

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2278227	(X3) Date Survey Completed 08/26/2026
Name of Provider or Supplier Crimson Medical Laboratories Inc	Street Address, City, State 1575 N Lake Ave, Pasadena, 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	ROUTINE CHEMISTRY CFR(s): 493.841(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 review of the American Proficiency Institute (API) proficiency testing (PT) records, interviews with the laboratory director (LD), technical supervisor (TS) and testing personnel (TP), and review of six (6) randomly selected patient test records; the laboratory failed to attain a score of at least 80 percent of acceptable responses for the HDL cholesterol, Carbon Dioxide, and UIBC-measured analytes. The findings included: 1. The laboratory obtained unacceptable scores for the following API-PT events as follows: a. The API-PT report for the first event of 2026 (Q1-2026), the laboratory obtained a score of 60% for the analyte HDL cholesterol as follows: Sample Reported Expected Performance CH-01 62 61-93 Acceptable CH-02 19 17-30 Acceptable CH-03 50 44-67 Acceptable CH-04 38 39-60 * CH-05 104 107-161 * *Unacceptable b. The API-PT reported for the first event of 2026, (Q1-2026), an unacceptable score of 20% for the analyte UIBC, measured, and c. The API-PT reported for the third event of 2025 (Q3-2025), an unacceptable score of 20% for the Carbon Dioxide analyte. 2. The LD, TS and TP confirmed by interview on August 26, 2026, at approximately 11:00 a.m. that the laboratory obtained for HDL cholesterol for Q1-2026 the unacceptable score as stated in 1. 3. The laboratory analyzed and reported on the form LAB 144 "Laboratory Testing Declaration" signed by the laboratory director on August 26, 2026, approximately 2,000 routine chemistry test samples which included the analyte HDL cholesterol, during the time that the laboratory obtained an unacceptable API-PT report.
D5437	CALIBRATION AND CALIBRATION VERIFICATION

CFR(s): 493.1255(a)

(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (a)(2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (a)(2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on the surveyor's observation during the laboratory tour and interviews with the laboratory's director (LD), technical supervisor (TS) and testing personnel (TP); the laboratory failed to perform annual calibration of the microscope's oculars, following the manufacturer's test system instructions. The findings included: 1. The laboratory performs and reports hematology manual WBC differentials as well as microscopic examination of urine sediments. 2. The laboratory did not have any calibration records of the microscope's oculars used for manual examinations. 3. The LD, TS, and TP affirmed on August 26, 2026, at approximately 1:30 p.m. that no calibration records of the microscope oculars were found for the years 2024, 2025, and 2026. 4. According to the testing volume declaration at the time of the survey, the laboratory performed 1,900 microscopic exams for WBC differentials and urine sediments with no calibration of the microscope oculars.

D6082

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(1)

(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;

This STANDARD is not met as evidenced by:

Based on the surveyors' review of the laboratory's policies and procedures, proficiency testing results, direct observation during the laboratory tour, and interviews with the laboratory director, technical supervisor and testing personnel; the laboratory director is cited herein for failure to provide quality laboratory services for the analytic phase of testing. See D2087 and D5437.