

**Clinical Study Report
of
VivaDiag™ COVID-19 IgM & IgG Rapid Test**

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1. Introduction

VivaDiag™ COVID-19 IgM/IgG Rapid Test is an in vitro diagnostic test for the qualitative determination of COVID-19's IgM and IgG antibodies in human whole blood (from vein or fingertip), serum or plasma.

The test devices contain:

- 1) Conjugate pad: recombinant SARS-CoV-2 antigen labeled with colloidal gold which linked FITC, FITC antibody and quality control antibody gold marker.
- 2) NC membrane: coated with two detection lines (IgG line and IgM line) and one quality control line (C line). The IgM line coated with mouse anti-human IgM monoclonal antibody detects the COVID-19 IgM antibody. The IgG line coated with mouse anti-human IgG monoclonal antibody detects the COVID-19 IgG antibody. The C line coated with quality control antibody.

2. Objective

Compare the clinical performance of VivaDiag™ COVID-19 IgM & IgG Rapid Test with COVID-19 RT-PCR Test & CT by 350 clinical samples in three hospitals.

3. Method

3.1 Instruments and Materials

VivaDiag™ COVID-19 IgM & IgG Rapid Test, Lot: 20200205,
COVID-19 RT-PCR test kit
CT

3.2 Samples

Total 350 subjects were invited to participate in this comparison study. All the samples have been tested by COVID-19 RT-PCR and CT, and the concentration distribution of result is as follows.

Table 1 - Concentration distribution of COVID-19 clinical specimen tested by RT-PCR&CT

COVID-19 clinical sample (by RT-PCT&CT)	Quantity
Negative (healthy people)	200
Positive (Infection time 4-10 days)	80
Positive (Infection time 11-24days)	70
Total	350

3.3 Procedure

- 1) Take out the test kit and leave it at room temperature for 30 minutes at least.
- 2) Put a test device on a dust-free clean surface.
- 3) Apply 10µL whole blood / serum / plasma onto the sample well of a test device first, and then apply 2 drops of buffer.
- 4) Read the result after 15 minutes.

3.4 Interpretation of Test Results

Positive result:

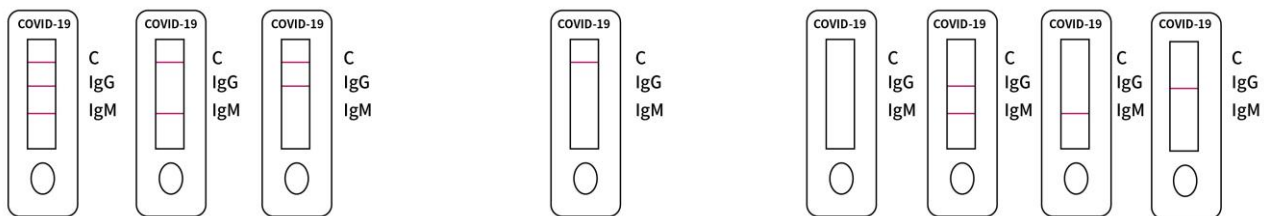
- 1) The COVID-19 IgM antibody is detected if the quality control line C and the detection line IgM are both colored, and the detection IgG line is not colored, that means the COVID-19 IgM antibody is positive.
- 2) The COVID-19 IgG antibody is detected if the quality control line C and the detection IgG line are both colored, and the detection IgM line is not colored, that means the COVID-19 IgG antibody is positive.
- 3) The COVID-19 IgG and IgM antibodies are detected if the quality control line C, the detection line IgM and IgG are both colored, that means both the COVID-19 IgG and IgM antibodies are positive.

Negative result:

If there is only quality control line C is colored, IgG and IgM detection lines are not colored, the COVID-19 IgM/IgG antibody is not detected, that means the result is negative.

Invalid result:

If the quality control line C is not colored, no matter whether the detection line IgG/IgM is colored or not, the result is invalid and needs to be tested again.



Positive: At least one purplish red line (IgG, IgM line) and one purplish red quality control line (C) appear in the detection area.

Negative: Only the quality control line (C) appears in the detection area.

Invalid: No purplish red quality control line (C) appears in the detection area no matter the IgG/IgM line is colored or not.

4. Results and Conclusions

Clinical Performance of negative sample			
Negative Cases (By PCR&CT)	Negative coincidence rate (VivaDiag™ COVID-19 IgM)	Negative coincidence rate (VivaDiag™ COVID-19 IgG)	Negative coincidence rate (Total)
200	200 (100%)	200 (100%)	200 (100%)
Clinical Performance of positive sample (infection time 4-10 days)			
Positive Cases (By PCR&CT)	Positive coincidence rate (VivaDiag™ COVID-19 IgM)	Positive coincidence rate (VivaDiag™ COVID-19 IgG)	Positive coincidence rate (Total)
80	65 (81.25%)	30 (37.5%)	65 (81.25%)
Clinical Performance of positive sample (infection time 11-24 days)			
Positive Cases (By PCR&CT)	Positive coincidence rate (VivaDiag™ COVID-19 IgM)	Positive coincidence rate (VivaDiag™ COVID-19 IgG)	Positive coincidence rate (Total)
70	68 (97.1%)	67 (95.7%)	68 (97.1%)

Relative Specificity: 100%

Relative Sensitivity (infection time 4-10 days, IgM & IgG): 81.25%

Relative Sensitivity (infection time 11-24 days, IgM & IgG): 97.1%

Accuracy (infection time 4-10 days, IgM & IgG): 94.6%

Accuracy (infection time 11-24 days, IgM & IgG): 99.3%

Total accuracy: 95.1%

From the results of 350 negative and positive samples, we can confirm that VivaDiag™ COVID-19 IgM& IgG rapid test has good clinical performance compare with RT-PCR&CT

5. Testing data

5.1 Results of negative samples:

Table 2 - Results of negative samples were tested with VivaDiag™ COVID-19 IgM & IgG Rapid Test and COVID-19 RT-PCR and CT

sample	VivaDiag™ COVID-19 IgM	VivaDiag™ COVID-19 IgG	PCR&CT	VivaDiag™ COVID-19 IgM coincidence	VivaDiag™ COVID-19 IgG coincidence	Total coincidence
1	Negative	Negative	Negative	Yes	Yes	Yes
2	Negative	Negative	Negative	Yes	Yes	Yes
3	Negative	Negative	Negative	Yes	Yes	Yes
4	Negative	Negative	Negative	Yes	Yes	Yes
5	Negative	Negative	Negative	Yes	Yes	Yes
6	Negative	Negative	Negative	Yes	Yes	Yes
7	Negative	Negative	Negative	Yes	Yes	Yes
8	Negative	Negative	Negative	Yes	Yes	Yes
9	Negative	Negative	Negative	Yes	Yes	Yes
10	Negative	Negative	Negative	Yes	Yes	Yes
11	Negative	Negative	Negative	Yes	Yes	Yes
12	Negative	Negative	Negative	Yes	Yes	Yes
13	Negative	Negative	Negative	Yes	Yes	Yes
14	Negative	Negative	Negative	Yes	Yes	Yes
15	Negative	Negative	Negative	Yes	Yes	Yes
16	Negative	Negative	Negative	Yes	Yes	Yes
17	Negative	Negative	Negative	Yes	Yes	Yes
18	Negative	Negative	Negative	Yes	Yes	Yes
19	Negative	Negative	Negative	Yes	Yes	Yes
20	Negative	Negative	Negative	Yes	Yes	Yes
21	Negative	Negative	Negative	Yes	Yes	Yes
22	Negative	Negative	Negative	Yes	Yes	Yes
23	Negative	Negative	Negative	Yes	Yes	Yes
24	Negative	Negative	Negative	Yes	Yes	Yes
25	Negative	Negative	Negative	Yes	Yes	Yes
26	Negative	Negative	Negative	Yes	Yes	Yes
27	Negative	Negative	Negative	Yes	Yes	Yes
28	Negative	Negative	Negative	Yes	Yes	Yes
29	Negative	Negative	Negative	Yes	Yes	Yes
30	Negative	Negative	Negative	Yes	Yes	Yes
31	Negative	Negative	Negative	Yes	Yes	Yes
32	Negative	Negative	Negative	Yes	Yes	Yes
33	Negative	Negative	Negative	Yes	Yes	Yes
34	Negative	Negative	Negative	Yes	Yes	Yes
35	Negative	Negative	Negative	Yes	Yes	Yes
36	Negative	Negative	Negative	Yes	Yes	Yes
37	Negative	Negative	Negative	Yes	Yes	Yes
38	Negative	Negative	Negative	Yes	Yes	Yes
39	Negative	Negative	Negative	Yes	Yes	Yes
40	Negative	Negative	Negative	Yes	Yes	Yes
41	Negative	Negative	Negative	Yes	Yes	Yes
42	Negative	Negative	Negative	Yes	Yes	Yes
43	Negative	Negative	Negative	Yes	Yes	Yes
44	Negative	Negative	Negative	Yes	Yes	Yes
45	Negative	Negative	Negative	Yes	Yes	Yes
46	Negative	Negative	Negative	Yes	Yes	Yes
47	Negative	Negative	Negative	Yes	Yes	Yes
48	Negative	Negative	Negative	Yes	Yes	Yes
49	Negative	Negative	Negative	Yes	Yes	Yes
50	Negative	Negative	Negative	Yes	Yes	Yes
51	Negative	Negative	Negative	Yes	Yes	Yes
52	Negative	Negative	Negative	Yes	Yes	Yes

181	Negative	Negative	Negative	Yes	Yes	Yes
182	Negative	Negative	Negative	Yes	Yes	Yes
183	Negative	Negative	Negative	Yes	Yes	Yes
184	Negative	Negative	Negative	Yes	Yes	Yes
185	Negative	Negative	Negative	Yes	Yes	Yes
186	Negative	Negative	Negative	Yes	Yes	Yes
187	Negative	Negative	Negative	Yes	Yes	Yes
188	Negative	Negative	Negative	Yes	Yes	Yes
189	Negative	Negative	Negative	Yes	Yes	Yes
190	Negative	Negative	Negative	Yes	Yes	Yes
191	Negative	Negative	Negative	Yes	Yes	Yes
192	Negative	Negative	Negative	Yes	Yes	Yes
193	Negative	Negative	Negative	Yes	Yes	Yes
194	Negative	Negative	Negative	Yes	Yes	Yes
195	Negative	Negative	Negative	Yes	Yes	Yes
196	Negative	Negative	Negative	Yes	Yes	Yes
197	Negative	Negative	Negative	Yes	Yes	Yes
198	Negative	Negative	Negative	Yes	Yes	Yes
199	Negative	Negative	Negative	Yes	Yes	Yes
200	Negative	Negative	Negative	Yes	Yes	Yes

5.2 Results of positive samples (4-10days):

Table 3 - Results of positive samples were tested with VivaDiag™ COVID-19 IgM & IgG Rapid Test and COVID-19 RT-PCR and CT

sample	VivaDiag™ COVID-19 IgM	VivaDiag™ COVID-19 IgG	PCR&CT	VivaDiag™ COVID-19 IgM coincidence	VivaDiag™ COVID-19 IgG coincidence	Total coincidence
1	Positive	Negative	Positive	Yes	No	Yes
2	Positive	Negative	Positive	Yes	No	Yes
3	Positive	Negative	Positive	Yes	No	Yes
4	Positive	Negative	Positive	Yes	No	Yes
5	Negative	Negative	Positive	No	No	No
6	Positive	Negative	Positive	Yes	No	Yes
7	Positive	Negative	Positive	Yes	No	Yes
8	Positive	Negative	Positive	Yes	No	Yes
9	Positive	Negative	Positive	Yes	No	Yes
10	Positive	Negative	Positive	Yes	No	Yes
11	Positive	Negative	Positive	Yes	No	Yes
12	Negative	Negative	Positive	No	No	No
13	Positive	Negative	Positive	Yes	No	Yes
14	Positive	Negative	Positive	Yes	No	Yes
15	Negative	Negative	Positive	No	No	No
16	Positive	Positive	Positive	Yes	Yes	Yes
17	Positive	Positive	Positive	Yes	Yes	Yes
18	Negative	Negative	Positive	No	No	No
19	Positive	Positive	Positive	Yes	Yes	Yes
20	Negative	Negative	Positive	No	No	No
21	Positive	Positive	Positive	Yes	Yes	Yes
22	Negative	Negative	Positive	No	No	No
23	Negative	Negative	Positive	No	No	No
24	Positive	Negative	Positive	Yes	No	Yes
25	Positive	Negative	Positive	Yes	Yes	Yes
26	Negative	Negative	Positive	No	No	No
27	Positive	Negative	Positive	Yes	No	Yes
28	Positive	Negative	Positive	Yes	No	Yes
29	Positive	Positive	Positive	Yes	Yes	Yes
30	Positive	Positive	Positive	Yes	Yes	Yes
31	Negative	Negative	Positive	No	No	No
32	Negative	Negative	Positive	No	No	No
33	Positive	Positive	Positive	Yes	Yes	Yes
34	Positive	Positive	Positive	Yes	Yes	Yes
35	Positive	Negative	Positive	Yes	No	Yes

36	Positive	Negative	Positive	Yes	No	Yes
37	Positive	Negative	Positive	Yes	No	Yes
38	Positive	Negative	Positive	Yes	No	Yes
39	Positive	Negative	Positive	Yes	No	Yes
40	Positive	Negative	Positive	Yes	No	Yes
41	Positive	Positive	Positive	Yes	Yes	Yes
42	Positive	Positive	Positive	Yes	Yes	Yes
43	Positive	Negative	Positive	Yes	No	Yes
44	Positive	Negative	Positive	Yes	No	Yes
45	Positive	Negative	Positive	Yes	No	Yes
46	Positive	Negative	Positive	Yes	No	Yes
47	Positive	Negative	Positive	Yes	No	Yes
48	Positive	Negative	Positive	Yes	No	Yes
49	Positive	Negative	Positive	Yes	No	Yes
50	Positive	Negative	Positive	Yes	No	Yes
51	Positive	Positive	Positive	Yes	Yes	Yes
52	Positive	Positive	Positive	Yes	Yes	Yes
53	Positive	Positive	Positive	Yes	Yes	Yes
54	Positive	Positive	Positive	Yes	Yes	Yes
55	Positive	Positive	Positive	Yes	Yes	Yes
56	Positive	Positive	Positive	Yes	Yes	Yes
57	Positive	Positive	Positive	Yes	Yes	Yes
58	Positive	Positive	Positive	Yes	Yes	Yes
59	Positive	Positive	Positive	Yes	Yes	Yes
60	Positive	Positive	Positive	Yes	Yes	Yes
61	Positive	Negative	Positive	Yes	No	Yes
62	Positive	Negative	Positive	Yes	No	Yes
63	Positive	Positive	Positive	Yes	Yes	Yes
64	Positive	Negative	Positive	Yes	No	Yes
65	Positive	Negative	Positive	Yes	No	Yes
66	Positive	Positive	Positive	Yes	Yes	Yes
67	Positive	Positive	Positive	Yes	Yes	Yes
68	Positive	Negative	Positive	Yes	No	Yes
69	Positive	Negative	Positive	Yes	No	Yes
70	Positive	Positive	Positive	Yes	Yes	Yes
71	Positive	Positive	Positive	Yes	Yes	Yes
72	Negative	Negative	Positive	No	No	No
73	Positive	Positive	Positive	Yes	Yes	Yes
74	Negative	Negative	Positive	No	No	No
75	Negative	Negative	Positive	No	No	No
76	Positive	Positive	Positive	Yes	Yes	Yes
77	Positive	Positive	Positive	Yes	Yes	Yes
78	Negative	Negative	Positive	No	No	No
79	Negative	Negative	Positive	No	No	No
80	Positive	Positive	Positive	Yes	Yes	Yes

5.3 Results of positive samples (11-24days):

Table 4 - Results of positive samples were tested with VivaDiag™ COVID-19 IgM & IgG Rapid Test and COVID-19 RT-PCR and CT

sample	VivaDiag™ COVID-19 IgM	VivaDiag™ COVID-19 IgG	PCR & CT	VivaDiag™ COVID-19 IgM coincidence	VivaDiag™ COVID-19 IgG coincidence	Total coincidence
1	Positive	Positive	Positive	Yes	Yes	Yes
2	Positive	Positive	Positive	Yes	Yes	Yes
3	Positive	Positive	Positive	Yes	Yes	Yes
4	Positive	Positive	Positive	Yes	Yes	Yes
5	Positive	Positive	Positive	Yes	Yes	Yes
6	Positive	Positive	Positive	Yes	Yes	Yes
7	Positive	Positive	Positive	Yes	Yes	Yes
8	Positive	Positive	Positive	Yes	Yes	Yes

