

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  18D2092214	<b>(X3) Date Survey Completed</b>  08/15/2019
<b>Name of Provider or Supplier</b>  Spero Health - Core Lab	<b>Street Address, City, State</b>  4545 Bishop Lane, Unit 101, Louisville, KY	
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>D5775</b>	<p>COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)</p> <p>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.</p> <p>This STANDARD is not met as evidenced by: Based on staff interview and record review on August 15, 2019, the laboratory failed to perform methods comparison between the two (2) Liquid Chromatography-Mass Spectrometry (LCMS) analyzers from August 30, 2017 through August 14, 2019. Findings include: Record review on 08/15/19, revealed there was no documented evidence the laboratory performed methods comparison between method one ( 1) and method two (2) of the Liquid Chromatography-Mass Spectrometry (LCMS) from 08 /30/17 through 08/14/19. Interview with the Laboratory Staff, on 08/15/19 at 1:59 PM, revealed the laboratory did not have a system in place to ensure the two (2) analyzers had methods comparisons performed on a six (6) month interval from 08/30 /17 through 08/14/19.</p>