

Certificate of Analysis

Product Category Blood Glucose Test Strips

Product Part Number 99GS550U21

Lot Number 212173106

| Items | Specification | Analysis Data |
|---|---|--|
| Precision testing 1 (Test by Normal Control Solution) | $CV \leq 5\%$ | 1.5% |
| 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. $R^2 = \underline{0.9969}$ 2. Recovery ratio: 1) $\underline{95.1\%}$ 2) $\underline{93.9\%}$ 3) $\underline{95.8\%}$ 4) $\underline{102.4\%}$ 5) $\underline{112.8\%}$ |

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: 2021.07.30

Date Issued: 2021.08.02

Expiration Date: 2023.07.29

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