

Clinical Report of The First Affiliated Hospital of Medical School of Zhejiang University

Purpose: Evaluate the clinical performance of One Step SARS-CoV-2 Antibody Test (Lateral Flow Method)

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Technician: Peng Cai (Testsealabs), Feng Cheng (The First Affiliated Hospital of Medical School of Zhejiang University)

Test Procedure: Collect 10 µL plasma or serum sample, add into the sample well of test cassette and add 3 drops of buffer solution into the buffer well. Read result after 15 minutes.

Test Result

No.	Date of collection	Testsealabs	PCR
1	2.25	G6	Positive
2	2.24	G9	Positive
3	2.24	G5	Positive
4	2.25	G7	Positive
5	2.25	G8	Positive
6	2.25	G8	Positive
7	2.26	G0	Negative
8	2.24	G4	Positive
9	2.25	G8	Positive
10	2.27	G5	Positive
11	2.27	G6	Positive
12	2.29	G5	Positive
13	2.29	G7	Positive
14	2.29	G8	Positive
15	2.28	G7	Positive
16	2.28	G7	Positive
17	2.29	G6	Positive
18	2.28	G6	Positive

19	2.27	G8	Positive
20	2.27	G4	Positive
21	2.27	G5	Positive
22	2.29	G6	Positive
23	2.29	G6	Positive
24	2.28	G6	Positive
25	2.29	G5	Positive
26	2.24	G7	Positive
27	2.29	G8	Positive
28	2.28	G7	Positive
29	2.28	G5	Positive
30	2.27	G6	Positive
31	2.24	G7	Positive
32	2.27	G8	Positive
33	2.27	G7	Positive
34	2.24	G7	Positive
35	2.29	G8	Positive
36	2.24	G5	Positive
37	2.28	G7	Positive
38	2.28	G8	Positive
39	2.28	G7	Positive
40	2.28	G6	Positive

No.	Date of collection	Testsealabs	PCR
1	2.29	G0	Negative
2	3.01	G0	Negative
3	2.29	G0	Negative
4	2.29	G0	Negative
5	3.01	G0	Negative
6	3.01	G0	Negative
7	3.01	G0	Negative

8	2.29	G0	Negative
9	2.29	G0	Negative
10	3.01	G0	Negative

Testsealabs result interpretation:

- G0 indicates negative result
- G1~G2 indicates slightly positive result
- G3~G5 indicates moderate positive result
- G6~G9 indicates strong positive result

Result analysis

Conclusion		PCR		Total
		Positive	Negative	
Testsealabs	Positive	39	0	39
	Negative	1	10	11
Total		40	10	50

Positive coincident rate: $39/40 \times 100\% = 97.5\%$

Negative coincident rate: $11/10 \times 100\% = 100\%$

Total coincident rate = $(39+10) / (40+10) = 98\%$

Kappa value is 0.942