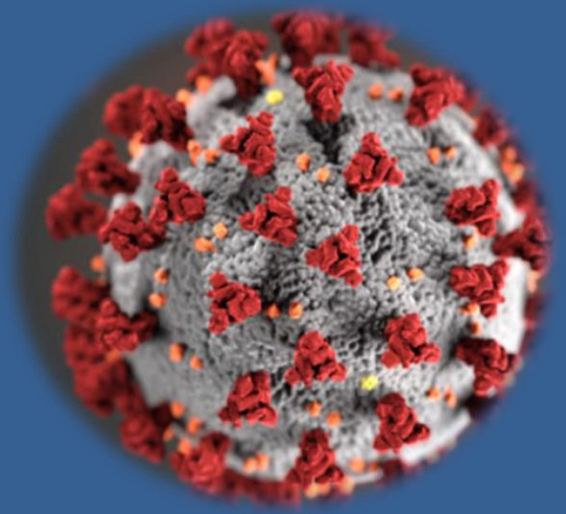
Wondfo Total Antibody Testing

Technical Support Team
International Marketing Division II

2020-08-12

Content



01

Advantage of Wondfo total antibody testing

Wondfo have high sensitivity while maintaining a high specificity.

COVID-19 Testing Project -Multidisciplinary team of researchers and physicians at UCSF,

UC Berkeley, Chan Zuckerberg Biohub, and Innovative Genomics Institute. - US

Wondfo have high sensitivity while maintaining a high specificity.

earlier intervals (Figure 1B). Four assays (Bioperfectus, Premier, Wondfo, in-house ELISA) achieved >80% positivity in the latest two time intervals (16-20 and >20 days) while maintaining >95% specificity. Some tests were not performed on a subset of specimens due exhausted sample material,

Our data demonstrate specificity greater than 95% for the majority of tests evaluated and >99% for 2 LFAs (Wondfo, Sure Biotech) and the in-house ELISA (adapted from Amanat et al, 2020)[18]. We

https://covidtestingproject.org/

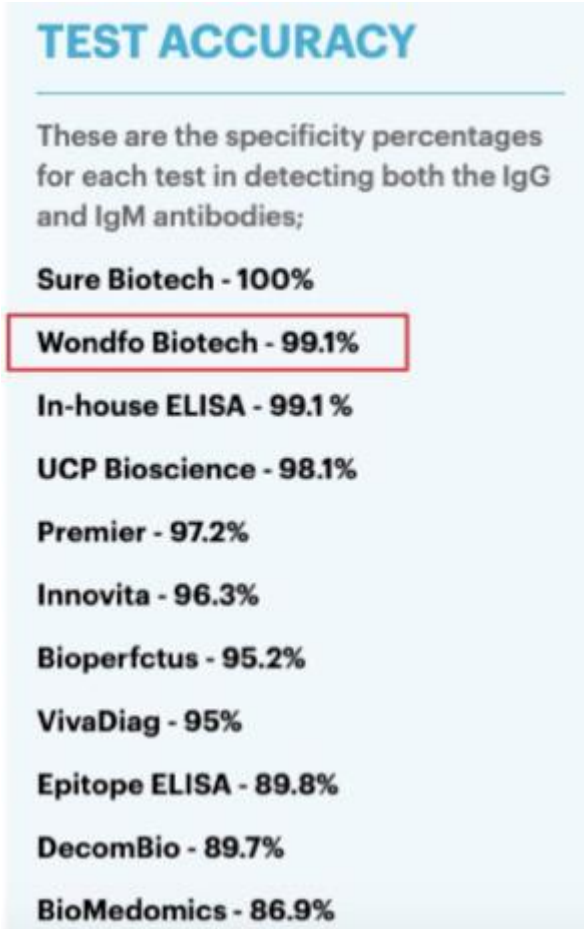
The New York Times

Each test was evaluated with the same set of blood samples: from 80 people known to be infected with the coronavirus, at different points after infection; 108 samples donated before the pandemic; and 52 samples from people who were positive for other viral infections but had tested negative for SARS-CoV-2.

Tests made by Sure Biotech and Wondfo Biotech, along with an in-house Elisa test, produced the fewest false positives.

https://www.nytimes.com/2020/04/24/health/coronavirus-antibody-tests.html

Wondfo



Daily Mail

https://www.dailymail.co.uk/news/article-8261179/Coronavirus-antibody-testing-accuracy-study-reveals-flawed-results.html

Remarkable results

Chan Zuckerburg Biohub and Massachusetts General Hospital found that only three tests had an accuracy rate of over 99 percent. These were made by Sure Biotech, Wondfo Biotech, and the researchers' in-house. Eight other tests scored 95 percent.

Read now: [Survival Rate of COVID-19 Patients on ECMO Machines are Three Times Higher Than On]

https://www.sciencetimes.com/articles/25498/20200428/experts-identified-one-antibody-test-100-accuracy-0-others-over.htm

Four of the tests produced false-positive rates ranging from 11-16 percent, while many of the rest hovered around 5 percent.

The four tests with the fewest false positives were made made by Sure Biotech, Wondfo Biotech, and two Eliza tests, the researchers said.

A test made by Bioperfectus detected antibodies in 100 percent of the infected samples, but only after three weeks of infection. "None of the tests did better than 80 percent until that time period, which was longer than expected," said Hsu.

https://english.alarabiya.net/en/coronavirus/2020/04/26/Coronavirus-antibody-tests-are-not-consistently-reliable-Study

Australia MOH evaluation-Wondfo highest sensitivity

Table 9: Comparative performance of IgG testing for 91 RT-PCR positive patients with confirmed COVID-19 infection, stratified by days post-symptom onset.

Days post-symptom onset	Total (samples)	Onsite IgG (%) [95% CI]	VivaDiag IgG (%) [95% CI]	EUROIMMUN EIA IgG (%) [95% CI]	Hangzhou AllTest IgG (%) [95% CI]	Hangzhou Unlabelled IgG (%) [95% CI]	Wondfo Test Result* (%) [95% CI]	Hightop IgG (%) [95% CI]
0-3	23	0 (0.0) [0.0, 14.8]	0 (0.0) [0.0, 14.8]	0 (0.0) [0.0, 14.8]	0 (0) [0, 14.8]	2 (8.7) [1.1, 28.0]	3 (13.0) [2.8, 38.6]	0 (0.0) [0.0, 14.8]
4-8	28	6 (21.4) [8.3, 41.0]	8 (28.6) [13.2, 48.7]	7 (25.0) [10.7, 44.9]	9 (32.1) [15.9, 52.4]	10 (35.7) [18.6, 55.9]	14 (50.0) [30.7, 69.4]	7 (25.0) [10.7, 44.9]
9-14	21	6 (28.6) [11.3, 52.2]	12 (57.1) [34.0, 78.2]	10 (47.6) [25.7, 70.2]	14 (66.7) [43, 84.5]	15 (8.7) [1.1, 28.0]	16 (76.2) [52.8, 91.8]	13 (61.9) [38.4, 81.9]
15-20	8	6 (75.0) [34.9, 96.8]	6 (75.0) [34.9.0, 96.8]	7 (87.5) [47.4, 99.7]	8 (100) [63.1, 100]	6 (75.0) [34.9, 96.8]	8 (100) [63.1, 100]	7 (87.5) [47.4, 99.7]
21-30	27	23 (85.2) [66.3, 95.8]	21 (77.8) [57.7, 91.4]	27 (100) [87.2, 100]	25 (92.6) [75.7, 99.1]	25 (92.6) [75.7, 99.1]	26 (96.3) [81.0, 99.9]	25 (96.2) [80.4, 99.9]#
>30	30	23 (76.7) [76.7, 57.7]	24 (80.0) [61.4, 92.3]	26 (86.7) [69.3, 96.2]	26 (86.7) [69.3, 96.2]	25 (83.3) [65.3, 94.4]	27 (90.0) [73.5, 97.9]	28 (93.3) [77.9, 99.1]
Total	**137**	**64 (46.7) [38.2, 55.4]**	**71 (51.8) [43.1, 60.4]**	**77 (56.2) [47.5, 64.7]**	**82 (59.9) [51.1, 68.1]**	**83 (60.6) [51.9, 68.8]**	**94 (68.6) [60.1, 76.3]**	**80 (58.8) [50.1, 67.2]**

CI = Confidence interval (Clopper-Pearson). * = Combined IgM/IgG. # = only 26 samples included for this test in this category.

https://www.health.gov.au/sites/default/files/documents/2020/06/post-market-validation-of-serological-assays-for-covid-19-updated-report_0.pdf

4. Discussion

Here, we present results of our post-market validation of the Hangzhou IgG/IgM Rapid Test assays, the Wondfo SARS-CoV-2 Antibody Test and the Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test. Our findings suggest that the performance characteristics of the Wondfo SARS-CoV-2 Antibody Test and the Hightop SARS-CoV-2 IgM/IgG Antibody Rapid Test are only in keeping with those reported in the IFU if samples collected 14 days or earlier following

A joint venture between The University of Melbourne and The Royal Melbourne Hospital

Wondfo specificity 100%, while sensitivity is on top

by Instituto de Salud Carlos III - SEMERGEN, Spain

Table1. **Wondfo evaluate the most patients and got the best result.**

SGTi flex covid19-test, sensitivity the highest, but spcificity 90% not acceptable

TABLA 1. Resumen de resultados (S: Sensibilidad, ESP: Especificidad)

TÉCNICA	FABRICANTE	DATOS SEGUN MARCADO CE	ESTUDIO DE FIABILIDAD	DATOS SOBRE ESTUDIO FIABILIDAD
2019-nCoV Ag GICA Rapid Test REF: YRLG22202025	SHENZHEN BIOEASY BIOTECHNOLOGY CO LTD	83% S, 100% ESP	S: 25% ESP: 100%	Estudio ISCIII **N=48 pacientes**
2019-nCoV Ag Test Fluorescence IC Assay REF: YRLF04401025	SHENZHEN BIOEASY BIOTECHNOLOGY CO LTD	92% S, 100% ESP	S: 58% ESP: 97%	Estudio Hospital Clínico Madrid, G Marañón y La Paz **N=121 pacientes**
COVID-19 IgG/IgM Rapid Test Cassette REF: GCCOV-402a	ZHEJIANG ORIENT GENE BIOTECH	88% S, 97% ESP (distingue IgM/IgG)	S: 58% ESP: 100% (S=85% en pacientes con >10 días de evolución) (SUERO)	Estudio Hospital de Toledo e ISCIII **N=250 pacientes**
2019-nCoV IgG/IgM Rapid Test Cassette REF: INCP-402	HANGZHOU ALL TEST BIOTECH CO LTD	100% S, 97% ESP (distingue IgM/IgG)	S: 56,5% ESP: 100% (S >75% en pacientes con >7 días de evolución) (SUERO)	Estudio Hospital Clínico de Madrid y Ramón y Cajal **N=119 pacientes**
SARS-CoV-2 Antibody Test REF: W1 95	GUANGZHOU WONDFO BIOTECH CO LTD	100% S, 90% ESP (Ac totales)	S: 66,3% ESP: 100% (S >75-80% en pacientes con >7 días de evolución) (SUERO)	Estudio la Princesa, Ramón y Cajal, Gregorio Marañón, Hospital de Toledo y Hospital Clínico de Madrid **N=386 pacientes**
SGTi flex COVID 19 IgM/IgG REF: COVT02SE	SUGENTECH INC	94% S, 96% ESP (distingue IgM/IgG)	S: 74% ESP: 90% (S=94% en pacientes con >10 días de evolución) (SUERO)	Estudio Hospital de la Princesa y Hospital Clínico de Madrid **N=200 pacientes**

https://www.semergen.es/files/docs/COVID-19/Documentos/informe-Iestrategia-microbiologico.pdf

Table2： In Madrid hospital, Wondfo perform great

TABLA 2. Resumen de resultados en pacientes recuperados y comparaciones venopunción vs digitopunción. (S: Sensibilidad, ESP: Especificidad)

TÉCNICA	FABRICANTE	DATOS SEGUN MARCADO CE	ESTUDIO DE FIABILIDAD	DATOS SOBRE ESTUDIO FIABILIDAD
COVID-19 IgG/IgM Rapid Test Cassette REF: GCCOV-402a	ZHEJIANG ORIENT GENE BIOTECH	88% S, 97% ESP (distingue IgM/IgG) Sangre/suero/plasma. El fabricante recomienda digitopunción	S en SUERO: 85,5% ESP en SUERO: 98.1%	**150 pacientes** Estudio ISCIII
			S en SANGRE: 82,1% ESP en SANGRE: 99%	**56 pacientes** Hospital Clínico de Madrid
			S en DIGITOPUNCIÓN: 82,1% ESP en DIGITOPUNCIÓN: 99%	**56 pacientes** Hospital Clínico de Madrid
SARS-CoV-2 Antibody Test REF: W1 95	GUANGZHOU WONDFO BIOTECH CO LTD	100% S, 90% ESP (Ac totales) Sangre/suero/plasma.	S en SUERO: 77,8% ESP en SUERO: 95%	**45 pacientes** Hospital Gregorio Marañón
			S en SANGRE: 84,5% ESP en SANGRE: 100%	**97 pacientes** Hospital Clínico de Madrid
			S en DIGITOPUNCIÓN: 61,5% ESP en DIGITOPUNCIÓN: 100%	**52 pacientes** Hospital Gregorio Marañón y Hospital Clínico de Madrid
2019-nCoV IgG/IgM Rapid Test Cassette REF: INCP-402	HANGZHOU ALL TEST BIOTECH CO LTD	100% S, 97% ESP (distingue IgM/IgG) Sangre/suero/plasma. El fabricante recomienda digitopunción	S en SUERO: 86% ESP en SUERO: 85%	**56 pacientes** Hospital Ramón y Cajal y Gregorio Marañón
			S en DIGITOPUNCIÓN: 74% ESP en DIGITOPUNCIÓN: 95%	**47 pacientes** Hospital Gregorio Marañón

Wondfo have 100% specificity

By-Brown University

- **The *specificity of SQ IgG and Wondfo Total is 100%*, the specificity of Abbott IgG is 99.62%, and the specificity of SQ IgM is 98.87%.**

Table 4. Positive rate in pre-pandemic and post-pandemic samples for 3 assays

Assay names	SQ IgM	SQ IgG	Abbott IgG
Random non-COVID-19 samples (early March 2020) (from Table 3)	**3/126**	0/126	0/125
Pre-pandemic samples from troponin study	**6/500**	0/500	**4/498**
Pre-pandemic samples from transfusion service	0/50	0/50	0/50
Pre-pandemic samples from Rhode Island Blood Center	**2/21**	0/21	0/21
Pre-pandemic samples from prenatal samples	**1/371**	0/371	0/371
Total	**12/1063**	0/1063	**4/1059**
Specificity (95% confidence interval)	98.87% (98.04%, 99.35%)	100% (99.64%, 100%)	99.62% (99.03%, 99.85%)

Validation and Performance Comparison of Three SARS-CoV-2 Antibody Assays

https://www.biorxiv.org/content/10.1101/2020.05.29.124776v1

Among 3 rapid tests, Wondfo has better performance

by Consorcio Hospital General Universitario, Valencia, Spain

- **"Overall results being better for Guangzhou Wondfo Biotech."**
- "Test 3 (Wondfo) showed the best specificity (100%), followed by Test 2 and 1"
- "Instead, we decided to use Test 3 (Wondfo), with acceptable specificity and sensitivity, combined with ELISA as a part of our daily workflow."
- **"IgM band in LFI had low sensitivities and might be inadequate for acute diagnosis of COVID-19 infection"**

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7323682/

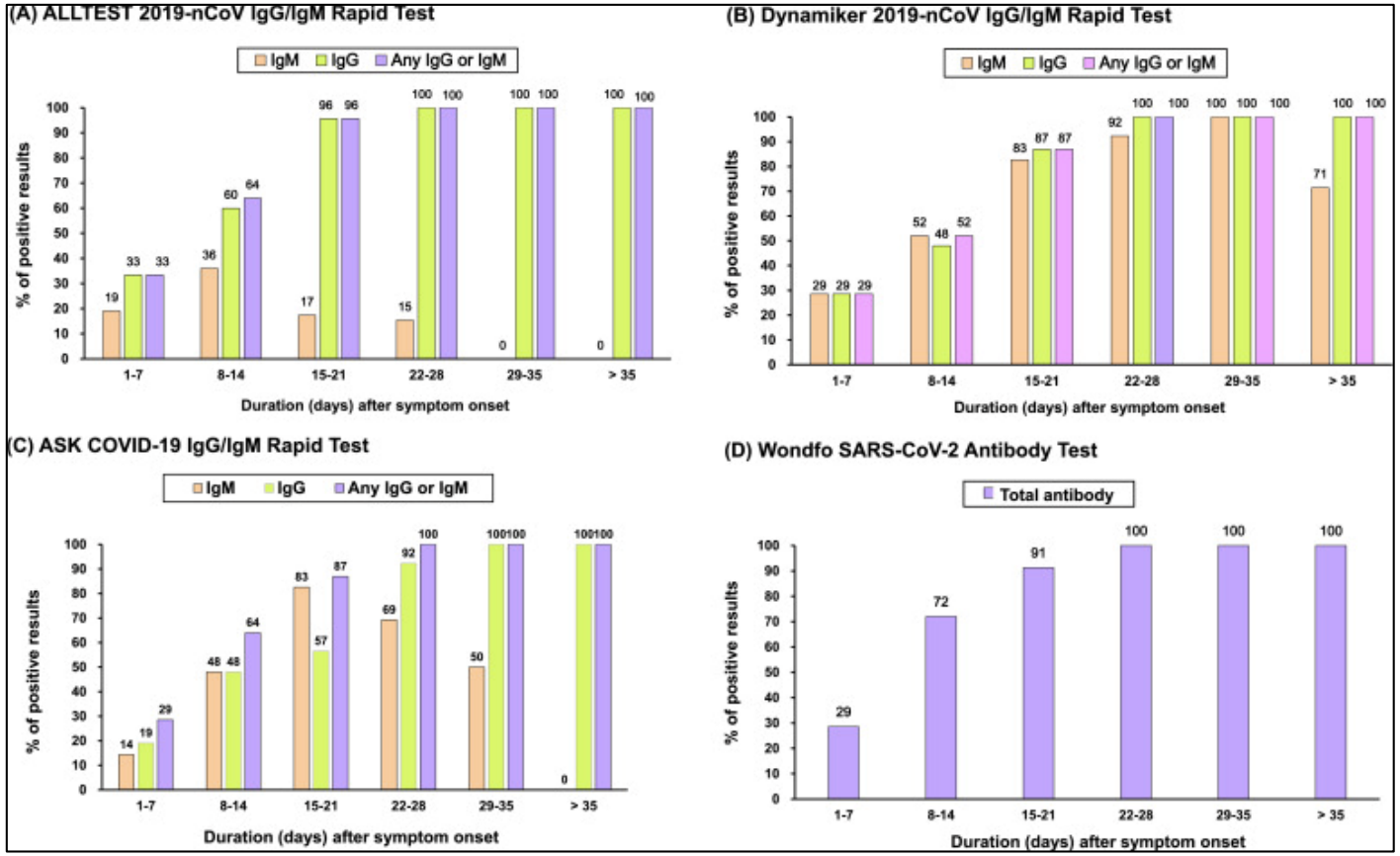
	Test 1			Test 2			Test 3		
Type of antibodies	IgM	IgG	IgM/IgG	IgM	IgG	IgM/IgG	IgM/IgG	IgA	IgG
No. tested samples (all)	84	84	84	81	81	81	84	84	84
Negative	79	83	78	73	78	71	80	69	84
Inconclusive/positive	5	1	6	8	3	10	4	15	0
Specificity (%)	94%	98.8%	92.8%	90.1%	96.3%	87.7%	95.2%	81.2%	100%
No. tested samples 2018/19	62	62	62	60	60	60	62	62	62
Negative	58	62	58	54	59	53	62	50	62
Inconclusive/positive	4	0	4	6	1	7	0	12	0
Specificity (%)	93.5%	100%	93.5%	90%	98.3%	88.3%	100%	80.6%	100%

Table 3. Sensitivity of the 3 LFI and 2 ELISA for different days after symptoms' onset .

Days after onset	ELISA Sensitivity (95%CI)				Lateral Flow Immunoassay Sensitivity (95%CI)									
					Test 1				Test 2				Test 3	
	N	IgA	N	IgG	N	IgM	N	IgG	N	IgM	N	IgG	N	IgM/IgG
1-7	22/28	71.4 (63.4-93.8)	15/28	53.5 (33.9-72.5)	8/27	29.6 (13.8-50.2)	13/27	48.1 (28.7-68.1)	16/24	66.7 (44.7-84.4)	14/24	58.3 (36.6-77.9)	18/27	66.7 (46-83.5)
8-14	38/39	97.4 (86.5-99.9)	32/39	82.1 (66.5-92.5)	17/39	43.6 (27.8-60.4)	28/39	71.8 (55.1-85)	24/32	75 (56.6-88.5)	30/32	93.8 (79.2-99.2)	38/39	97.4 (86.5-99.9)
15-28	49/50	98 (89.4-99.9)	48/50	96 (86.3-99.5)	12/49	24.5 (13.3-38.9)	41/49	83.7 (70.3-92.7)	23/25	92 (74-99)	25/25	100 (86.3-100)	49/50	98 (89.4-99.9)
Asymptomatic	13/13	100 (75.3-100)	12/13	92.3 (64-99.8)	4/11	36.3 (10.9-69.2)	7/11	63.6 (30.8-89.1)	7/11	63.6 (30.8-89.1)	10/11	90.9 (58.7-99.8)	11/13	84.6 (54.6-98.1)
Total	121/130	93.1 (87.3-96.8)	106/130	81.5 (73.8-87.8)	41/126	32.5 (24.5-41.5)	89/126	70.6 (61.9-78.4)	70/92	76.1 (66.1-84.4)	79/92	85.9 (77-92.3)	116/129	89.9 (83.4-94.5)

National Taiwan University-Alltest and Wondfo are the best

- Compared to detection of all antibodies, **detection of IgM and IgG separately using rapid tests did not improve the performance** of the tests in terms of early diagnosis of COVID-19 infection.



https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7295501/

Wondfo Finecare and rapid test have better performance than other two methods.

-By Bacteriology and Hygiene Bicetre Laboratory Hospital, France

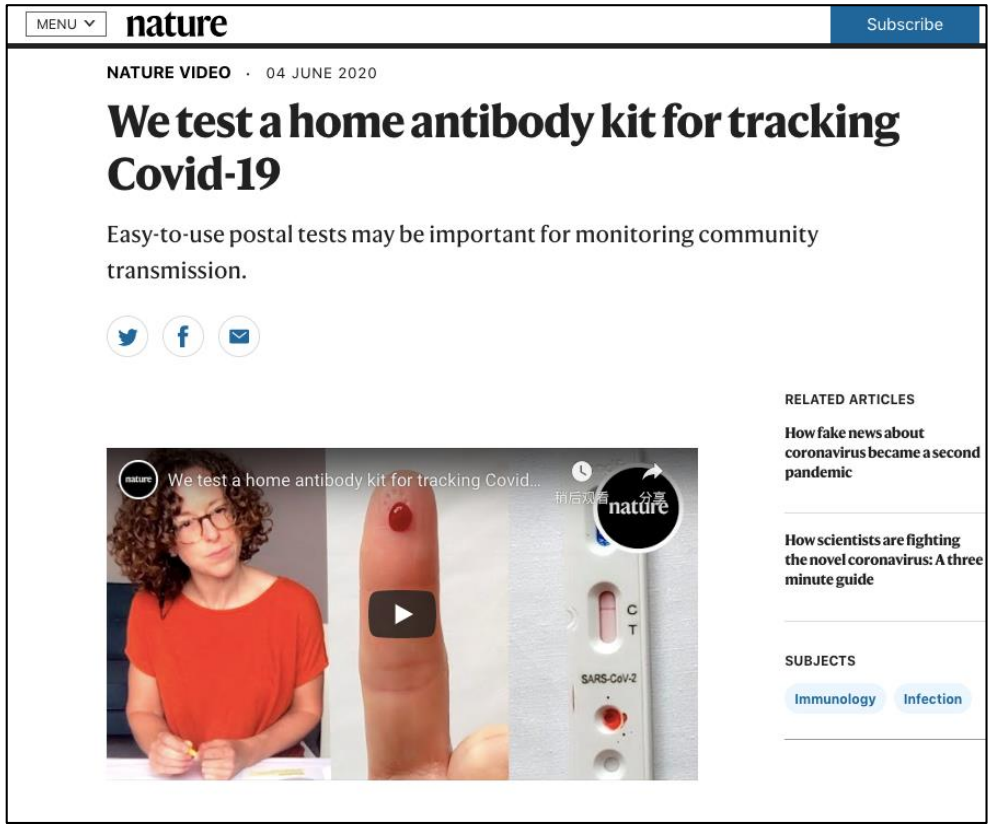
Laboratory	Country	City	Test Name	Manufacturer	Target	Sensitivity	Specificity	Link to Publication
University of Californ	United States	San Francis	COVID-19 IgM-IgG Dual Antibod	BioMedomics, Inc.	IgM	61.7	87.9	https://covidtestingproject.org/
University of Californ	United States	San Francis	COVID-19 IgM-IgG Dual Antibod	BioMedomics, Inc.	IgG	55.5	96.3	https://covidtestingproject.org/
University of Californ	United States	San Francis	COVID-19 IgM-IgG Dual Antibod	BioMedomics, Inc.	IgG; IgM	64.8	86.9	https://covidtestingproject.org/
University of Californ	United States	San Francis	Novel Coronavirus (2019-nCoV)	Innovita Biological Technology C	IgG	53.4	100	https://covidtestingproject.org/
University of Californ	United States	San Francis	PerfectPOC Novel Corona Virus	Jiangsu Bioperfectus Technologi	IgM	71.1	97.1	https://covidtestingproject.org/
University of Californ	United States	San Francis	PerfectPOC Novel Corona Virus	Jiangsu Bioperfectus Technologi	IgG	62.5	98.1	https://covidtestingproject.org/
University of Californ	United States	San Francis	PerfectPOC Novel Corona Virus	Jiangsu Bioperfectus Technologi	IgG; IgM	74.2	95.2	https://covidtestingproject.org/
University of Californ	United States	San Francis	COVID-19 (SARS-CoV-2) IgG/IgM	DeepBlue Medical Technology C	IgM	72.3	84.3	https://covidtestingproject.org/
University of Californ	United States	San Francis	COVID-19 (SARS-CoV-2) IgG/IgM	DeepBlue Medical Technology C	IgG	53.1	99.1	https://covidtestingproject.org/
University of Californ	United States	San Francis	Novel Coronavirus (SARSCoV-2)	Decombio Biotechnology Co Ltd.	IgG; IgM	67.5	89.7	https://covidtestingproject.org/
University of Californ	United States	San Francis	COVID-19 (SARS-CoV-2) IgG/IgM	DeepBlue Medical Technology C	IgG; IgM	73.1	84.3	https://covidtestingproject.org/
University of Californ	United States	San Francis	Novel Coronavirus (SARSCoV-2)	Decombio Biotechnology Co Ltd.	IgG	66.7	91.6	https://covidtestingproject.org/
University of Californ	United States	San Francis	Novel Coronavirus (SARSCoV-2)	Decombio Biotechnology Co Ltd.	IgM	67.5	90.7	https://covidtestingproject.org/
University of Californ	United States	San Francis	Novel Coronavirus (2019-nCoV)	Innovita Biological Technology C	IgM	28.7	96.3	https://covidtestingproject.org/
University of Californ	United States	San Francis	Novel Coronavirus (2019-nCoV)	Innovita Biological Technology C	IgG; IgM	56.9	96.3	https://covidtestingproject.org/
University of Californ	United States	San Francis	COVID-19 IgG/IgM Rapid Test C	Premier Biotech	IgG; IgM	70.5	97.2	https://covidtestingproject.org/
University of Californ	United States	San Francis	SARS-CoV-2 IgM/IgG Ab Rapid T	Sure Bio-Tech (USA) Co., Ltd	IgM	48.1	100	https://covidtestingproject.org/
University of Californ	United States	San Francis	SARS-CoV-2 IgM/IgG Ab Rapid T	Sure Bio-Tech (USA) Co., Ltd	IgG	56.6	100	https://covidtestingproject.org/
University of Californ	United States	San Francis	COVID-19 IgG/IgM Rapid Test C	Premier Biotech	IgM	69	98.1	https://covidtestingproject.org/
University of Californ	United States	San Francis	SARS-CoV-2 IgM/IgG Ab Rapid T	Sure Bio-Tech (USA) Co., Ltd	IgG; IgM	57.4	100	https://covidtestingproject.org/
University of Californ	United States	San Francis	COVID-19 IgG/IgM Rapid Test C	Premier Biotech	IgG	53.5	99.1	https://covidtestingproject.org/
University of Californ	United States	San Francis	Coronavirus IgG/IgM Antibody (	UCP Biosciences	IgM	60.8	98.1	https://covidtestingproject.org/
University of Californ	United States	San Francis	Coronavirus IgG/IgM Antibody (	UCP Biosciences	IgG	56.2	98.1	https://covidtestingproject.org/
University of Californ	United States	San Francis	EDI? Novel Coronavirus COVID-	Epitope Diagnostics, Inc.	IgM	56.9	97.2	https://covidtestingproject.org/
University of Californ	United States	San Francis	Coronavirus IgG/IgM Antibody (	UCP Biosciences	IgG; IgM	61.5	98.1	https://covidtestingproject.org/
University of Californ	United States	San Francis	EDI? Novel Coronavirus COVID-	Epitope Diagnostics, Inc.	IgG	73.8	90.7	https://covidtestingproject.org/
University of Californ	United States	San Francis	VivaDiag COVID-19 IgM/IgG Rap	VivaChek Biotech (Hangzhou) Co	IgM	65.3	94.9	https://covidtestingproject.org/
University of Californ	United States	San Francis	EDI? Novel Coronavirus COVID-	Epitope Diagnostics, Inc.	IgG; IgM	75.4	89.8	https://covidtestingproject.org/
University of Californ	United States	San Francis	VivaDiag COVID-19 IgM/IgG Rap	VivaChek Biotech (Hangzhou) Co	IgG	63.6	96	https://covidtestingproject.org/
University of Californ	United States	San Francis	VivaDiag COVID-19 IgM/IgG Rap	VivaChek Biotech (Hangzhou) Co	IgG; IgM	65.3	94.9	https://covidtestingproject.org/
University of Californ	United States	San Francis	SARS-CoV-2 Antibody Test (Late	Guangzhou Wondfo Biotech Co.,	IgG; IgM	69	99.1	https://covidtestingproject.org/
Bacteriology and Hyg	France	Kremlin-Bic	Finecare SARS-CoV-2 Antibody	Guangzhou Wondfo Biotech Co.,	Total Ig	78.3	98.4	Not available
Bacteriology and Hyg	France	Kremlin-Bic	2019-nCoV IgG/IgM Rapid Test	AutoBio Diagnostics	IgG; IgM	73.9	94	Not available
Bacteriology and Hyg	France	Kremlin-Bic	2019-nCoV IgG/IgM Rapid Test	Avioq Bio-Tech Co., Ltd	IgG; IgM	68	94.5	Not available
Bacteriology and Hyg	France	Kremlin-Bic	SARS-CoV-2 Antibody Test (Late	Guangzhou Wondfo Biotech Co.,	Total Ig	77.5	96.4	Not available

https://www.finddx.org/covid-19/dx-data/

Wondfo on research conducted by Imperial College

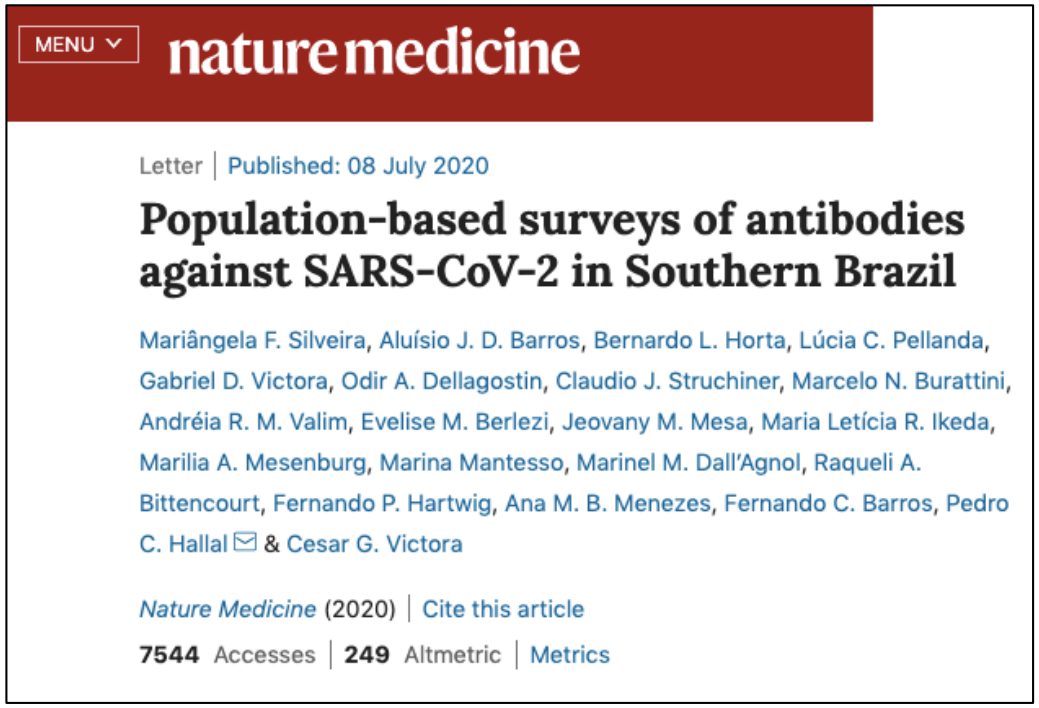
- REACT (Real-time Evaluation of Community Communication)， UK

- 10,000 tests had been sent to the community



https://www.nature.com/articles/d41586-020-01677-y

Wondfo on Brazill Covid-19 epidemic research



MENU

nature medicine

Letter | Published: 08 July 2020

Population-based surveys of antibodies against SARS-CoV-2 in Southern Brazil

Mariângela F. Silveira, Aluísio J. D. Barros, Bernardo L. Horta, Lúcia C. Pellanda, Gabriel D. Victora, Odir A. Dellagostin, Claudio J. Struchiner, Marcelo N. Burattini, Andréia R. M. Valim, Evelise M. Berlezi, Jeovany M. Mesa, Maria Letícia R. Ikeda, Marilia A. Mesenburg, Marina Mantesso, Marinel M. Dall'Agnol, Raqueli A. Bittencourt, Fernando P. Hartwig, Ana M. B. Menezes, Fernando C. Barros, Pedro C. Hallal & Cesar G. Victora

Nature Medicine (2020) | Cite this article

and 108 pre-COVID-19 negative controls. The sensitivity of the Wondfo test was 81.5% (95% CI = 70.0–90.1%) among 65 patients with a positive RT-PCR 11 d or more before the test, and the specificity was 99.1% (95% CI = 94.9–100.0%). Of the ten tests studied, the Wondfo test was one of the two lateral flow tests with the best performance. Lastly, we carried out our own validation study, based on 83 volunteers with a positive quantitative RT-PCR result 10 d or more before the rapid test. This analysis showed a sensitivity of 77.1% (95% CI = 66.6–85.6%). We also analyzed 100 serum samples collected in 2012 from participants of the 1982 Pelotas (Brazil) Birth Cohort Study[19] and found 98 negative results, yielding a specificity estimate of 98.0% (95% CI = 93.0–99.8%). By pooling the results from the four separate validations studies, weighted by sample sizes, the sensitivity was estimated at 84.8% (95% CI = 81.4–87.8%) and the specificity was estimated at 99.0% (95% CI = 97.8–99.7%).

https://www.nature.com/articles/s41591-020-0992-3

Wondfo is recommend to UNCTAD

（United Nations Conference on Trade and Development）

UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT
PROSPERITY FOR ALL

Letter to UNCSTD for sharing Guangdong's experience in containing COVID-19 by the scientific and technological method

Confronting with the crisis of the COVID-19 epidemic, the Chinese science and technology experts and personnel are always working in utilizing science and technology to tackle the COVID-19 in the frontline. They reached some scientific and technological outcomes and breakthroughs. In this context, science and technology play a crucial role in preventing and containing epidemics. In respond to the call from the UNCSTD, according to our principle and philosophy of being openness, transparent and sincerity, I would like to introduce several successful practices of Guangdong province in providing technical support for preventing and containing COVID-19 and related medical treatment measures. I would like to express my willingness to share these experiences with our CSTD member states and strengthen the international collaboration in dealing with the COVID-19 epidemic through our joint efforts.

I. **Invent the products for testing COVID-19 in a technological way.** Shenzhen BGI Group developed a new coronavirus nucleic acid detection kit (fluorescent PCR method) which has been applied in more than 70 countries all over the world. The BGI group maintain the competency of producing PCR detection kits for 300 000 persons per day and sequencing detection kits for 10 000 persons per day. BGI has fourteen "Fire Eye" COVID-19 testing laboratories which can test 50 000 persons per day. Daan Gene Co., Ltd of Sun Yat-sen University developed novel coronavirus nucleic acid detection kit and maintains the competency of producing 500 000 PCR detection kits (fluorescent PCR method) per person per day. Guangzhou Wondfo Biotech Co., Ltd developed novel coronavirus antibody detection (colloidal gold method) which was the first approved antibody detection reagent in China, with daily production for 600 000 persons, is able to test novel coronavirus antibody from human body's serum, plasma, and whole blood.

https://unctad.org/en/PublicationsLibrary/CSTD_COVID19_c05_China_en.pdf

Wondfo application precautions

Window period-- false negative

- The immune system takes time to response and produce enough detectable antibody.
- On the first week symptom onset, the detection rate could be <30%.

Total N=500
Total Positive N=249

		Delay symptoms onset				
		0-5 d	6-10 d	11-15 d	16-21 d	>21 d
WONDFO	N Case sera	30	104	67	38	10
	Case sera testing positive	7.0	78.0	65.0	33.0	10.0
	Sensitivity (%)	23.3	75.0	97.0	86.8	100.0
	IC 95%	9.9 42.3	65.6 83.0	89.6 99.6	71.9 95.6	69.2 100.0

Faint line– even 2 week after symptom

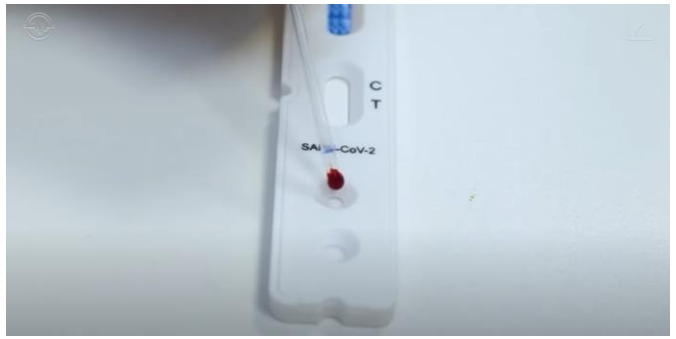
- Most patient are mild symptom, have low antibody level. Wondfo show faint line, need to pay good attention and check carefully.

- Some sample, Igg/Igm separte fail to detect, but Wondfo catch it.

- If using whole blood, must read within 20 minutes, or the background will become red.
- The Igg/Igm separate test show more visible line than Wondfo.

Capillary blood testing

Take blood



Sample loading

Drop buffer

Tips：1. If the sample is collected by digital puncture, use a sterile lancet

2. When piercing the finger, use 70% alcohol to disinfect, wait for it to dry before piercing

3. Results need to wait at least 15 minutes, up to 20 minutes

https://www.youtube.com/watch?v=ePIi6Z7ixSw

Precautions for serological testing

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1 There is compelling evidence that using total antibody or combined IgG/IgM detection offered the highest sensitivity of detection. Data from preliminary studies indicated that additional investigations should examine the clinical correlation of different isotypes and titers to disease severity. 2 It is also clear that the timing of sample acquisition is a crucial determinant of test accuracy, although this important information was not always clearly presented in the current literature.[16] The earliest positive results were reported by day 5 post onset of symptoms, and accuracy peaked by the second week of symptoms. Early in the course of the disease, when RT-PCR sensitivity was reported as 50% to 60%, the concomitant use of serologic tests significantly added sensitivity with consistently reported values over 90%. Moreover, after 10 to 14 days post onset of symptoms, the sensitivity of RT-PCR dropped significantly while serology testing reached its peak. As fully validated methods become commercially available, 3 serology methods may be utilized as an adjunct tool to RT-PCR testing protocols in patients with suspected infection.

https://academic.oup.com/ajcp/article/154/3/293/5862535

Practical Implementation of Serologic Testing

- **Diagnosis in Symptomatic Patients**

The sensitivity of RT-PCR testing decreased over time post onset of symptoms and that this change was observed to be concurrent with the increasing sensitivity of antibody detection methods.

- **Serology Use in Monitoring Disease Course**

Antibody responses may vary according to disease severity, and monitoring titers may be applied in clinical practice to guide earlier aggressive treatment.

- **Serology Use for Screening Asymptomatic Patients**

Implementation of serology testing to screen the general population and asymptomatic health care workers is currently of significant interest. Nonetheless, the available evidence is limited to support its use in these scenarios.

- **Utility for Possible Convalescent Serum Donors**

Understanding the utility of routine serologic methods (ie, ELISA, CLIA) in the prediction of convalescence is complex. Further comprehensive studies in this area are warranted.

https://academic.oup.com/ajcp/article/154/3/293/5862535

THANK YOU!