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Clinical Study (internal clinical assessment) Report

COVID-19 Antigen Rapid Test (Latex)

Prepared By: Yanhua ZHANG Date: 18/12/2020

Reviewed By: Qian XU Date: 18/12/2020

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1 Purpose:

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

2 Operation Information

2.3 Materials:

COVID-19 Antigen Rapid

Lot：COV2008003L-T

Competitors: 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 used as the "gold standard" reagent.

3 Method:

309 samples of the novel coronavirus SARS-CoV-2 from 103 COVID-19 patients and 318 samples from 106 healthy peoples were included in the testing plan. A total of 209 saliva samples, 209 sputum samples and 209 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 Test results are as follows:

Novel Coronavirus	Test reagent			RT-PCR
	Saliva	Stool	Sputum	throat swab
Health 1	-	-	-	-
Health 2	-	-	-	-
Health 3	-	-	-	-
Health 4	-	-	-	-
Health 5	-	-	-	-
Health 6	-	-	-	-
Health 7	-	-	-	-
Health 8	-	-	-	-
Health 9	-	-	-	-
Health 10	-	-	-	-
Health 11	-	-	-	-
Health 12	-	-	-	-
Health 13	-	-	-	-
Health 14	-	-	-	-

Health 15	–	–	–	–
Health 16	–	–	–	–
Health 17	–	–	–	–
Health 18	–	–	–	–
Health 19	–	–	–	–
Health 20	–	–	–	–
Health 21	–	–	–	–
Health 22	–	–	–	–
Health 23	–	–	–	–
Health 24	–	–	–	–
Health 25	–	–	–	–
Health 26	–	–	–	–
Health 27	–	–	–	–
Health 28	–	–	–	–
Health 29	–	–	–	–
Health 30	–	–	–	–
Health 31	–	–	–	–
Health 32	–	–	–	–
Health 33	–	–	–	–
Health 34	–	–	–	–
Health 35	–	–	–	–
Health 36	–	–	–	–
Health 37	–	–	–	–
Health 38	–	–	–	–
Health 39	–	–	–	–
Health 40	–	–	–	–
Health 41	–	–	–	–
Health 42	–	–	–	–
Health 43	–	–	–	–
Health 44	–	–	–	–
Health 45	–	–	–	–
Health 46	–	–	–	–
Health 47	–	–	–	–
Health 48	–	–	–	–
Health 49	–	–	–	–
Health 50	–	–	–	–
Health 51	–	–	–	–
Health 52	–	–	–	–
Health 53	–	–	–	–
Health 54	–	–	–	–
Health 55	–	–	–	–

Health 56	–	–	–	–
Health 57	–	–	–	–
Health 58	–	–	–	–
Health 59	–	–	–	–
Health 60	–	–	–	–
Health 61	–	–	–	–
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Health 64	–	–	–	–
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Health 69	–	–	–	–
Health 70	–	–	–	–
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Health 89	–	–	–	–
Health 90	–	–	–	–
Health 91	–	–	–	–
Health 92	–	–	–	–
Health 93	–	–	–	–
Health 94	–	–	–	–
Health 95	–	–	–	–
Health 96	–	–	–	–

Health 97	-	-	-	-
Health 98	-	-	-	-
Health 99	-	-	-	-
Health 100	-	-	-	-
Health 101	-	-	-	-
Health 102	-	-	-	-
Health 103	-	-	-	-
Health 104	-	-	-	-
Health 105	-	-	-	-
Health 106	-	-	-	-
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 9 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	-	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 8 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 2 day	-	-	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 3 day	-	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 1 day	-	-	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 8 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+

A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 9 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 1 day	−	−	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	−	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 9 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 2 day	−	−	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 1 day	−	+	−	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 4 day	−	+	−	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 2 day	+	−	−	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 2 day	−	−	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 6 day	−	+	+	+

A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 6 day	−	+	−	+
A confirmed diagnosis for 1 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 6 day	−	+	−	+
A confirmed diagnosis for 2 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 3 day	−	−	−	+
A confirmed diagnosis for 5 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 4 day	+	+	+	+
A confirmed diagnosis for 3 day	+	+	+	+
A confirmed diagnosis for 8 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 7 day	+	+	+	+
A confirmed diagnosis for 6 day	+	+	+	+
A confirmed diagnosis for 5 day	+	+	+	+

4.2 The above results are summarized as follows：

Saliva Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	91	0	91
	Negative	12	106	118
Total		103	106	209

Sputum Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	95	0	95
	Negative	8	106	114
Total		103	106	209

Stool Sample		Gold standard reagent		Total
		Positive	Negative	
Test reagent	Positive	96	0	96
	Negative	7	106	113
Total		103	106	209

Result analysis

Saliva samples: The COVID-19 Antigen Rapid Test (Latex) showed 88.4% sensitivity and 100% specificity in saliva samples.

Clinical sensitivity (%) = [91 / (91 + 12)] ×100% = 88.4%

Clinical specificity (%) = [106/ (0+ 106)] ×100% = 100%

Total agreement rate (%) = [(91 +106) / (91 + 12+ 0+ 106)] ×100% = 94.3%

Sputum samples: The COVID-19 Antigen Rapid Test (Latex) showed 92.2% sensitivity and 100% specificity in sputum samples.

Clinical sensitivity (%) = [95/ (95+ 8)] ×100% = 92.2%

Clinical specificity (%) = [106/ (0+ 106)] ×100% = 100%

Total agreement rate (%) = [(95 +106) / (95 +8+ 0+ 106)] ×100% = 96.2%

Stool samples: The COVID-19 Antigen Rapid Test (Latex) showed 93.2% sensitivity and 100% specificity in stool samples.

Clinical sensitivity (%) = [96/ (96+ 7)] ×100% = 93.2%

Clinical specificity (%) = [106/ (0+ 106)] ×100% = 100%

Total agreement rate (%) = [(96 +106) / (96 +7+ 0+ 106)] ×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.

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
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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:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

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

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浙江省医疗器械行业协会

中华人民共和国
PEOPLE'S REPUBLIC OF CHINA
医疗器械产品出口销售证明
CERTIFICATE FOR EXPORTATION OF MEDICAL PRODUCTS

证书编号: 20200007
Certificate NO.: 20200007

产品名称: 见附件（共 1 页）
Product(s): See Attachment (1 Page)

规格型号: 见附件（共 1 页）
Model: See Attachment (1Page)

生产企业: 中翰盛泰生物技术股份有限公司

Manufacturer: Joinstar Biomedical Technology Co., Ltd.

生产企业住所: 浙江杭州余杭经济开发区兴国路 519 号
Address of manufacturer: No.519 XingguoRD, Yuhang Economic and Technological Development Zone, 311118, Hangzhou, P.R. China

出口企业: 中翰盛泰生物技术股份有限公司

Manufacturer: Joinstar Biomedical Technology Co., Ltd.

出口企业住所: 浙江杭州余杭经济开发区兴国路 519 号
Address of manufacturer: No.519 XingguoRD, Yuhang Economic and Technological Development Zone, 311118, Hangzhou, P.R. China

兹证明上述产品未在中国注册，尚未进入中国市场，该产品出口不受限制。
This is to certify that the above product(s) are not registered in China and not distributed on the Chinese market. The exportation of the product(s) is not restricted.

证明有效日期至: 2022 年 9 月 23 日
This certification valid until: 2022/09/23

Zhejiang Provincial Association For Medical Equipment Industry
(浙江省医疗器械行业协会)

Date of issue: 2020/09/23
(2020 年 9 月 23 日)

地址：杭州环城东路23号　电话：0571-87043144　传真：0571-87043191　邮政编码：310009
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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 III
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