

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1071297	(X3) Date Survey Completed 06/26/2025
Name of Provider or Supplier Ravi Shankar Md	Street Address, City, State 44215 15th St West Ste 115, Lancaster, 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 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 Partial Pressure of Carbon Dioxide (pCO2), Partial pressure of Oxygen (pO2), and pH analytes in the first event of 2025 (Q1-2025). The findings include: 1. The surveyor reviewed the PT records for Q1-2025, where API reported unsatisfactory scores for pCO2, pO2, and pH. The results were as follows: a. pCO2 PT Q1-2025 Overall score: 60% Specimen Reported Expected BG-01 67 60 - 71 BG-02 55 48 - 59 BG-03 *24 28 - 39 BG-04 *34 17 - 28 BG-05 26 19 - 30 b. pO2 PT Q1-2025 Overall score: 60% Specimen Reported Expected BG-01 60 47 - 78 BG-02 150 119 - 163 BG-03 *130 78 - 109 BG-04 *94 106 - 144 BG-05 80 66 - 97 c. pH PT Q1-2025 Overall score: 60% Specimen Reported Expected BG-01 7.14 7.11 - 7.19 BG-02 7.21 7.17 - 7.26 BG-03 *7.62 7.38 - 7.47 BG-04 *7.42 7.58 - 7.67 BG-05 7.57 7.55 - 7.63 Legend: * = unsatisfactory score reported 2. The TP affirmed by interview on June 16, 2025, at approximately 10: 10 a.m. that the laboratory obtained the PT unsatisfactory scores mentioned in statement #1. Thus, the accuracy and reliability of patient test reported cannot be determined. 3. According to the testing declaration form submitted on the day of the survey, the laboratory performed approximately 100 Blood Gas patient test samples that included pCO2, pO2, and pH analytes during the time the laboratory received unsatisfactory proficiency testing scores.</p>

D5209

PERSONNEL COMPETENCY ASSESSMENT POLICIES

CFR(s): 493.1235

As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

This STANDARD is not met as evidenced by:

Based on the surveyor's review of seven (7) patient records, lack of personnel competency documentation, and an interview with the testing personnel (TP); as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to perform competency assessments for the testing personnel (TP) prior to the start of patient testing. The findings include: 1. Surveyor's review of 7 patient records showed that competency assessment for the TP was missed to be performed for the years 2024 and 2025 prior to the start of patient testing. 2. The TP affirmed by interview on June 26, 2025, at approximately 10:25 a.m. that no competency records were available for review for the years 2024 and 2025. Thus, the quality and reliability of patient results reported could not be assured. 3. According to the testing declaration form submitted at the time of the survey, the laboratory reported and performed approximately 100 Blood Gas patient samples annually including the time when competency assessment for TP was missed.

D6036

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413

The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section.

This STANDARD is not met as evidenced by:

Based on the surveyor's findings on June 26, 2025, and an interview with the testing personnel, the laboratory director, as technical consultant, is herein cited for deficient practice in failure to provide technical and scientific oversight of the laboratory. The findings include: 1. Unsatisfactory proficiency testing score. See D2087.

D6046

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)

(b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to--

This STANDARD is not met as evidenced by:

Based on the lack of competency assessment documentation for the years 2024 and 2025, review of laboratory's policy/procedure, patient records, and an interview with the testing personnel; it was determined that the laboratory director, who also served as the technical consultant is herein cited for the deficient practice in failure to perform or document the personnel competency assessment to ensure that the

individual maintained the necessary competency to conduct test procedures in a timely, accurate, and proficient manner. See D5209.