

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0605512	(X3) Date Survey Completed 01/30/2019
Name of Provider or Supplier Allied Laboratories, Inc	Street Address, City, State 453 Ravendale Dr Ste B, Mountain View, 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
D6128	<p>TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)</p> <p>The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.</p> <p>This STANDARD is not met as evidenced by: Based on review of documentation for annual competency evaluation(s) for the testing personnel and interview with the laboratory manager and technical supervisor, it was determined that the technical supervisor failed to evaluate and document the performance of individuals responsible for high complexity testing at least annually after the first year unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. The findings included: a. No competency evaluation documentation could be retrieved for testing personnel performing high complexity testing in 2017 and 2018, (493-1495; Testing personnel responsibilities). b. The laboratory manger and technical supervisor confirmed on 01/30/2019 14:30 (survey date) that the laboratory had no documentation to show that the testing personnel annual competency and evaluation was performance. c. Based on the laboratory's annual testing declaration submitted for 2019, the laboratory analyzed and reported 1,345,136 patient test results.</p>