

Certificate of Analysis

Product Category Blood Glucose Test Strips

Product Part Number 99GS570U21

Lot Number 212331401

Items	Specification	Analysis Data
Precision testing 1 (Test by Normal Control Solution)	$CV \leq 5\%$	1.8%
Precision testing 2 (Test by venous blood / 90 ± 10 mg/dL)	$CV \leq 5\%$	1.8%
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. $R^2 = \underline{0.9988}$ 2. Recovery ratio: 1) $\underline{101.3\%}$ 2) $\underline{108.9\%}$ 3) $\underline{112.2\%}$ 4) $\underline{114.8\%}$ 5) $\underline{110.4\%}$

Final Product Evaluation: PASS ☒ FAIL ☐

Storage Condition: Store at 4-30°C

Shelf-Life: 24 months

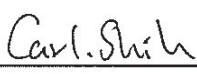
Complying Standards: ISO 13485: 2016 and 98/79/EC and ISO 15197:2013

Dates of Manufacturing: 2023.03.14

Date Issued: 2023.03.15

Expiration Date: 2025.03.13


 QA Supervisor


 QA Manager

No.: FT-82-03-0024-0004F

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