

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0981428	(X3) Date Survey Completed 05/14/2025
Name of Provider or Supplier Samir Anabi Md / Anabi Medical Corp	Street Address, City, State 160 E Artesia St Ste 225, Pomona, 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 review of the American Proficiency Institute (API) proficiency testing (PT), the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, five (5) randomly selected patient test records, and interviews with the laboratory staff (LS); the laboratory failed to attain at least 80 percent of the acceptable score in Routine Chemistry for direct bilirubin, magnesium, and LDL cholesterol analytes for the third event in 2024 (Q3-2024). The findings include: 1. Review of PT records for Q3-2024, API reported an unsatisfactory score report as follows: Direct Bilirubin 60% Magnesium 20% and LDL Cholesterol (calculated) 0%. 2. LS confirmed by interview on May 14, 2025, at approximately 2:30 p.m. that the laboratory obtained the PT scores mentioned in statements #1. 3. According to the laboratory's testing declaration submitted on the day of the survey May 15, 2025, the laboratory performed approximately 55,000 Routine Chemistry tests including direct bilirubin, magnesium, and LDL cholesterol analytes during the time the laboratory received unsatisfactory proficiency testing results</p>
D2099	<p>ENDOCRINOLOGY CFR(s): 493.843(b)</p> <p>(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p>

This STANDARD is not met as evidenced by:
 Based on review of the America Proficiency Institute (API) proficiency testing (PT) records and the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, five (5) randomly selected patient results, and interview with the laboratory staff (LS); the laboratory failed to attain a score of at least 80 percent of acceptable responses for Endocrinology folate analyte. The finding included: 1. Based on review of PT records from API for the first event of 2025 (Q1-2025) the laboratory obtained a 0% for the folate analyte which constitutes an unacceptable performance. 2. Based on the laboratory testing declaration submitted at the time of the survey on May 14, 2025, and signed by the laboratory director on May 10, 2025, the laboratory analyzed and reported approximately 4,500 Endocrinology tests including folate analyte during the time the laboratory had unsatisfactory proficiency testing results. 3. The LS affirmed on 05/14/2024 at approximately 2:20 p.m. that the laboratory received the above unsatisfactory proficiency testing score from API.

D2122

HEMATOLOGY
 CFR(s): 493.851(b)

(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
 Based on the surveyor's review of the laboratory's American Proficiency Institute (API) proficiency testing (PT) records, the Certification and Survey Provider Enhanced Reporting (CASPER) Report 0155D Individual Laboratory Profile, five (5) random patients sampling, and interview with the laboratory staff (LS); the laboratory failed to attain a score of at least 80 percent of acceptable responses for the hematocrit analyte in Hematology on the first event of 2025 (Q1-2025) which was unsatisfactory performance for the testing event. The findings included: 1. The API proficiency program gave an overall unsatisfactory score of 0% for the hematocrit analyte for Q1-2025. 2. The LS confirmed on May 14, 2025, at approximately 2:30 p.m. that the laboratory received the above proficiency score of 0% for the hematocrit analyte for the event Q1-2025. 3. The laboratory's testing declaration form, signed by the laboratory director on 5/10/2025 stated that the laboratory performed 15,000 tests in hematology annually.

D6007

LABORATORY DIRECTOR RESPONSIBILITIES
 CFR(s): 493.1407(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 deficiencies given, the laboratory director is herein cited for deficient practice in ensuring that systems for the preanalytic, analytic, and postanalytic phases of the laboratory were monitored and followed. Findings include: 1. The laboratory received an unsatisfactory performance score for Routine Chemistry. See D2087 2. The laboratory received an unsatisfactory performance score for Endocrinology. See

D 2099 3. The laboratory received an unsatisfactory performance score for Hematology. See D2122