

CERTIFICATE OF ANALYSIS

I. Product Information:

Product name: Malaria Pf / Pan Ag Rapid Test (Cassette)
Catalog No.: R0113C
Lot No.: F0712V3J00
Manufacture date: 2024.07.15
Expiration date: 2026.07.14
Blood lysis buffer: Catalog: SB-R0113, Lot: S016209-106, Exp.: 2027.07.14
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. Pouch	Ac ≤ 7	0
c. Inset	Ac ≤ 7	0
d. 5 µL blood transfer devices	Ac ≤ 7	0
e. Blood lysis buffer	Ac ≤ 7	0
f. Desiccant in the Pouch	Ac ≤ 7	0
g. Cassette in the Pouch	Ac ≤ 7	0
h. 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>Level</u>	<u>Acceptance</u>	<u>Criteria</u>	<u>Test Results</u>
a. Positivity	1 Pf positive sample (Pf: HRP- II)		Positive	Positive
	1 Pan positive sample (Pan: Pf-LDH)		Positive	Positive
	1 Pan positive sample(Pan : Pv-LDH)		Positive	Positive
b. Negativity	20 negative samples		All negative	All negative
c. Precision	10 replicates test (Pf: HRP- II)		Uniformed band	Uniformed band
	10 replicates test (Pan: Pf-LDH)		Uniformed band	Uniformed band
	10 replicates test (Pan: Pv-LDH)		Uniformed band	Uniformed band
d. LOD	R0113-L1(Pf: HRP- II)		Positive	Positive
	R0113-L2(Pf: HRP- II)		Positive	Positive
	R0113-L3(Pf: HRP- II)		Positive/Negative	Negative
	R0113-L4(Pan: Pf-LDH)		Positive	Positive
	R0113-L5(Pan: Pf-LDH)		Positive	Positive
	R0113-L6(Pan: Pf-LDH)		Positive/Negative	Negative
	R0113-L7(Pan: Pv-LDH)		Positive	Positive
	R0113-L8(Pan: Pv-LDH)		Positive	Positive
	R0113-L9(Pan: Pv-LDH)		Positive/Negative	Negative
e. Blood lysis buffer	SB-R0113		Negative	Negative
f. Background	5 Female blood	5 replicates	Clear	Clear
	5 Male blood	5 replicates	Clear	Clear
g. Flow Rate	Completion of run in membrane		In 2 minutes	In 2 minutes

III. Comments:

All data are from Q.C. test 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)

2024.07.25

Date