79 - 97 4 184 174 - 213 5 223 207 - 253 Legend: * = unsatisfactory score 2. The TP affirmed by an interview on February 3, 2026 at approximately 9:35 a.m. that the laboratory obtained the unsatisfactory PT scores for all the analytes mentioned in statement #1. 3. The accuracy and reliability of patient tests reported cannot be determined. 4. According to the laboratory's testing declaration form (Lab-144) submitted on the day of the survey, the laboratory performed approximately 2,500 CO2, 2,500 ALT, 200 Phosphorus, and 600 Cholesterol patient test samples annually including the time when the laboratory received unsatisfactory PT scores. .</p>

D2098

ENDOCRINOLOGY

CFR(s): 493.843(a)

(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the American Association of Bioanalysts - Medical Laboratory Evaluation (AAB-MLE) proficiency testing (PT) records and an interview with the testing personnel (TP), the laboratory failed to attain at least 80 percent of the acceptable score in Endocrinology for the T3 Uptake and Total Thyroxine (TT4) analytes for the second event of 2025 (Q2-2025). The findings include: 1. The surveyor reviewed the AAB-MLE PT performance evaluation documentation and found that the laboratory obtained an unsatisfactory score of 60% for the T3 Uptake and TT4 analytes in Q2-2025 event. The report is as followed: a. T3 Uptake analyte score for the Q2-2025 event: Sample Result Expected 6 44.7 33.5 - 48.2 7 33.7 31.7 - 45.6 8 *59.3 36.8 - 52.9 9 37.3 32.2 - 46.4 10 *28.4 29.3 - 42.1 b. TT4 analyte score for the Q2-2025 event: Sample Result Expected 6 *4.5 4.7 - 7.0 7 9.9 9.4- 14.1 8 *1.1 1.2- 3.2 9 7.6 7.4 - 11.0 10 12.8 12.0 - 18.1 Legend: * = unsatisfactory score 2. The TP affirmed by an interview on February 3, 2026, at approximately 9:35 a.m. that the laboratory obtained the unsatisfactory PT scores for the T3 Uptake and TT4 analytes during the Q2-2025 event as mentioned in statement #1. 3. According to the laboratory's testing declaration, the laboratory performed and reported approximately 500 T3 Uptake and 600 TT4 patient test samples annually including the time the laboratory received unsatisfactory proficiency testing scores. Thus, the accuracy and reliability of patient test reported cannot be determined. .

D6089

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part;

This STANDARD is not met as evidenced by:

Based on surveyor's review of the laboratory's proficiency testing (PT) records and an interview with the testing personnel on February 3, 2026; it was determined that the laboratory director failed to ensure that the proficiency testing was performed as required under subpart H of this part. The findings include: 1. The laboratory received unsatisfactory scores for Carbon Dioxide, Alanine Aminotransferase, Phosphorus and Cholesterol analytes in Routine Chemistry. See D2087 2. The laboratory received unsatisfactory scores for T3 Uptake and Total Thyroxine 4 analytes in the second event of 2025. See D2098