BIONIME

Certificate of Analysis

Product Category: Blood Glucose Test Strips

Product Part Number: 99GS700R51

Lot Number: 212012002

Items	Specification	Analysis Data
Precision testing 1 (Test by Normal Control Solution)	CV≦5%	1.6%
Precision testing 2 (Test by venous blood / 90±10 mg/dL)	CV≦5%	1.5%
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 = 0.9995 2. Recovery ratio: 1) 95.1% 2) 108.9% 3) 109.7% 4) 113.9% 5) 112.2%

Final Product Evaluation: PASS【 V 】 FAIL【 】

Storage Condition: Store at 4-30℃

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

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