

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0577865	(X3) Date Survey Completed 04/15/2021
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
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on a review of the competency reporting data and interviews with the LP, it was determined that the staff competency reports were missing for 2019 and 2020. The director is responsible for ensuring that policies and procedures are established for monitoring individuals who conduct testing. See D-6040</p>
D6040	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)</p> <p>The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for evaluation of</p>

competency reporting and an interview with laboratory personnel (LP) on 4/15//2021 between 1:30 p.m . and 3:00 p.m, it was determined that the staff competency reports for 2019 and 2020 were missing. Findings include: 1.On 4/15/2021, an inspection was conducted between 1:30 p.m. and 3:00 p.m. 2.During a review of the laboratory documentation for staff competency, the reports for the testing personnel (TP) were missing for 2019 and 2020. 3.Annual Competency reporting is required for testing personnel. 4.The findings were discussed with the LP, and they verified that the 2019 and 2020 records were absent.