

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D2095272	<b>(X3) Date Survey Completed</b>  05/27/2021
<b>Name of Provider or Supplier</b>  Kbmo Diagnostics	<b>Street Address, City, State</b>  4 Business Way, Hopedale, MA	
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>D0000</b>	A CLIA recertification survey was conducted for the KBMO Diagnostics laboratory pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493. .
<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 procedural review and interview, the laboratory failed to adequately evaluate their system that twice a year evaluated and defined the relationship between multiple analyzers performing the same type of testing as evidenced by the following: a) The laboratory performs testing on three Chromate plate readers performing general immunology and routine chemistry testing. b) The laboratory's procedure for plate reader correlation stated that, "Plate reader data must be compared twice per year, at minimum, and the degree of correlation must be assessed". c) The general supervisor confirmed in an interview on 5/27/21 at 10:25 AM that cross comparison correlations between the three plate readers had not been performed for calendar years 2019 and 2020.</p>