

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2246390	(X3) Date Survey Completed 04/27/2023
Name of Provider or Supplier Lab Quest	Street Address, City, State 2183 Fairview Rd Ste 100, Costa Mesa, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory failed at least twice annually to verify and ensure the accuracy of the test procedure it performed that is not included in subpart I of 42 CFR part 493. The findings included: a. The laboratory failed, at least twice annually, to verify and ensure the accuracy of a Covid testing procedure it performed that is not included in subpart I of 42 CFR part 493. b. The laboratory performed Covid qualitative testing using EUA Covid CFX Opus 384 Molecular Covid Testing with ATILA BioSystems reagent i-AMP and elected to enroll with API (American Proficiency Institute) proficiency testing for Covid testing to verify and ensure the accuracy of the test procedure. c. The laboratory attained a score of 0% for Covid testing in Q3 2022 API PT event which was unsatisfactory performance. d. The laboratory performed in approximately 833 patient samples monthly. e. The laboratory personnel affirmed (4/27/2023 @ 12:10 pm) that the laboratory attained a score of 0% for CFX Opus 384 Molecular Covid testing which was unsatisfactory performance and failed at least twice annually to verify and ensure the accuracy of the test procedure.</p>
D6089	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i)</p> <p>The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part.</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory's proficiency testing (PT) result reports, and interview with the laboratory personnel, it was determined that the laboratory director failed to ensure the proficiency testing samples were tested. The findings included: a. The laboratory director failed to ensure the proficiency testing samples were tested as required. b. The laboratory performed CFX Opus 384 Molecular Covid Testing, an EUA, which is not listed in the subpart I of 42 CFR part 493 and elected to enroll with API (American Proficiency Institute) proficiency testing for Covid test to verify and ensure the accuracy of the test procedure the laboratory performed. c. The laboratory attained a score of 0% for Covid EUA testing in the Q3 2022 API PT event which was unsatisfactory performance (see D-5217)