

CERTIFICATE OF ANALYSIS

I Product Information:

Product name: OnSite COVID-19 IgG/IgM Rapid Test
Catalog No. : R0180C
Lot No. : F0316R2A00
Manufacture date: 2020.03.09
Expiration date: 2021.03.08
Storage: Room temperature (2-30°C)
Extraction buffer Catalog: SB-R0180, Lot: F0316R2A00, Exp.: 2021.03.08

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 ≤ 0	0
b. Pouch	Ac ≤ 3	0
c. Desiccant in the pouch	Ac ≤ 3	0
d. Cassette in the pouch	Ac ≤ 3	0
e. Label on the cassette	Ac ≤ 3	0
f. Detection buffer	Ac ≤ 0	0
g. Plastic droppers	Ac ≤ 0	0
h. Insert	Ac ≤ 0	0

AC (Acceptance Number) is the maximum allowable defectives in a sample for the lot to be accepted based on the inspection plan.

2. Performance Characteristic Inspection:

<u>Test Description</u>		<u>Criteria</u>	<u>Test Results</u>	
a. Positivity	IgG	R0180-P1	Positive	Positive
		R0180-P2	Positive	Positive
		R0180-P3	Positive	Positive
	IgM	R0180-P4	Positive	Positive
		R0180-P5	Positive	Positive
		R0180-P6	Positive	Positive
b. LOD	IgG	R0180-L1	Positive	Positive
		R0180-L2	Positive	Positive
		R0180-L3	Positive/negative	Positive
	IgM	R0180-L4	Positive	Positive
		R0180-L5	Positive	Positive
		R0180-L6	Positive/negative	Positive
c. Detection buffer	SB-R0180	Negative	Negative	
d. Specificity	30 clinical samples	All negative	All negative	
e. Precision	IgG 10 replicates	Uninformed band	Uninformed band	
	IgM 10 replicates	Uninformed band	Uninformed band	
f. Background	Female blood 10 replicates	Clear	Clear	
	Male blood 10 replicates	Clear	Clear	

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 []


Shuwu Han (QA Manager)

2020.03.18

Date