

Certificate of Analysis

Product Category Blood Glucose Test Strips

Product Part Number 99GS700R21

Lot Number 212191101

Items	Specification	Analysis Data
Precision testing 1 (Test by Normal Control Solution)	$CV \leq 5\%$	1.7%
Precision testing 2 (Test by venous blood / 90 ± 10 mg/dL)	$CV \leq 5\%$	1.4%
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. $R^2 = 0.9981$ 2. Recovery ratio: 1) <u>98.7%</u> 2) <u>101.2%</u> 3) <u>102.8%</u> 4) <u>108.2%</u> 5) <u>109.8%</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: 2021.09.10

Date Issued: 2021.09.11

Expiration Date: 2023.09.09

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