Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	22D2095272	02/27/2019
Name of Provider or Supplier	**Street Address, City, State**	
Kbmo Diagnostics	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	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.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to establish performance specifications for one (1) of one (1) newly implemented test systems not subject to FDA clearance as evidenced by the following: Zonulin: Specificity A review of validation studies for the Zonulin assay revealed that the laboratory failed to perform specificity studies as part of the validation. The technical supervisor stated in an interview on 2/27/19 at 9:59 a.m. that specificity studies had not been included as part of the validation. The laboratory performs 2,560 Zonulin assays annually.