Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D2272104	10/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Qugene Scientific Llc	1525 Bourbon Pkwy, Streamwood, IL	

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 direct observation, review of laboratory records, lack of documentation, and interview with testing personnel (TP) #1; the laboratory failed to establish the performance specifications for one of one laboratory developed test (LDT), Sperm DNA Fragmentation (SDF), on the BD FACSCalibur instrument (Serial Number: E5253) prior to reporting patient results, affecting 58 patients from 12/20/2022 to the survey date, 10/09/2024. Findings include: 1. Review of laboratory records revealed the laboratory failed to perform a verification of performance study for SDP testing prior to patient testing. The laboratory failed to address the following characteristics of a verification of performance study for the LDT SDP: a. Accuracy. b. Precision. c. Analytical sensitivity. d. Analytical specificity to include interfering substances. e. Reportable range of test results for the test system. f. Reference intervals (normal values). g. Any other performance characteristic required for test performance. 2. Review of laboratory testing records found 58 patient tests were reported for SDP

	from 12/20/2022 to the survey date, 10/09/2024. 3. Interview with TP #1 on 10/09 /2024, at 12:43 pm, confirmed the laboratory failed to establish the performance specifications for one of one LDT, SDF, prior to reporting patient results.