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SARS-CoV-2 Antigen Rapid Test

Clinical Validation Report

Selfdiagnostics Deutschland GmbH

1.Summary

The clinical performance of SARS-CoV-2 Antigen Rapid Test manufactured by Selfdiagnostics Deutschland GmbH presented in this report is based on its OEM clinical evaluation conducted in 4 investigational sites in the USA and 2 investigational sites in China from September 2020 through December 2020. A total of 605 nasal swab specimens for the evaluation were collected from infected and non-infected patients at multiple sites in U.S and China. Data was analyzed by the Azure Institute, 10125 Mesa Rim Road, San Diego, California in December 2020.

The comparison methods were:

- In U.S sites: 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.
- In Chinese sites: RT-PCR, Novel Coronavirus (2019-nCoV) Nucleic Acid Diagnostic Kit (PCR-F1uorescence Probing), FDA authorized RT-PCR test for emergency use, manufactured by Sansure BioTech Inc.

Conclusion:

The SARS-CoV-2 Antigen rapid test is highly specific and very sensitive test showing:

- relative sensitivity of 97.1% over all tested subjects and
- relative specificity of 99.5%.

The test is even more sensitive with CT levels below 33, showing:

- relative sensitivity of 100% at CT level ≤30 and
- relative sensitivity of 98.7% at CT level ≤33.

1.1 Summary of combined clinical studies at all sites:

Candidate method		RT-PCR method		
		Negative	Positive	Total
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%)

1.2 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	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: Eight samples did not have Ct value available.

Comparing with RT-PCR, the positive percent agreement (PPA) of the SARSCoV-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%.

1.3 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	81	46.3%	80	98.8%
4-7	62	37.0%	60	96.8%
>7	19	11.7%	17	89.5%

Note: Four patients were asymptomatic and four patients did not have "Days Since Symptom Onset" information.

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

1.4 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)	565	132	128	97.0%
Elderly (Age ≥ 60)	23	22	22	100%

Note: Four patients did not have age information.

2. Intended Use

The SARS-CoV-2 Antigen Rapid Test is a lateral flow chromatographic immunoassay for thequalitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasal swab specimensdirectly from individuals who are suspected of COVID-19 by their healthcare provider. The SARS-CoV-2 Antigen Rapid Test does not differentiate between SARS-CoV and SARS-CoV-2.

3. 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.

4. 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 Downtown San Diego (DTSD) 1350 Third Avenue San Diego - San Diego County	Site 4: COVID CLINIC Downtown 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, PR. 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

Initiation Date: September 2020
Completion Date: December 2020

5. Study acceptance criteria

Total Sensitivity: ≥85%

Total Specificity: ≥98%

6. Clinical Study in USA

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
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%)

7. Clinical Study in China

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
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%)

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