

Certificate of Analysis

Product Category Blood Glucose Test Strips

Product Part Number 99GS700R21

Lot Number 212012005

Items	Specification	Analysis Data
Precision testing 1 (Test by Normal Control Solution)	$CV \leq 5\%$	1.1%
Precision testing 2 (Test by venous blood / 90 ± 10 mg/dL)	$CV \leq 5\%$	1.7%
	1. The correlation coefficient (R^2)	1. $R^2 = 0.9993$
Linearity testing	2. The recovery of each sample must be greater than 0.99. 2. The recovery of each sample must be between 80%~120%.	2. Recovery ratio: 1) <u>97.4%</u> 2) <u>108.6%</u> 3) <u>107.6%</u> 4) <u>108.1%</u> 5) <u>111.9%</u>

Final Product Evaluation: PASS ☒ 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: 2020.01.20

Date Issued: 2020.01.21

Expiration Date: 2022.01.18

Guo Gu
QA Supervisor

Carol. Chao
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