

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0577865	(X3) Date Survey Completed 03/20/2024
Name of Provider or Supplier Cheng Laboratory-Laguna Hills	Street Address, City, State 24953 Paseo De Valencia, Ste 25b, Laguna Hills, 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
D0000	Based on receipt of acceptable plan of correction the State agency recommends recertification in 400 Hematology.
D2128	<p>HEMATOLOGY CFR(s): 493.851(e)</p> <p>(1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the hematology automated analyzer testing records and interview with the testing personnel on 03/20/2024 at 3:30 PM, the laboratory failed to take the remedial action for unacceptable results of erythrocyte count, platelet count, MCH, MCV, MCHC and RWD in the 2022 3rd event. The finding include: 1) The laboratory performed Complete Blood Cell Counts (CBC) using HORIBA ABX Micros 60 Hematology Analyzer. The laboratory participated in the American Proficiency Institute (API) proficiency testing program in 2022 and 2023. The laboratory attained a score of 80% for erythrocyte count, platelet count, MCH, MCV, MCHC and RWD in the 2022 3rd event. The laboratory failed to take the remedial action for unacceptable results. Therefore, the accuracy of the laboratory's test results cannot be assured and may have potential to harm patients. 2) On 03/20/2024 at 3:30 PM, the laboratory testing personnel confirmed the laboratory did not take remedial action for unacceptable hematology results. 3) The laboratory's testing declaration form, signed by the laboratory director on 03/06/2024 stated that the laboratory performed approximately 3123 tests in hematology, annually.</p>

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on surveyor review of the hematology automated analyzer testing records and interview with the testing personnel on 03/20/2024 at 3:45 PM, the laboratory director failed to assure compliance with the applicable regulations and potentially may have harmed patients. The finding include: See 2128