

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0602385	(X3) Date Survey Completed 09/18/2025
Name of Provider or Supplier Equaltox, Llc	Street Address, City, State 550 N Golden Circle, Ste B, Santa Ana, 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
D2076	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(b)</p> <p>(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's policy and procedure, American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the laboratory supervisor (LS); it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in General Immunology for the Rheumatoid Factor (RF) analyte. The findings include: 1. The surveyor reviewed the PT records wherein API reported an unsatisfactory score of 60% for the RF analyte in the third event of 2024. 2. The LS affirmed by an interview on September 18, 2025, at approximately 10:30 a.m. that the laboratory obtained the unsatisfactory PT scores mentioned in statement #1. 3. According to the laboratory's testing declaration form (Lab-144) submitted on the day of the survey, the laboratory performed approximately 8,700 patient test samples annually for General Immunology, including the RF analyte during the period when the unsatisfactory score was obtained. Thus, the accuracy and reliability of patient test reported cannot be determined</p>
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:</p>

Based on the surveyor's review of the laboratory's policy and procedure, American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the laboratory supervisor (LS); it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for the Alkaline Phosphatase (ALP), and Gamma-Glutamyl Transferase (GGT) analytes. The findings include: 1. The surveyor reviewed the PT records wherein API reported unsatisfactory scores for ALP and GGT analytes. The results were as follows: a. ALP PT analyte in second event of 2024 (Q2-2024), Overall score: 60% Specimen Reported Expected CH-06 184 183 - 341 CH-07 *98 100 - 187 CH-08 22 22 - 42 CH-09 *79 80 - 150 CH-10 42 40 - 76 b. GGT PT analyte in the first event of 2025 (Q1-2025), Overall score: 20% Specimen Reported Expected CH-01 *66 71 - 97 CH-02 *24 25 - 36 CH-03 *147 158 - 215 CH-04 22 22 - 33 CH-05 *45 48 - 65 Legend: * = unsatisfactory score reported 2. The LS affirmed by an interview on September 18, 2025, at approximately 10:10 a.m. that the laboratory obtained the unsatisfactory PT scores 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 17,000 patient test samples annually for Routine Chemistry, which included the ALP and GGT analytes, including the time the laboratory received unsatisfactory proficiency testing scores.

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 patient records, American Proficiency Institute proficiency testing (PT) records, and an interview with the laboratory supervisor on September 18, 2025; it was determined that the laboratory director failed to ensure that PT was performed for the years 2024 and 2025 as required under subpart H of this part. The findings include: 1. PT unsatisfactory score for Genral Immunology. See D2076 2. PT unsatisfactory score for Routine Chemsitry. See D2087