



Clinical trail 临床试验数据 (CHINA)

A part of clinical verification with president Xiaokun Li of Wenzhou medical university who is also the CAE academician has been completed.

Blood samples were collected from COVID-19 patients from a number of Chinese hospitals and China CDC (Centers for Disease Control) laboratories, and the tests were performed at each location. A total of 370 cases were detected: 188 clinically confirmed(positive) (Including nucleic acid testing system validation) new coronavirus infections 182 cases of non-new coronavirus infection (negative).

Comparison of test results with clinical reference standards

The kit detects the results	Clinical Reference Standard Results		Total
	Positive Samples	Negative Samples	
Positive Samples	170	0	352
Negative Samples	18	182	18
Total	188	182	370

Sensitivity: $A / (A + C) \times 100\%$; $170 / (170 + 18) \times 100\% = 90.43\%$

Specificity: $D / (B + D) \times 100\%$; $182 / (182 + 0) \times 100\% = 100\%$

Total coincidence rate: $= (A + D) / (A + B + C + D) \times 100\%$

$$= (170 + 182) / (170 + 182 + 18 + 0) = 95.14\%$$

The diagnostic kit for antibody IgM/IgG of novel coronavirus COVID-19 (Colloidal Gold Immunochromatography Assay) developed by Shanghai Liangrun Biomedical Technology Co.,Ltd. has a diagnostic sensitivity of 90.43%, a specificity of 100% and a total coincidence rate of 95.14%. With its test results being highly consistent with the clinical diagnosis results, the kit has a strong clinical application value.



Todos Medical Ab Fingerprick Clinical Data (USA)

A total of 73 cases were detected: 32 Positive by PCR, 17 Negatives by PCR, 24 Negatives from pre-pandemic (2017) cancer patients (controls).

Comparison of test results with clinical reference standards (1 Time Test)

The kit detects the results	Clinical Reference Standard Results		Total
	Positive Samples	Negative Samples	
Positive Samples	31	1	32
Negative Samples	1	40	41
Total	32	41	73

Sensitivity: $A / (A+C) \times 100\%$; $31 / (31+1) \times 100\% = 96.88\%$

Specificity: $D / (B+D) \times 100\%$; $40 / (40+1) \times 100\% = 97.56\%$

Comparison of test results with clinical reference standards (Retest within 3-5 Days)

The kit detects the results	Clinical Reference Standard Results		Total
	Positive Samples	Negative Samples	
Positive Samples	32	1	33
Negative Samples	0	40	40
Total	32	41	73

Sensitivity: $A / (A+C) \times 100\%$; $32 / (32+0) \times 100\% = 100\%$

Specificity: $D / (B+D) \times 100\%$; $40 / (40+1) \times 100\% = 97.56\%$

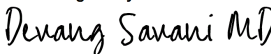
Todos Medical Ab Fingerprick Clinical Data 03/2020 - 04/2020

Shanghai Liangrun IgM/IgG antibody test kit

5/7/2020

Physician #1 Devang Savani, MD

Signature

DocuSigned by:

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Devang Savani MD Inc., Phone 949-533-6629

17 Negatives by PCR

30 Positive by PCR

Physician #2: John Whitehead, MD

Signature

DocuSigned by:

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Dr. John Whitehead, Phone: 312-498-3862, Email: jlwdo@me.com

2 Positive by PCR

Provista Diagnostics, Inc., Phone 678-580-0613 x 1005, Email. kusiatinu@provistadx.com

24 Negatives from pre-pandemic (2017) cancer patients (controls)

PCR Negatives

Patient ID	Date	Clinical Truth	Test Result	Suspected?*	Setting	Vs.	Specimen	IgM	IgG	User	Retest
1	4/15/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
2	4/16/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
3	4/20/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
4	4/22/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
5	4/22/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
6	4/22/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
7	4/23/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
8	4/24/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
9	4/24/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
10	4/24/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
11	4/11/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
12	4/11/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
13	4/9/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
14	4/10/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
15	4/13/2020	Negative	Positive	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	+	Dr. Savani	N/A

16	4/10/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
17	4/3/2020	Negative	Negative	YES	Hosp. 7-10 days post-Admit	PCR	Finger Pr.	-	-	Dr. Savani	N/A
18	4/15/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
19	4/15/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
20	4/15/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
21	4/15/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
22	4/15/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
23	4/18/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
24	4/18/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
25	4/18/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
26	4/18/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
27	4/14/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
28	4/14/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
29	4/14/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
30	4/14/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
31	4/14/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
32	4/11/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
33	4/11/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
34	4/11/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
35	4/11/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
36	4/11/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
37	4/11/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
38	4/8/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
39	4/8/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
40	4/8/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A
41	4/8/2020	Negative	Negative	NO	2017 Sample	2017 Blood	Venous	-	-	Provista	N/A

* YES = Clinical History + Initial lab results (lymphopenia/elevated LFT)

PCR Positive

Patient ID	Date	Clinical Truth	Test Result	Suspected*	Setting	Vs.	Specimen	IgM	IgG	User	Retest
42	4/1/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Finger Pr.	-	+	Dr Savani	N/A
43	3/30/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
44	4/6/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
45	4/9/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
46	4/11/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A

47	4/14/2020	Positive	Negative	YES	Hosp. 3-5 Days Post Admit	PCR	Fingerprick	-	-	Dr Savani	+
48	4/13/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
49	4/18/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
50	4/10/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
51	4/19/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
52	4/10/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
53	4/3/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
54	4/21/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
55	4/17/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
56	4/2/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
57	4/8/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
58	4/19/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
59	4/19/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
60	4/22/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
61	4/7/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
62	4/10/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
63	4/15/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
64	4/8/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
65	4/13/2020	Positive	Positive	YES	> Days Post Hosp. Discharge	PCR	Fingerprick	-	+	Dr. Whitehead	N/A
66	4/13/2020	Positive	Positive	YES	> Days Post Hosp. Discharge	PCR	Fingerprick	-	+	Dr. Whitehead	N/A
67	4/13/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
68	3/29/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
69	4/16/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
70	4/13/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
71	4/21/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
72	4/17/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A
73	4/22/2020	Positive	Positive	YES	Hosp. 7-10 Days Post Admit	PCR	Fingerprick	-	+	Dr Savani	N/A

Screening (1 time test)

		RT-PCR	
		Negative	Positive
Covid IgM/IgG Test	Negative	40	1
	Positive	1	31
PPA		96.77%	
NPA		97.50%	

Confirmation (Retest within 3-5 days)

		RT-PCR	
		Negative	Positive
Covid IgM/IgG Test	Negative	40	0
	Positive	1	32
PPA		100%	
NPA		97.6%	



Clinical Data (JAPAN)

A total of 70 cases were detected: 23 Positive by PCR, 47 Negatives by PCR.

Comparison of test results with clinical reference standards

(1 Time Test)

The kit detects the results	Clinical Reference Standard Results		Total
	Positive Samples	Negative Samples	
Positive Samples	21	1	22
Negative Samples	2	46	48
Total	23	47	70

Sensitivity: $A / (A + C) \times 100\%$; $21 / (21 + 2) \times 100\% = 91.30\%$

Specificity: $D / (B + D) \times 100\%$; $46 / (46 + 1) \times 100\% = 97.87\%$

Comparison of test results with clinical reference standards

(Retest 8 Days later)

The kit detects the results	Clinical Reference Standard Results		Total
	Positive Samples	Negative Samples	
Positive Samples	21	1	22
Negative Samples	1	46	47
Total	22	47	69

Sensitivity: $A / (A + C) \times 100\%$; $21 / (21 + 1) \times 100\% = 95.45\%$

Specificity: $D / (B + D) \times 100\%$; $46 / (46 + 1) \times 100\% = 97.87\%$

Reference: ロキ・コンサルティング株式会社と相模原協同病院でのκ係数（カッパ係数）を活用した日本、イギリス、中国での抗体検査キットと PCR の比較データを発表。