

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0930353	(X3) Date Survey Completed 03/26/2025
Name of Provider or Supplier Pasteur Inc Dba Sinai Labs	Street Address, City, State 16530 Ventura Blvd, Ste 407, Encino, 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 laboratory's policy and procedure, American Proficiency Institute (API) proficiency testing (PT) records, and an interview with the technical consultant (TC), it was determined that the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for Chloride (Cl) and Carbon Dioxide (CO2) analytes in the third event of 2023 (Q3-2023). The findings include: 1. The surveyor reviewed the PT records for Q3-2023, where API reported an unsatisfactory score. The results were as follows: a. Cl PT Q3-2023 Overall score: 60% Specimen Reported Expected CHM-11 *116 103 - 115 CHM-12 *101 89 - 100 CHM-13 110 99 - 111 CHM-14 104 97 - 108 CHM-15 104 94 - 105 b. CO2 PT Q3-2023 Overall score: 0% Specimen Reported Expected CHM-11 *46 24 - 41 CHM-12 *43 15 - 28 CHM-13 *50 21 - 37 CHM-14 *46 19 - 35 CHM-15 *46 18 - 33 Legend: * = unsatisfactory score reported 2. The TC affirmed by interview on March 26, 2025, at approximately 11:35 a.m. that the laboratory obtained the PT scores mentioned in statement #1. 3. According to the laboratory's testing declaration submitted on the day of the survey, the laboratory performed approximately 8,460 Cl and CO2 test samples during the time the laboratory received unsatisfactory proficiency testing results. Thus, the accuracy and reliability of patient test reports cannot be determined.</p>
D2127	<p>HEMATOLOGY CFR(s): 493.851(d)</p> <p>(d) Failure to return proficiency testing results to the proficiency testing program</p>

within the time frame specified by the program is unsatisfactory performance and results in a score of 0 for the testing event.

This STANDARD is not met as evidenced by:

Based on review of the American Proficiency Institute (API) proficiency testing (PT) reports and an interview with the technical consultant (TC); it was determined that the laboratory failed to return the proficiency testing results for Hematology for the third quarter event of 2023 (Q3-2023) to the proficiency testing program within the time frame specified resulting to an unsatisfactory performance score of zero percent (0%). The findings include: 1. The CASPER system showed the PT result of an unsatisfactory score of 0% for Hematology comprising of Cell ID or WBC Diff, RBC, Hct (non-waived), Hgb (non-waived), WBC count, and Platelets. 2. The TC affirmed on March 26, 2025 at approximately 11:35 a.m. that the API Hematology proficiency score for Q3 2023 of zero (0%) was was a direct result of the laboratory's failure to submit the results on time, as mandated by the program. 3. The laboratory analyzed and reported approximately 55,218 Hematology tests during the time the PT results obtained an unsatisfactory score. Thus, the accuracy and reliability of patient results reported cannot be assured.

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 American Proficiency Institute (API) 2023 proficiency testing (PT) scores in the Certification and Survey Provider Enhanced Reporting (CASPER) system, request for the laboratory's 2023 PT results, and an interview with the technical consultant (TC) on March 26, 2025 at approximately 11:35 a.m.; the laboratory failed to perform/document a corrective action for the unsatisfactory scores for Chloride (Cl) analyte, Carbon Dioxide (CO₂) analyte, and overall Hematology specialty. The findings include: 1. The laboratory obtained an unsatisfactory score of 60 percent for the Cl analyte in the third event of 2023. 2. The laboratory obtained an unsatisfactory score of 0 percent for the CO₂ analyte in the third event of 2023. 3. The laboratory failed to participate and obtained an unsatisfactory score of 0 percent for the Hematology specialty in the third event of 2023. 4. The TC affirmed by interview on March 26, 2025 at approximately 11:35 a.m., that the corrective action documentation were not performed for the above unsatisfactory proficiency testing scores mentioned in statements #1, #2, and #3. 5. The laboratory usually performs five samples for Cl and CO₂ analytes as well as in Hematology specialty per proficiency testing event.

D6018

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iii)

(e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and

This STANDARD is not met as evidenced by:

Based on the surveyor's review of the laboratory's proficiency testing records from the American Proficiency Institute for the third event of 2023 and an interview with the technical consultant on March 26, 2025 at approximately 11:35 a. m., the laboratory director is herein cited for failing to ensure that all proficiency testing reports received are reviewed to evaluate the laboratory ' s performance and to identify any problems that require corrective action. See D2087 and D2127.

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 records from the American Proficiency Institute for the third event of 2023 and an interview with the technical consultant on March 26, 2025 at approximately 11:35 a. m., the laboratory director is herein cited for failing to ensure that the laboratory followed an approved corrective action plan when any proficiency testing result received are found to be unacceptable or unsatisfactory. See D5221.