

Certificate of Analysis

Product Category Blood Glucose Test Strips

Product Part Number 99GS570U21

Lot Number 2123B2801

Items	Specification	Analysis Data
Precision testing 1 (Test by Normal Control Solution)	$CV \leq 5\%$	1.6%
Precision testing 2 (Test by venous blood / 90 ± 10 mg/dL)	$CV \leq 5\%$	1.9%
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. $R^2 = \underline{0.9987}$ 2. Recovery ratio: 1) $\underline{98.7\%}$ 2) $\underline{115.1\%}$ 3) $\underline{117.7\%}$ 4) $\underline{114.7\%}$ 5) $\underline{115.6\%}$

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: 2023.11.28

Date Issued: 2023.11.29

Expiration Date: 2025.11.27

Guo-Lu
QA Supervisor

Carl Shih
QA Manager

No.: FT-82-03-0024-0004F

BIONIME CORPORATION
No. 100, Sec. 2, Daqing St., South Dist.,
Taichung City 40242, Taiwan
P 886 4 23692388 F 886 4 22617586