

## CERTIFICATE OF ANALYSIS

### I Product Information:

**Product name:** Dengue IgG/IgM Combo Rapid Test (Cassette)  
**Catalog No. :** R0061C  
**Lot No. :** F0418T1J01DR1  
**Manufacture date:** 2022.04.19  
**Expiration date:** 2024.04.18  
**Sample diluent:** Catalog: SB-R0061, Lot: S013328-162, Exp.: 2024.11.08  
**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. Sample diluent	$Ac \leq 0$	0
b. Pouch	$Ac \leq 1$	0
c. Desiccant in the pouch	$Ac \leq 1$	0
d. Cassette in the pouch	$Ac \leq 1$	0
e. Label on the cassette	$Ac \leq 1$	0
f. 5 $\mu$ L capillary tubes	$Ac \leq 0$	0
g. Insert	$Ac \leq 0$	0
h. Label	$Ac \leq 0$	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-IgG +IgM positive samples		Both positive	Both positive
	1 IgG+IgM whole blood positive sample		Positive	Positive
b. Negative	20 negative samples		All negative	All negative
c. LOD	R0061-L1(IgG)		Positive	Positive
	R0061-L2(IgG)		Positive	Positive
	R0061-L3(IgG)		Positive/negative	Negative
	R0061-L4(IgM)		Positive	Positive
	R0061-L5(IgM)		Positive	Positive
	R0061-L6(IgM)		Positive/negative	Negative
d. Precision	10 replicates (IgG+IgM)		Uniformed band	Uniformed band
e. Sample diluent	SB-R0061		Negative	Negative
f. Background	Female blood	10 replicates	Clear	Clear
	Male blood	10 replicates	Clear	Clear

### 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

Sandy Liu(QA representative)

2022.06.18

Date