

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D2102333	<b>(X3) Date Survey Completed</b> 08/08/2018
<b>Name of Provider or Supplier</b> Dynamic Clinical Laboratories Inc	<b>Street Address, City, State</b> 516 N Larchmont Blvd, Los Angeles, 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>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's policy &amp; procedure, proficiency testing records, lack of documentation for annual test verification, and interview with the laboratory technical supervisor, the laboratory failed to verify, at least twice annually, the accuracy of the test it performs using LCMS/MS system. The findings include: a. The laboratory does testing for 54 drugs/metabolites using Agilent LCMS/MS system. The laboratory provides both qualitative and quantitative results for all of the drugs /metabolites. None of these drug test is included in the subpart I, and therefore the laboratory requires to verify the test accuracy twice annually. However, the laboratory did not have any records showing that it verifies, at least twice annually, the accuracy of any of its quantitative tests that uses the Agilent LCMS/MS system. b. On August 8, 2018 at 12:10 pm laboratory technical supervisor affirmed that the laboratory did not verify the test accuracy, at least twice annually, for its LCMS/MS system. c. The laboratory's testing declaration form, signed by the laboratory Director on July 27, 2018, stated that the laboratory performs 105,150 tests annually using the LCMS/MS system.</p>
<b>D6088</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)</p> <p>The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.</p>

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's policy & procedure, proficiency testing records, lack of documentation for annual test verification, and interview with the laboratory technical supervisor, the laboratory Director failed to ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed using the LCMS/MS system. The findings include: a. See D5217.