

CERTIFICATE OF ANALYSIS

I. Product Information:

Product name: FOB Rapid Test (Cassette) (50 ng/ml)
Catalog No. : R2010C
Lot No. : F0301U2D00D
Manufacture date: 2023.03.04
Expiration date: 2025.03.03
Extraction buffer: Catalog: SB-R2010, Lot: S014722-161, Exp.: 2026.01.04
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. Pouch	Ac ≤ 5	0
b. Label	Ac ≤ 5	0
c. Insert	Ac ≤ 5	0
d. Extraction buffer	Ac ≤ 5	0
e. Patient ID stickers	Ac ≤ 5	0
f. Desiccant in the Pouch	Ac ≤ 5	0
g. Cassette in the Pouch	Ac ≤ 5	0
h. Label on the Cassette	Ac ≤ 5	0

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 Criteria</u>	<u>Test Results</u>
a. Negativity	10 negative samples	All negative	All negative
b. Positivity	10 positive samples	All positive	All positive
c. Precision	10 replicates	Uniformed band	Uniformed band
d. LOD	R2010-L1(100ng/ml) R2010-L2(50ng/ml) R2010-L3(25ng/ml)	Positive Positive Positive/Negative	Positive Positive Positive
e. Hook effect(4mg/ml)	3 replicates	All positive	All positive
f. Extraction buffer	SB-R2010	Negative	Negative
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)

2023.03.14

Date