

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D2109888	(X3) Date Survey Completed 06/09/2022
Name of Provider or Supplier Capstone Clinical Laboratories Llc	Street Address, City, State 15375 Barranca Parkway, Ste F103, Irvine, 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
D2057	<p>VIROLOGY CFR(s): 493.831(b)</p> <p>Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the CMS Casper report 096 and the lack of documentation related to proficiency testing (PT) program for a single cycle and an interview with the laboratory personnel (LP), it was determined that the laboratory failed to enroll in proficiency testing (PT) for Cycle 2 of 2020. The laboratory inspection occurred on 6/9/2022 between 9 a.m. and 11 a.m. Findings include: 1. The Casper 096 report for the Cycle 2 2020 was reviewed, and there were no entries for the CMS specialties of Bacteriology (0005) and Virology (0045). 2. The LP indicated that they utilized the American Proficiency Institute (API) proficiency testing during the 2020 time period. 3. There were no API results for Cycle 2 2020 for any analytes, and there were results for Cycle 1 and Cycle 3 for 2020. 4. At approximately 10:15 a.m. on 6/9/2022, the LP affirmed that they did not complete proficiency testing (PT) for Cycle 2 of 2020.</p>
D6015	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

This STANDARD is not met as evidenced by:

Based on a review of the CMS Casper report 096 and the lack of documentation related to proficiency testing (PT) program for a single cycle and an interview with the laboratory personnel (LP), it was determined that the laboratory failed to enroll in proficiency testing (PT) for Cycle 2 of 2020. The laboratory inspection occurred on 6/9/2022 between 9 a.m. and 11 a.m. Findings include: 1. The laboratory director did not ensure that the laboratory was enrolled in an HHS approved proficiency program for each testing cycle. 2. See D 2057.