

Certificate of Analysis

Product Category	Blood Glucose Test Strips
Product Part Number	99GS570U21
Lot Number	2123C2601

Items	Specification	Analysis Data
Precision testing 1 (Test by Normal Control Solution)	CV≤5%	1.4%
Precision testing 2 (Test by venous blood / 90±10 mg/dL)	CV≤5%	1.6%
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. $R^2 = \underline{0.9970}$ 2. Recovery ratio: 1) <u>96.3%</u> 2) <u>107.5%</u> 3) <u>109.3%</u> 4) <u>112.2%</u> 5) <u>112.3%</u>

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: 2024.01.04

Date Issued: 2024.01.05

Expiration Date: 2026.01.03

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