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CE

DECLARATION OF CONFORMITY

Manufacturer: Joinstar Biomedical Technology Co.,Ltd.

Address: 10th Floor, Administration Building, NO.519, XingGuo RD., Yuhang Economic and Technological Development Zone,Hangzhou, Zhejiang,China,311188

EC Representative's Name: Lotus NL B.V.

EC Representative's Address: Koningin Julianaplein 10,1e Verd, 2595AA,The Hague,Netherlands.

Declares, that the product

Product Name and Model:

COVID-19 Antigen Rapid Test (Latex)

1 Test/Kit, 25 Tests/Kit

as described above are in conformity with the requirements as defined in IVDD98/79/EC Annex III.

Additional information:

Conformity assessment route:	Directive 98/79/EC, Annex II
Classification:	List Others

I, the undersigned, hereby declare that the medical devices specified above conform with the Directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements.

Date Signed: 2020.09.02

Xuyi ZHOU

General Manager

Joinstar Biomedical Technology Co.,Ltd.

Joinstar Biomedical Technology Co.,Ltd.

Version:0.0

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

Product Service

Certificate

No. Q5 087635 0004 Rev. 01

Holder of Certificate: **JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.**
10th Floor, Administration Building
No.519 Xingguo Rd.
Yuhang Economic and Technological Development Zone
311188 Hangzhou
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
10th Floor, Administration Building, No.519 Xingguo Rd., Yuhang Economic and Technological Development Zone, 311188 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
No. 1 Factory Building, No. 519 Xingguo Rd., Yuhang Economic and Technological Development Zone, 311188 Hangzhou, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

Scope of Certificate: **Design, Development, Production and Distribution of Biochemical Reagent, ELISA Reagent, Clinical Laboratory Instruments and Rapid Diagnostic Reagents**

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH2087401

Valid from: 2020-05-27
Valid until: 2023-05-26

Date, 2020-05-07

Christoph Dicks
Head of Certification/Notified Body

TÜV®

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

JOINSTAR BIOMEDICAL TECHNOLOGY CO., LTD.
Add: NO.519 Xingguo RD. Yuhang Economic and Technological Development Zone, Hangzhou, Zhejiang, China
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Clinical Study (internal clinical assessment) Report

COVID-19 Antigen Rapid Test (Latex)

Prepared By: Yanhua ZHANG Date: 02/09/2020

Reviewed By: Qian XU Date: 02/09/2020

Approval By: Zhong WANG Date: 03/09/2020

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1 Purpose:

To determine the performance of COVID-19 Antigen Rapid Test compared to a commercially available competitor assay.

2 Operation Information

2.3 Materials:

COVID-19 Antigen Rapid Lot：COV2008003L-T

Competitor assay: Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR Kit produced by Shanghai ZJ Bio-Tech Co., Ltd., a commercial SARS-COV-2 kit approved by CFDA, is referred herein as the "gold standard" reagent.

3 Method:

180 samples of the novel coronavirus SARS-CoV-2 and 90 samples of healthy people were included in the testing plan. A total of 90 saliva samples, 90 sputum samples and 90 stool samples were tested in the COVID-19 Antigen Rapid assay and the Novel Coronavirus (SARS-COV-2) real-time multiplex RT-PCR kit, and the clinical sensitivity, specificity and overall agreement between the 2 assays calculated.

4. Clinical research results and analysis

4.1 Clinical research results

4.1.1 The Test results were as follows:

Novel Coronavirus	Covid 19 antigen Rapid Test			RT-PCR
	Saliva	Stool	Sputum	throat swab
Healthy 1	-	-	-	-
Healthy 2	-	-	-	-
Healthy 3	-	-	-	-
Healthy 4	-	-	-	-
Healthy 5	-	-	-	-
Healthy 6	-	-	-	-
Healthy 7	-	-	-	-
Healthy 8	-	-	-	-
Healthy 9	-	-	-	-
Healthy 10	-	-	-	-
Healthy 11	-	-	-	-
Healthy 12	-	-	-	-
Healthy 13	-	-	-	-
Healthy 14	-	-	-	-

Healthy 15	-	-	-	-
Healthy 16	-	-	-	-
Healthy 17	-	-	-	-
Healthy 18	-	-	-	-
Healthy 19	-	-	-	-
Healthy 20	-	-	-	-
Healthy 21	-	-	-	-
Healthy 22	-	-	-	-
Healthy 23	-	-	-	-
Healthy 24	-	-	-	-
Healthy 25	-	-	-	-
Healthy 26	-	-	-	-
Healthy 27	-	-	-	-
Healthy 28	-	-	-	-
Healthy 29	-	-	-	-
Healthy 30	-	-	-	-

	Covid 19 antigen Rapid Test			RT-PCR	
DAY	Saliva	Stool	Sputum	throat swab	throat swab （notes）
Day 1 of disease onset	+	+	+	+	
Day 9 of disease onset	+	+	+	+	
Day 3 of disease onset	+	+	+	+	
Day 6 of disease onset	+	+	+	+	
Day 2 of disease onset	+	+	-	+	
Day 5 of disease onset	+	+	+	+	
Day 8 of disease onset	+	+	+	+	
Day 4 of disease onset	+	+	+	+	
Day 7 of disease onset	+	+	+	+	
Day 7 of disease onset	+	+	+	+	
Day 2 of disease onset	+	+	+	+	
Day 2 of disease onset	-	-	+	+	confirm by retest
Day 2 of disease onset	+	+	+	+	
Day 1 of disease onset	+	+	+	+	
Day 1 of disease onset	+	+	+	+	
Day 6 of disease onset	+	+	+	+	

Day 4 of disease onset	+	+	+	+	
Day 4 of disease onset	+	+	+	+	
Day 3 of disease onset	+	+	+	+	
Day 3 of disease onset	+	+	+	+	
Day 1 of disease onset	+	+	+	+	
Day 2 of disease onset	+	+	+	+	
Day 3 of disease onset	-	+	+	+	
Day 2 of disease onset	+	+	+	+	
Day 3 of disease onset	+	+	+	+	
Day 6 of disease onset	+	+	+	+	
Day 1 of disease onset	-	-	+	+	confirm by retest
Day 6 of disease onset	+	+	+	+	
Day 8 of disease onset	+	+	+	+	
Day 4 of disease onset	+	+	+	+	
Day 3 of disease onset	+	+	+	+	
Day 2 of disease onset	+	+	+	+	
Day 5 of disease onset	+	+	+	+	
Day 7 of disease onset	+	+	+	+	
Day 9 of disease onset	+	+	+	+	
Day 3 of disease onset	+	+	+	+	
Day 1 of disease onset	-	-	+	+	confirm by retest
Day 2 of disease onset	+	+	+	+	
Day 5 of disease onset	+	+	+	+	
Day 4 of disease onset	+	+	-	+	
Day 3 of disease onset	+	+	+	+	
Day 3 of disease onset	+	+	+	+	
Day 5 of disease onset	+	+	+	+	
Day 5 of disease onset	+	+	+	+	
Day 9 of disease onset	+	+	+	+	
Day 7 of disease onset	+	+	+	+	
Day 2 of disease onset	-	+	+	+	
Day 3 of disease onset	+	+	+	+	
Day 1 of disease onset	-	+	-	+	
Day 1 of disease onset	+	+	+	+	
Day 2 of disease onset	+	+	+	+	
Day 4 of disease onset	+	+	+	+	
Day 3 of disease onset	+	+	+	+	
Day 7 of disease onset	+	+	+	+	

Day 5 of disease onset	+	+	+	+	
Day 6 of disease onset	+	+	+	+	
Day 4 of disease onset	+	+	+	+	
Day 6 of disease onset	+	+	+	+	
Day 1 of disease onset	+	+	+	+	
Day 2 of disease onset	+	+	+	+	

4.2 The above results are summarized as follows：

Saliva Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	54	0	54
	Negative	6	30	36
Total		60	30	90

Sputum Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	57	0	57
	Negative	3	30	33
Total		60	30	90

Stool Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	57	0	57
	Negative	3	30	33
Total		60	30	90

Result analysis

Saliva samples: The Novel Coronavirus Spike Glycoprotein Detection Kit showed 90% sensitivity and 100% specificity in saliva samples.

Clinical sensitivity (%) = [54 / (54 + 6)] ×100% = 90%

Clinical specificity (%) = [30/ (0+ 30)] ×100% = 100%

Total agreement rate (%) = [(54 +30) / (54 + 6+ 0+ 30)] ×100% = 93.3%

Sputum samples: The Novel Coronavirus Spike Glycoprotein Detection Kit showed 95%

sensitivity and 100% specificity in sputum samples.

Clinical sensitivity (%) = [57/ (57+ 3)] ×100% = 95%

Clinical specificity (%) = [30/ (0+ 30)] ×100% = 100%

Total agreement rate (%) = [(57 +30) / (57 +3+ 0+ 30)] ×100% = 96.7%

Stool samples: The Novel Coronavirus Spike Glycoprotein Detection Kit showed 95% sensitivity and 100% specificity in stool samples.

Clinical sensitivity (%) = [57/ (57+ 3)] ×100% = 95%

Clinical specificity (%) = [30/ (0+ 30)] ×100% = 100%

Total agreement rate (%) = [(57 +30) / (57 +3+ 0+ 30)] ×100% = 96.7%

5 Discussion and conclusion

The overall clinical performance of the Joinstar COVID-19 Antigen Rapid Test was comparable with the data obtained in the Novel Coronavirus (SARS-COV-2) Real Time Multiplex RT-PCR assay and supports the use of the Joinstar assay in the detection of SARS-CoV-2.