

# Certificate of Analysis

Product Category Blood Glucose Test Strips

Product Part Number 99GS550U21

Lot Number 212152803

Items	Specification	Analysis Data
Precision testing 1 (Test by Normal Control Solution)	$CV \leq 5\%$	1.9%
Precision testing 2 (Test by venous blood / $90 \pm 10$ mg/dL)	$CV \leq 5\%$	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. $R^2 = \underline{0.9985}$ 2. Recovery ratio: 1) <u>95.0%</u> 2) <u>90.1%</u> 3) <u>98.0%</u> 4) <u>109.1%</u> 5) <u>111.5%</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: 2021.05.27

Date Issued: 2021.05.28

Expiration Date: 2023.05.26

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