

Certificate of Analysis

Product Category Blood Glucose Test Strips

Product Part Number 99GS770U21

Lot Number 2122B1704

Items	Specification	Analysis Data
Precision testing 1 (Test by Normal Control Solution)	$CV \leq 5\%$	1.2%
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. $R^2 = \underline{0.9993}$ 2. Recovery ratio: 1) $\underline{97.7\%}$ 2) $\underline{98.8\%}$ 3) $\underline{101.3\%}$ 4) $\underline{104.3\%}$ 5) $\underline{108.5\%}$

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

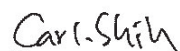
Dates of Manufacturing: 2022.11.17

Date Issued: 2022.11.18

Expiration Date: 2024.11.16



 QA Supervisor



 QA Manager