

CERTIFICATE OF ANALYSIS

I. Product Information:

Product name: HIV 1/2 Ab Plus Combo Rapid Test (Cassette)
Catalog No. : R0011C
Lot No. : –F0210T6A00
Manufacture date: 2021.12.16
Expiration date: 2023.12.15
Sample diluent: Catalog: SB-R0011, Lot: S013499-211, Exp.: 2024.12.16
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. Plastic dropper	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>Sample Code</u>	<u>Sample Type</u>	<u>Acceptance Criteria</u>	<u>Results</u>	
a.	LoD of HIV-1 samples	R0011-P1 (HIV-1)	Whole blood	20 replicates, positive rate ≥95%.	100%
		R0011-P2 (HIV-1)	Whole blood	20 replicates, positive rate =60±20%.	65%
		R0011-L1 (HIV-1)	Serum	20 replicates, positive rete =100%.	100%
		R0011-L2 (HIV-1)	Serum	20 replicates, positive rate ≥95%.	100%
		R0011-L3 (HIV-1)	Serum	20 replicates, positive rate =60±20%.	70%
		R0011-L4 (HIV-1)	Serum	20 replicates, positive rate <40%.	5%
		R0011-L5 (HIV-1)	Plasma	20 replicates, positive rate =100%.	100%
		R0011-L6 (HIV-1)	Plasma	20 replicates, positive rate ≥95%.	100%
		R0011-L7 (HIV-1)	Plasma	20 replicates, positive rate =60±20%.	60%
	R0011-L8 (HIV-1)	Plasma	20 replicates, positive rate <40%.	0%	
	LoD of HIV-2 samples	R0011-P3 (HIV-2)	Whole blood	20 replicates, positive rate ≥95%.	100%
		R0011-P4 (HIV-2)	Whole blood	20 replicates, positive rate =60±20%.	60%
		R0011-L9 (HIV-2)	Serum	20 replicates, positive rete =100%.	100%
		R0011-L10 (HIV-2)	Serum	20 replicates, positive rate ≥95%.	100%
		R0011-L11 (HIV-2)	Serum	20 replicates, positive rate =60±20%.	65%
		R0011-L12 (HIV-2)	Serum	20 replicates, positive rate <40%.	0%
		R0011-L13 (HIV-2)	Plasma	20 replicates, positive rete =100%.	100%
		R0011-L14 (HIV-2)	Plasma	20 replicates, positive rate ≥95%.	100%
		R0011-L15 (HIV-2)	Plasma	20 replicates, positive rate =60±20%.	50%
	R0011-L16 (HIV-2)	Plasma	20 replicates, positive rate <40%.	0%	
LoD of HIV-O samples	R0011-P5 (HIV-O)	Whole blood	20 replicates, positive rate ≥95%.	100%	
	R0011-P6 (HIV-O)	Whole blood	20 replicates, positive rate =60±20%.	75%	
	R0011-L17 (HIV-O)	Plasma	20 replicates, positive rete =100%.	100%	
	R0011-L18 (HIV-O)	Plasma	20 replicates, positive rate ≥95%.	100%	
	R0011-L19 (HIV-O)	Plasma	20 replicates, positive rate =60±20%.	70%	
R0011-L20 (HIV-O)	Plasma	20 replicates, positive rate <40%.	0%		
b.	Cross-reactivity samples	R0011-C1 (HBsAg strong positive)	Plasma	1 replicate, result is negative.	Negative
		R0011-C2 (HBsAg strong positive)	Plasma	1 replicate, result is negative.	Negative

		R0011-C3 (HCV Strong positive)	Plasma	1 replicate, result is negative.	Negative
		R0011-C4 (HCV Strong positive)	Plasma	1 replicate, result is negative.	Negative
		R0011-C5 (Syphilis Strong positive)	Plasma	1 replicate, result is negative.	Negative
		R0011-C6 (Syphilis Strong positive)	Plasma	1 replicate, result is negative.	Negative
c.	Clinical negative samples	R0011-NI~N200	Plasma	Negative rate \geq 99.5%.	100%

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)

2022.06.29

Date