

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0960705	(X3) Date Survey Completed 12/04/2025
Name of Provider or Supplier T I M M A Diagnostic Laboratory	Street Address, City, State 5620 Wilbur Ave Ste 330, Tarzana, 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 Proficiency Institute (API) proficiency testing (PT) records and an interview+ with the office manager (OM), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for the Total Bilirubin, Magnesium and Triglycerides analytes. The findings include: 1. The surveyor reviewed the PT records wherein API reported an unsatisfactory score of the following: a. Total Bilirubin, first event of 2023 (Q1-2023) Sample Reported Expected CH-01 0.4 0.0 - 0.8 CH-02 0.1 0.0 - 0.4 CH-03 *4.9 3.0 - 4.6 CH-04 1.3 0.7 - 1.5 CH-05 *3.3 2.0 - 3.2 b. Magnesium, first event of 2024 (Q1-2024) Sample Reported Expected CH-01 *2.2 1.0 - 1.7 CH-02 4.6 2.7 - 4.7 CH-03 3.9 2.2 - 3.9 CH-04 *2.3 1.2 - 2.1 CH-05 >4.8 3.5 - 6.0 c. Triglycerides, third event of 2025 (Q3-2025) Sample Reported Expected CH-11 *164 117 - 160 CH-12 267 202 - 275 CH-13 *119 84 - 115 CH-14 178 134 - 183 CH-15 205 151 - 206 Legend: * = unsatisfactory score 2. The OM affirmed by an interview on December 4, 2025, at approximately 9:40 a.m. that the laboratory obtained the unsatisfactory PT scores for Total Bilirubin, Magnesium and Triglycerides analytes mentioned in statement #1. 3. The accuracy and reliability of patient test 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 80,665 patient test samples annually for Routine Chemistry including the Total Bilirubin, Magnesium and Triglycerides analytes during the time the laboratory received an unsatisfactory proficiency testing scores.</p>

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE

CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:

Based on the review of the laboratory's policy and procedure, American Proficiency Institute (API) proficiency testing (PT) records and an interview with the office manager (OM) on December 4, 2025; the laboratory failed to perform/document a corrective action for all analytes that achieved an unsatisfactory score of 80 percent. The findings include: 1. The laboratory failed to follow their established and approved policy and procedure for PT that stated a corrective action must be performed for any unsatisfactory scores received. 2. The laboratory obtained an unsatisfactory score of 80 percent for the following analytes and events: a. Monocyte analyte, third event of 2024 b. Alanine Transpartase and free T3, first event of 2023 c. Sodium, second event of 2023 d. Iron and Magnesium, second event of 2024 e. Carbon Dioxide and Sodium, first event of 2025 f. Creatinine and Lactate Dehydrogenase, second event of 2025 g. Magnesium and Vitamin D, third event of 2025 3. The laboratory lacked a corrective action documentation for all analytes mentioned in statement #2. 4. The OM affirmed by an interview on December 4, 2025 at approximately 9:40 a.m., that the corrective action documentation was not performed for the above unsatisfactory proficiency testing scores received by the laboratory. 5. According to the testing declaration form (Lab-144) submitted at the time of the survey, the laboratory performed and reported approximately 80,665 for Routine Chemistry and 22,480 for Hematology including the time when all unsatisfactory PT scores were received and no corrective action was documented.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(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 the surveyor's review of the American Proficiency Institute proficiency testing documentation for all event from the years 2023, 2024 and 2025, interviews with the office manager on December 4, 2025; this deficiency is herein cited for the laboratory director due to failure to ensure that proficiency testing samples were tested as required under Subpart H of this part. See D2087.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(iv)

(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory;

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's proficiency testing documentation from the American Proficiency Institute for all events in the years 2023, 2024 and 2025, and an interview with the office manager on December 4, 2025, the laboratory

director is herein cited for failing to ensure that the laboratory followed an established policy and an approved corrective action plan when any proficiency testing result received are found to be unacceptable or unsatisfactory. See D5221.