SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva)

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Clinical Study Report

Selfdiagnostics Deutschland GmbH

1. Intend for Use

The SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) is a lateral flow chromatographic immunoassay for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab and saliva specimens directly from individuals who are suspected of COVID-19 by their healthcare provider. The SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) does not differentiate between SARS-CoV and SARS-CoV- 2.

2. Objective

A multi-site clinical study was conducted in China to evaluate the performance of the SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) when compared to RT-PCR method.

3. Clinical Study Site and Study Period

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: Nov, 2020
Study Completion Date: Mar, 2021

4. Study acceptance criteria

Total Sensitivity: ≥85%

Total Specificity: ≥98%

5. Study Procedure:

The clinical performance of the SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) was evaluated at two (2) investigational sites in China using a total of 341 Saliva specimens collected from the patients at multiple sites in China.

5.1 Material:

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

5.2 Procedure:

A total of 341 saliva 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 saliva specimens 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.

5.3 Test results:

Candidate method		RT-PCR method		
		Negative	Positive	Total
Test Results	Negative	235	9	244
	Positive	1	96	97
	Total	236	105	341

Relative Sensitivity: 91.4% (95% CI: 84.3%-95.6%)

Relative Specificity: 99.6% (95% CI: 97.4% - 99.9%)

Accuracy: 97.1% (95% CI: 94.6%-98.5%)

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
≤25	59	56.2%	59	100%
25-30	42	40%	36	85.7%
>30	4	3.8%	1	25%

Comparing with RT-PCR, the positive percent agreement (PPA) of the SARS-CoV-2 Antigen Rapid Test (Nasal/Saliva) is 100% for samples with Ct value ≤25, 85.7% for samples with Ct value from >25 to 30. And 25% for samples with Ct value >30.

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	46	43.8%	42	91.3%
4-7	45	42.9%	42	93.3%
>7	9	8.6%	7	77.8%

Note: There are 5 patients is asymptomatic individuals.

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

6. Conclusions:

Using a total of 341 saliva specimens tested at multiple sites in China, the saliva-based SARS-CoV-2 Antigen Rapid Test has sensitivity of 91.4%, specificity of 99.6%, and accuracy of 97.1% when comparingwith FDA EUA RT-PCR.

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