

CERTIFICATE OF ANALYSIS

I. Product Information:

Product name: Strep A Rapid Test (Cassette)
Catalog No. : R0184C
Lot No. : F0920T6A00
Manufacture date: 2022.09.27
Expiration date: 2024.09.26
Extraction Reagent A: Catalog: SB-R0184A, Lot: F0920T6A00-A Exp.: 2024.09.26
Extraction Reagent B: Catalog: SB-R0184B, Lot: F0920T6A00-B Exp.: 2024.09.26
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 ≤ 5	0
b. Pouch	Ac ≤ 5	0
c. Insert	Ac ≤ 5	0
d. Sample extraction tubes	Ac ≤ 5	0
e. Extraction reagent A	Ac ≤ 5	0
f. Extraction reagent B	Ac ≤ 5	0
g. Sterile swabs	Ac ≤ 5	0
h. Strep A Positive Control	Ac ≤ 5	0
i. Strep A Negative Control	Ac ≤ 5	0
j. Desiccant in the Pouch	Ac ≤ 5	0
k. Cassette in the Pouch	Ac ≤ 5	0
l. Label on the Cassette	Ac ≤ 5	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 positive sample		Positive	Positive
b. Negativity	10 negative samples		All negative	All negative
c. Precision	10 replicates test		Uniformed band	Uniformed band
d. LOD	R0184-L1		Positive	Positive
	R0184-L2		Positive	Positive
	R0184-L3		Negative	Negative
e. Positive Control	R0184-P		Positive	Positive
f. Negative Control	R0184-N		Negative	Negative
g. Extraction Reagent	SB-R0184A/SB-R0184B		Negative	Negative
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 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)

2022.10.08

Date