

Certificate of Analysis

Product Category Blood Glucose Test Strips

Product Part Number 99GS770U21

Lot Number 212130316

Items	Specification	Analysis Data
Precision testing 1 (Test by Normal Control Solution)	$CV \leq 5\%$	1.4%
Precision testing 2 (Test by venous blood / 90 ± 10 mg/dL)	$CV \leq 5\%$	1.3%
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. $R^2 = \underline{0.9994}$ 2. Recovery ratio: 1) $\underline{98.5\%}$ 2) $\underline{107.4\%}$ 3) $\underline{107.3\%}$ 4) $\underline{113.0\%}$ 5) $\underline{110.2\%}$

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: 2021.03.04

Date Issued: 2021.03.05

Expiration Date: 2023.03.03

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