Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D2303234	05/29/2025
Name of Provider or Supplier	**Street Address, City, State**	
Genetikaplus Us Inc	78 John Miller Way, Kearny, NJ	

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) (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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on surveyor review of the Performance Specification (PS) records, Standard Operating Procedures, Patient Test Records and interview with the Laboratory Director (LD), the laboratory failed to ensure that all PS procedures were adequate for the NeuroKaire Pharmacogenetics (PGx) tests before reporting patient test results from 2/7/24 to 5/29/25. The findings include: 1. Patient Barcode number NK-LX35MGG whole blood sample was collected on 4/4/25. The laboratory received and processed the sample on 4/7/25. 2. Patient Barcode number NK-BPWTWCP whole blood sample was collected on 4/3/25. The laboratory received and processed the sample on 4/7/25. 3. The laboratory did not perform a stability study for samples processed greater than 24 hours after the collection date. 4. The LD confirmed on 5/29/25 at 1:00 pm, the laboratory did not perform a stability study.