Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D0919496	08/02/2022
Name of Provider or Supplier	**Street Address, City, State**	
Mosaic Diagnostics, Llc	9221 Quivira Road, Overland Park, KS	

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
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 review of the performance validation documents for the Luminex Flexmap 3D, performance validation documents for the GSD Bolt, patient test volumes, and interview, the laboratory failed to validate the reference intervals (normal values) for the 190 of 190 food IgG assays performed on the Luminex Flexmap 3D and failed to validate the reportable range and reference intervals (normal values) for the glyphosate assay performed on the GSD Bolt. Findings: 1. Review of the performance validation documents for the Luminex Flexmap 3D revealed no validation of normal values. 2. The Luminex Flexmap 3D was approved for the 190 food IgG assays by the laboratory director (LD) on 7/28/20. From 7/28/20 to 8/2/22, a volume of 8,571,280 patient test results have been reported. 3. Interview with Technical Supervisor (TS) #4 on 8/2/22 at 9:45 a.m. confirmed, the laboratory failed to validate the reference intervals (normal values) for the 190 of 190 food IgG assays performed on the Luminex Flexmap 3D were appropriate for the laboratory's patient population 4. Review of the performance validation documents for the GSD Bolt revealed no validation of the reportable range and reference intervals (normal values) for the

	glyphosate assay. 5. The GSD Bolt was approved for the glyphosate assay by the LD on 6/21/21. From 6/21/21 to 4/20/22, a volume of 3,438 patient test results have been reported. 6. Interview with TS#1 on 8/2/22 at 2:40 p.m. confirmed the laboratory failed to validate the reportable range for the glyphosate assay and failed to validate that the reference intervals (normal values) for the glyphosate assay was appropriate for the laboratory's patient population as performed on the GSD Bolt .