Clinical Study Report
for
SARS-CoV-2 Antigen Rapid Test

I. Intend for Use

The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first seven days of the onset of symptoms. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

II. Objective

A multi-site clinical study was conducted in China and USA to evaluate the performance of the SARS-CoV-2 Antigen Rapid Test when compared to RT-PCR method.

III. Clinical Study Site and Study Period

Clinical Study Sites in USA:

Sample collection sites in USA	Testing sites in USA
Site 1: Boca Raton 6877 SW 18th Street Boca Raton, FL 33433	Site 1: 7200 Parkway drive Suite 117, La Mesa, CA91942
Site 2: COVID CLINIC Westminster (WM) 2109 Westminster Mall Westminster, CA 92683	Site 2: COVID CLINIC Westminster (WM) 2109 Westminster Mall Westminster, CA 92683
Site 3: COVID CLINIC La Mesa (LM) 5601 Grossmont Center Drive La Mesa, CA 91942	Site 3: COVID CLINIC La Mesa (LM) 5601 Grossmont Center Drive La Mesa, CA 91942
Site 4: COVID CLINIC Down Town San Diego 1350 Third Avenue San Diego - San Diego County	Site 4: COVID CLINIC Down Town San Diego 1350 Third Avenue San Diego - San Diego County

Clinical Study Sites in China:

Sample collection sites in China	Testing sites in China
Site 1: Shenzhen CDC No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China	Site 1: Shenzhen CDC No. 8 Longyuan Road, Nanshan District, Shenzhen, P.R. China
Site 2: Adicon No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China	Site 2: Adicon No.208 Zhenzhong Road, West Lake District, Hangzhou, Zhejiang, P.R. China

Study Period

Study Initiation Date: Sep, 2020

Study Completion Date: Dec, 2020

IV. Study acceptance criteria

Total Sensitivity: ⩾85%

Total Specificity: ⩾99%

V. Study Procedure:

The clinical performance of the SARS-CoV-2 Antigen Rapid Test was evaluated at four (4) investigational sites in U.S and two (2) investigational sites in China using a total of 577 nasal swab specimens collected from the patients at multiple sites in U.S and China.

5.1 Clinical Study in USA

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- Comparison method: TaqPath COVID-19 Combo Kit, FDA authorized RT-PCR test for emergency use, manufactured by Thermo Fisher Scientific, Inc.
- Nasal swab samples from infected patients and non-infected patients

Procedure:

A total of 125 nasal swab specimens were collected from the patients at multiple sites in U.S. The patients presenting the COVID-19 like symptoms within 14 days of symptom onset at the collection sites are enrolled.

The nasal swabs were randomized and blinded tested by operators following

product package insert.

A companion nasopharyngeal (NP) swab was also collected from the same patient and confirmed as positive or negative and validated with Ct counts by the FDA EUA RT-PCR as a comparator method.

Test results:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Test Results	Negative	32	3*	35
	Positive	1	89	90
	Total	33	92	125

***3 samples with PCR CT value 32.9-33**

5.2 Clinical Study in China

Material:

- SARS-CoV-2 Antigen Rapid Test, Lot# 202009001
- RT-PCR, Novel Coronavirus (2019-nCoV) Nucleia Acid Diagnostic Kit (PCR-Fluorescence Probing), FDA authorized RT-PCR test for emergency use, manufactured by Sansure BioTech Inc.
- Nasal swab samples from infected patients and non-infected patients

Procedure:

A total of 452 nasal swab specimens were collected from the patients at multiple sites in China. The patients presenting the COVID-19 like symptoms within 14 days of symptom onset at the collection sites are enrolled.

The nasal swabs were randomized and blinded tested by operators following product package insert.

A companion nasopharyngeal (NP) swab was also collected from the same patient and confirmed as positive or negative and validated with Ct counts by the FDA EUA RT-PCR as a comparator method.

Test results:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Test Results	Negative	381	2*	383
	Positive	1	68	69
	Total	382	70	452

***2 samples with PCR CT value 34-35**

5.3 Summary of combined clinical studies at all sites:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Test Results	Negative	413	5	418
	Positive	2	157	159
	Total	415	162	577

5.4 Positive results to be reported by different Ct value range

Ct value	RT-PCR Positive (+)	Proportion	SARS-CoV-2 Antigen Rapid Test Positive (+)	PPA
≤27	86	53.1%	86	100%
27-30	38	23.5%	38	100%
>30-33	26	16.0%	24	92.3%
>33	5	3.1%	2	40%

Note: There are seven samples only have the PCR result of positive and no Ct value available.

Comparing with RT-PCR, the positive percent agreement (PPA) of the SARS-CoV-2 Antigen Rapid Test is 100% for samples with Ct value ≤30, 92.3% for samples with Ct value from 30 to 33. For samples with Ct value >33, the PPA is 40%.

5.5 Positive results to be reported by days since symptom onset

Days Since Symptom Onset	RT-PCR Positive (+)	Proportion	SARS-CoV-2 Antigen Rapid Test Positive (+)	PPA
0-3	75	46.3%	74	98.7%
4-7	60	37.0%	58	96.7%
>7	19	11.7%	17	89.5%

Note: There are four patients is asymptomatic individuals. And there are four patients lack “Days Since Symptom Onset” information.

Nasal swab specimens obtained early (≤7 days) after symptom onset may contain higher viral concentration.

5.6 Patient Demographics

Age Group	Total	RT-PCR Positive (+)	SARS-CoV-2 Antigen Rapid Test Positive (+)	PPA
Children (Age < 18)	13	12	11	91.7%
Adult (Age 18 to 60)	538	124	120	96.8%
Elderly (Age ≥ 60)	22	22	22	100%

Note: There are four patients lack age information.

VI. Conclusions:

The SARS-CoV-2 Antigen Rapid Test has sensitivity of 96.9%, specificity of 99.5%, and accuracy of 98.8% when comparing with FDA EUA RT-PCR. It is meet the acceptance criteria.

	Performance	95% CI
Sensitivity	96.9% (157/162)	92.8%-98.9%
Specificity	99.5% (413/415)	98.1%- 99.9%
Accuracy	98.8% (570/577)	97.5% -99.5%