

## CERTIFICATE OF ANALYSIS

### I Product Information:

**Product name:** Dengue Ag Rapid Test (Cassette)  
**Catalog No. :** R0063C  
**Lot No. :** F0218T16F00  
**Manufacture date:** 2022.02.21  
**Expiration date:** 2024.02.20  
**Sample diluent:** Catalog: SB-R0063, Lot: S013037-162, Exp.: 2024.08.27  
**Storage:** Room temperature (2-30°C)

### II Applicable Inspection and Evaluation of Specification:

#### 1. Physical Inspection:

<u>Test Description</u>	<u>Acceptance Criteria</u>	<u>Test Results</u>
a. Label	Ac ≤ 1	0
b. Pouch	Ac ≤ 5	0
c. Desiccant in the pouch	Ac ≤ 5	0
d. Cassette in the pouch	Ac ≤ 5	0
e. Label on the cassette	Ac ≤ 5	0
f. Sample diluent	Ac ≤ 1	0
g. Plastic droppers	Ac ≤ 1	0
h. Insert	Ac ≤ 1	0

Note: Ac (Acceptance Number) is the maximum allowable defectives in a sample for the lot to be accepted based on the sampling plan.

#### 2. Performance Characteristic Inspection:

<u>Test Description</u>	<u>Level</u>	<u>Acceptance</u>	<u>Criteria</u>	<u>Test Results</u>
a. Positivity	2 positive samples		Both positive	Both positive
	1 whole blood positive sample		Positive	Positive
b. Negative	20 negative samples		All negative	All negative
c. LOD	Dengue type I L1-L2		Positive	Positive
	Dengue type II L4-L5		Positive	Positive
	Dengue type III L7-L8		Positive	Positive
	Dengue type IV L10-L11		Positive	Positive
	Type I L3		Positive/Negative	Negative
	Type II L6		Positive/Negative	Negative
	Type III L9		Positive/Negative	Negative
	Type IV L12		Positive/Negative	Negative
d. Precision	10 replicates		Uniformed band	Uniformed band
e. Sample diluent	SB-R0063		Negative	Negative
f. Background	Female blood	10 replicates	Clear	Clear
	Male blood	10 replicates	Clear	Clear
g. Flow rate	Completion of run in membrane		In 3 minutes	In 3 minutes

### III Comments:

All data are from QC test of manufacturer unless otherwise indicated.

### IV Safety Certification:

There is no biohazard materials utilized in this product, no radioactive materials, no narcotic reagents, neither their derivatives, no virus neither their reagent, nor metabolic by-products.

### V Disposition:

Released [ ☒ ]

Rejected [ ☐ ]

Sandy Liu

2022.02.24

Sandy Liu(QA representative)

Date