

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1071297	(X3) Date Survey Completed 02/02/2022
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
D2089	<p>ROUTINE CHEMISTRY CFR(s): 493.841(c)</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 the lab proficiency testing (PT) program, and an interview with the laboratory personnel (LP) , it was determined that the laboratory failed to submit proficiency testing (PT) over several event cycles for Chemistry during 2020 and 2021. The laboratory inspection occurred on 2/2/22 between 11 a.m. and 12:30 p.m. Findings include: 1. The Casper 096 report for the 2020-2021 was reviewed, and there was a score of 0 (zero) for several submissions. 2. The LP indicated that API (American Proficiency institute) was used for 2020 and 2021 for PT. 3. The failure to submit metrics are below: 2020 Event Cycle 3 Analyte CMS PT value Routine Chemistry 0 Ph Blood Gas 0 PO2 Blood Gas 0 PCO2 Blood Gas 0 2021 Event Cycles 1,2 and 3 Analyte CMS PT value Routine Chemistry 0 Ph Blood Gas 0 PO2 Blood Gas 0 PCO2 Blood Gas 0 4. At approximately 11:30 a.m. on 2/2/2022, the LP affirmed that there were no API proficiency report values submitted for the timeframes mentioned above. 5. There were no patients tested during the 2020 and</p>

2021 timeframes listed above. 6. Reagent controls were run during the above periods and were deemed acceptable. 7. PT testing was initiated with Event cycle 1 for 2022- lab is awaiting results. 8. Testing is moderate complexity.

D6015

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)

The laboratory director is responsible for the overall operation and administration of 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 and an interview with the laboratory personnel (LP) , it was determined that the laboratory failed to enroll in proficiency testing (PT) for Event cycle 3 of 2020 and all of 2021. The laboratory inspection occurred on 2/2/22 between 11 a.m. and 12:30 p.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 2089.