

CERTIFICATE OF ANALYSIS

I. Product Information:

Product name: Duo Dengue Ag-IgG/IgM Rapid Test (Cassette)
Catalog No.: R0062C
Lot No.: F0712V1L06
Manufacture date: 2024.07.15
Expiration date: 2026.07.14
Sample diluent: Catalog: SB-R0062, Lot:S015973-162, Exp.: 2027.04.17
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 ≤ 7	0
b. Plastic droppers	Ac ≤ 7	0
c. 5µL capillary tubes	Ac ≤ 7	0
d. Sample diluent	Ac ≤ 7	0
e. Insert	Ac ≤ 7	0
f. Pouch	Ac ≤ 7	0
g. Desiccant in the pouch	Ac ≤ 7	0
h. Cassette in the pouch	Ac ≤ 7	0
i. Label on the cassette	Ac ≤ 7	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>Criteria</u>	<u>Test Results</u>
Dengue Ag	Level	Criteria	Ag
a. Positivity	2 positive samples 1 whole blood positive sample	Both positive Positive	Both positive Positive
b. Negativity	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 -R0062	Negative	Negative
f. Specificity	50 clinical samples	Positive Rate ≤ 6%	0%
g. Background	Female blood	10 replicates Clear	Clear
	Male blood	10 replicates Clear	Clear
h. Flow rate	Completion of run in membrane	In 3 minutes	In 3 minutes

<u>Test Description</u>	<u>Acceptance</u>	<u>IgG</u>	<u>IgM</u>	<u>Test Results</u>	
Dengue IgG/IgM	Level			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)	Positive	Negative	Positive	Negative
	L2(IgG)	Positive	Negative	Positive	Negative
	L3(IgG)	Positive/negative	Negative	Positive	Negative
	L4(IgM)	Negative	Positive	Negative	Positive
	L5(IgM)	Negative	Positive	Negative	Positive
	L6(IgM)	Negative	Positive/negative	Negative	Positive
d. Precision	10 replicates (IgG+IgM)	Uniformed band		Uniformed band	
e. Sample diluent	SB-R0062	Negative		Negative	
f. Specificity	50 clinical samples	Positive Rate ≤ 6%		0%	
g. Background	Female blood 10 replicates	Clear		Clear	
	Male blood 10 replicates	Clear		Clear	
h. 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 are 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)

2024.07.24

Date