

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  05D2155294	<b>(X3) Date Survey Completed</b>  09/20/2019
<b>Name of Provider or Supplier</b>  Los Angeles Ivf Laboratory	<b>Street Address, City, State</b>  16055 Ventura Blvd, Ste 1000, Encino, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D6128</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> 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 and the lack of documentation for competency assessments and interview with the testing personnel, for five (5) out of five (5) random patient test records reviewed from 7/15/2018 to 9/10/2019, it was determined that; the Laboratory Director/Technical Supervisor failed to perform and document the performance of individuals responsible for high complexity testing at least semiannually during the first year and yearly thereafter the individual tests patient specimens. The evaluations must include but are not limited to the following: The findings included: a. There was no documentation to show that the testing personnel for five (5) out of five (5) were evaluated during the first six months and annually thereafter for Hematology. The evaluation must include following: Direct observations of the testing performed (including sample handling, processing and testing) Monitoring the recording and reporting of results Direct observation of instrument maintenance Review of intermediate worksheets, quality control records. Assessment of testing previously analyzed specimens (external QC and proficiently testing) Assessment of problem solving skills b. The testing personnel confirmed (9/20/2019, 1300) that no competency assessments were performed and documented by the Laboratory Director /Technical Supervisor.</p>