

CERTIFICATE OF ANALYSIS

I. Product Information:

Product name: Duo Dengue Ag-IgG/IgM Rapid Test (Cassette)
Catalog No. : R0062C
Lot No. : F0412T3L05DR1
Manufacture date: 2022.04.13
Expiration date: 2024.04.12
Sample diluent: Catalog: SB-R0062, 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. Label	$Ac \leq 0$	0
b. Plastic droppers	$Ac \leq 0$	0
c. 5µL capillary tubes	$Ac \leq 0$	0
d. Sample diluent	$Ac \leq 0$	0
e. Insert	$Ac \leq 0$	0
f. Pouch	$Ac \leq 1$	0
g. Desiccant in the pouch	$Ac \leq 1$	0
h. Cassette in the pouch	$Ac \leq 1$	0
i. Label on the cassette	$Ac \leq 1$	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>Acceptance</u>	<u>Test Results</u>
Dengue Ag	Level	Criteria
a. Positivity	2 positive samples	Both positive
	1 whole blood positive sample	Positive
b. Negativity	20 negative samples	All negative
c. LOD	Dengue type I L1-L2	Positive
	Dengue type II L4-L5	Positive
	Dengue type III L7-L8	Positive
	Dengue type IV L10-L11	Positive
	Type I L3	Positive/Negative
	Type II L6	Positive/Negative
	Type III L9	Positive/Negative
	Type IV L12	Positive/Negative
d. Precision	10 replicates	Uniformed band
e. Sample diluent	SB -R0062	Negative
f. Background	Female blood 10 replicates	Clear
	Male blood 10 replicates	Clear
g. Flow rate	Completion of run in membrane	In 3 minutes

<u>Test</u>		<u>Acceptance</u>		<u>Test Results</u>	
<u>Description</u>					
Dengue IgG/IgM	Level	IgG	IgM	IgG	IgM
a. Positivity	2 positive samples 1 whole blood positive sample	Both positive Positive	Both positive Positive	Both positive Positive	Both positive Positive
b. Negative	20 negative samples	All negative	All negative	All negative	All negative
c. LOD	L1(IgG) L2(IgG) L3(IgG) L4(IgM) L5(IgM) L6(IgM)	Positive Positive Positive/negative Negative Negative Negative	Negative Negative Negative Positive Positive Positive/negative	Positive Positive Negative Negative Negative Negative	Negative Negative Negative Positive Positive Negative
d. Precision	10 replicates (IgG+IgM)	Uniformed band		Uniformed band	
e. Sample diluent	SB-R0062	Negative		Negative	
f. Background	Female blood 10 replicates Male blood 10 replicates	Clear Clear		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

Sandy Liu(QA representative)

2022.06.18

Date