

Certificate of Analysis

Product Category Blood Glucose Test Strips

Product Part Number 99GS550U21

Lot Number 212181205

Items	Specification	Analysis Data
Precision testing 1 (Test by Normal Control Solution)	$CV \leq 5\%$	0.8%
Precision testing 2 (Test by venous blood / 90 ± 10 mg/dL)	$CV \leq 5\%$	1.5%
Linearity testing	1. The correlation coefficient (R^2) must be greater than 0.99. 2. The recovery of each sample must be between 80%~120%.	1. $R^2 = \underline{0.9979}$ 2. Recovery ratio: 1) $\underline{97.6\%}$ 2) $\underline{89.8\%}$ 3) $\underline{98.5\%}$ 4) $\underline{108.3\%}$ 5) $\underline{112.8\%}$

Final Product Evaluation: PASS 【 V 】 FAIL 【 】

Storage Condition: Store at 4-30°C

Shelf-Life: 24 months

Complying Standards: ISO 13485: 2016 and 98/79/EC and ISO 15197:2013

Dates of Manufacturing: 2021.08.12

Date Issued: 2021.08.13

Expiration Date: 2023.08.11

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