

CERTIFICATE OF ANALYSIS

I. Product Information:

Product name: HIV 1/2 Ab Plus Combo Rapid Test (Cassette)
Catalog No.: R0011C
Lot No.: F0327W4E03
Manufacture date: 2025-03-28
Expiration date: 2027-03-27
Sample diluent: Catalog: SB-R0011, Lot: S016681-212, Exp.: 2027-12-02
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 ≤ 10	0
b. Pouch	Ac ≤ 10	0
c. Desiccant in the pouch	Ac ≤ 10	0
d. Cassette in the pouch	Ac ≤ 10	0
e. Label on the cassette	Ac ≤ 10	0
f. 20µL capillary tubes	Ac ≤ 10	0
g. Sample diluent	Ac ≤ 10	0
h. Insert	Ac ≤ 10	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	10 HIV-1 positive samples		All positive	All positive
	2 HIV-2 positive samples		Both positive	Both positive
	1 HIV-1 whole blood positive sample		Positive	Positive
	1 HIV-2 whole blood positive sample		Positive	Positive
b. Negativity	20 negative samples		All negative	All negative
c. LOD	R0011-L1 (HIV-1)	20 replicates	Positive rate =100%	100%
	R0011-L2 (HIV-1)	20 replicates	Positive rate ≥95%	100%
	R0011-L3 (HIV-1)	20 replicates	Positive rate =10%-90%	40%
	R0011-L4 (HIV-2)	20 replicates	Positive rate =100%	100%
	R0011-L5 (HIV-2)	20 replicates	Positive rate ≥95%	95%
	R0011-L6 (HIV-2)	20 replicates	Positive rate =10%-90%	10%
d. Precision	10 replicates (HIV-1)		Uniformed band	Uniformed band
	10 replicates (HIV-2)		Uniformed band	Uniformed band
e. Sample diluent	SB-R0011		Negative	Negative
f. Specificity	200 negative samples		100% Negative	100%
g. Background	Female blood	10 replicates	Clear	Clear
	Male blood	10 replicates	Clear	Clear
h. Flow rate	Completion of run in membrane		In 2 minutes	In 2 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)

2025-04-07

Date