AZURE
INSTITUTE

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

I. Intend for Use

The Flowflex 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. The Flowflex 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 Flowflex 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: Dr. Fowl 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 (DTSD) 1350 Third Avenue San Diego - San Diego County	Site 4: COVID CLINIC Down Town San Diego (DTSD) 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: September, 2020

Study Completion Date: December, 2020

IV. Study acceptance criteria

Total Sensitivity: ≥85%

Total Specificity: ≥98%

V. Study Procedure:

The clinical performance of the Flowflex 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 605 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.
CDC 2019-nCoV RT-PCR, ABI 7500DX, FDA authorized RT-PCR test for emergency use

- Nasal swab samples from infected patients and non-infected patients

Procedure:

A total of 153 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
Flow*flex* Test Results	Negative	52	3*	55
	Positive	1	97	98
	Total	53	100	153

***3 samples with PCR CT value 32.9-33**
Relative Sensitivity: 97.0% (95% CI: 91.2%-99.4%)
Relative Specificity: 98.1% (95% CI: 89.1%-99.9%)
Accuracy: 97.4% (95% CI: 93.2%-99.2%)

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.

Also the RT-PCR test results were confirmed by the clinical diagnostic result. RT-PCR positive specimens were all from diagnosis of COVID-19 patients

and RT-PCR negative specimens were all from non COVID-19 patients.

Test results:

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

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

Relative Sensitivity: 97.1% (95% CI: 89.6%-99.8%)
Relative Specificity: 99.7% (95% CI: 98.4%-99.9%)
Accuracy: 99.3% (95% CI: 98.0%-99.9%)

5.3 Summary of combined clinical studies at all sites:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Flow*flex* Test Results	Negative	433	5	438
	Positive	2	165	167
	Total	435	170	605

Relative Sensitivity: 97.1% (95% CI: 93.1%-98.9%)
Relative Specificity: 99.5% (95% CI: 98.2%-99.9%)
Accuracy: 98.8% (95% CI: 97.6%-99.5%)

5.4 Positive results to be reported by different Ct value range

Ct value	RT-PCR Positive (+)	Proportion	Flowflex SARS-CoV-2 Antigen Rapid Test Positive (+)	PPA
≤27	86	50.6%	86	100%
27-30	38	22.4%	38	100%
>30-33	29	17.1%	27	93.1%
>33	9	5.3%	6	66.7%

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

Comparing with RT-PCR, the positive percent agreement (PPA) of the Flowflex SARS-CoV-2 Antigen Rapid Test is 100% for samples with Ct value ≤30, 93.1% for samples with Ct value from >30 to 33. For samples with Ct value >33, the PPA is 66.7%.

5.5 Positive results to be reported by days since symptom onset

Days Since Symptom Onset	RT-PCR Positive (+)	Proportion	Flowflex SARS-CoV-2 Antigen Rapid Test Positive (+)	PPA
0-3	81	46.3%	80	98.8%
4-7	62	37.0%	60	96.8%
>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 (+)	Flowflex SARS-CoV-2 Antigen Rapid Test Positive (+)	PPA
Children (Age < 18)	13	12	11	91.7%
Adult (Age 18 to 60)	565	132	128	97.0%
Elderly (Age ≥ 60)	23	22	22	100%

Note: There are four patients lack age information.

VI. Conclusions:

Using a total of 605 specimens tested at multiple sites in U.S and China, the Flowflex SARS-CoV-2 Antigen Rapid Test has sensitivity of 97.1%, specificity of 99.5%, and accuracy of 98.8% when comparing with FDA EUA RT-PCR.

*Clinical data was collected in USA and China. Data analysis was performed by Azure Institute.

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Azure Institute
10125 Mesa Rim Road,
San Diego, California
CA 92130, USA