Clinical Study Report
of
VivaDiag™ SARS-CoV-2 Ag FIA Test

Performance Evaluation--Clinical Study Report

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Ver1.1

1. Introduction

The VivaDiag™ SARS-CoV-2 Ag FIA Test is a fluorescent immunochromatographic assay for the rapid and qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab or throat swab specimen that is automatically analyzed on the VivaDiag™ POCT Analyzer.

The test devices contain:

1) Conjugate pad: anti-SARS-CoV-2 nucleocapsid protein monoclonal antibody labeled with fluorescence microspheres.

2) NC membrane: coated with one detection line (T line) and one quality control line (C line). The T line coated with anti-SARS-CoV-2 nucleocapsid protein monoclonal antibody. The C line coated with anti-mouse IgG polyclonal antibody.

2. Important information

- It is for in vitro diagnostic use by professionals.
- Use only VivaDiag™ POCT Analyzer with VivaDiag™ SARS-CoV-2 Ag FIA Test. Do not use other brand, otherwise it will not guarantee the reliability of the measured data.
- Please read this User's Manual carefully before you use your analyzer and keep your User's Manual in a safe place for referring it in the future

3. Objective

Compare the clinical performance of VivaDiag™ SARS-CoV-2 Ag FIA Test with SARS-CoV-2 RT-PCR Test & CT by 156 clinical samples.

4. Method

4.1 Instruments and Materials

VivaDiag™ SARS-CoV-2 Ag FIA Test, Lot: T2006004
VivaDiag™ POCT Analyzer, model: VIM1000, SN: NQY191209-006
SARS-CoV-2 RT-PCR test kit
CT
Timer

4.2 Samples

Total 156 subjects were invited to participate in this comparison study at 3 clinical sites. All nasal swab samples were obtained from the subjects were analyzed by RT-PCR for the presence of SARS-CoV-2 and CT method was employed to confirm the infection. From the 156 subjects, 121 are negative for SARS-CoV-2 infection and 35 are positive.

Table 1 - Distribution of SARS-CoV-2 clinical specimen tested by RT-PCR & CT

SARS-CoV-2 clinical sample (by RT-PCT & CT)	Quantity
Negative	121
Positive	35
Total	156

Note:

Both nasal swab specimen and throat swab specimen can be used by VivaDiag™ SARS-CoV-2 Ag FIA Test to detect the presence of SARS-CoV-2 antigen in the specimen. Internal validation studies based on Matrix Equivalency (Report No.TF026-013) were performed on both nasal swab specimens and throat swab specimens, no statistic difference was observed among those specimens.

4.3 Procedure

1) Specimen collection

- **Nasal swab specimen**

In this clinical studies, 156 specimens are collected from the nasal swabs. It is important to obtain as much secretion as possible.

Insert the sterile swab into one nostril. The swab tip should be inserted up to 2.5 cm (1 inch) from the edge of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected. Repeat this process for the other nostril to ensure that an adequate specimen is collected from both nasal cavities (use the same swab).

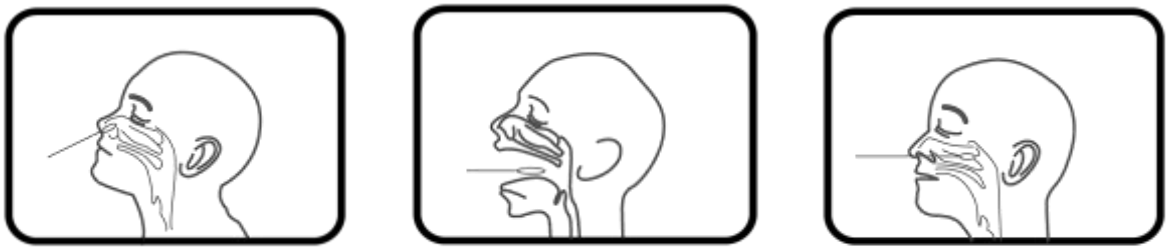
Oropharyngeal and Nasopharyngeal are also acceptable for VivaDiagTM SARS-CoV-2 Ag FIA Test.

- **Oropharyngeal swab specimen (optional)**

It is important to obtain as much secretion as possible. Insert the sterile swab into throat that presents the most secretion from the red area of the throat wall and maxillary tonsils to collect throat swab specimen. Rub the bilateral throat tonsils and throat wall moderately to obtain the specimen. Please do not touch the tongue when remove the swab.

- **Nasopharyngeal swab specimen (optional)**

It is important to obtain as much secretion as possible. Insert the sterile swab into the nostril that presents the most secretion under visual inspection. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab 5 times then remove it from the nasopharynx.



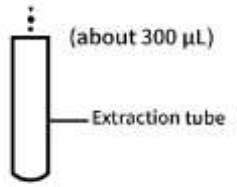
2) Specimen handling

Freshly collected specimens should be tested as soon as possible. It is essential that correct specimen collection and preparation methods are followed.

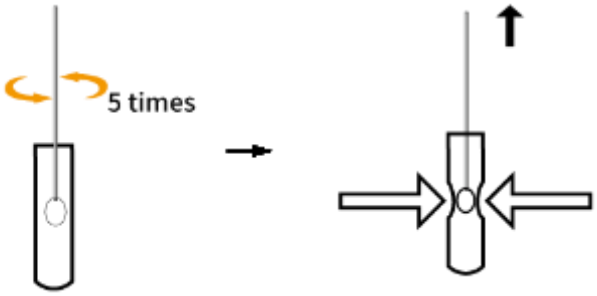
3) Testing Procedure

Allow the Test Devices and Extraction Solution to equilibrate to 15-30°C prior to testing.

1. Connect the power adapter and turn on the power switch to start the analyzer.
2. Remove the code chip from VivaDiagTM SARS-CoV-2 Ag FIA Test, and insert it into the code chip slot of the analyzer.
3. Take out a test device from sealed foil pouch and put it on a clean and level surface.
4. Add 300 µL extraction solution into extraction tube on tube stand. Please avoid bubbles when operation.

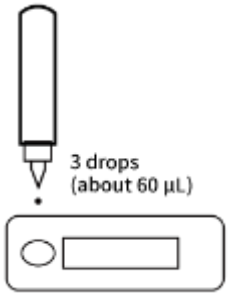


5. Collect specimen refer to **Specimen Collection.**
6. Insert sterile swab with collected specimen into extraction tube. Roll the swab 5 times. while pressing the head against the bottom and side of the extraction tube. Roll the swab head against the inside of the extraction tube when remove it. Try to release as much liquid as possible. Dispose of the used swab in the biohazard waste.



7. Put on the tube tip.

8. Apply 3 drops (about 60 μL) of extracted specimen onto the specimen well. Please avoid bubbles when operation.



9. Insert test device into the test device slot of the analyzer, push the device back all the way. Click “Standard Test” of analyzer, the analyzer will automatically start to count down and display the result after 15 minutes.

Note:

- *Do not interchange or mix extraction solution from different lots.*
- *Handle extraction solution with caution, do not contact with eyes or skin. If spilled on eyes or skin, wash thoroughly with water.*
- *Please follow local regulations to handle the used materials.*

4.4 Interpretation of Test Results

The VivaDiag™ POCT Analyzer (provided separately) must be used for interpretation of all test result. Operators should not attempt to interpret result directly from the test device contained within the VivaDiag™ SARS-CoV-2 Ag FIA Test.

Positive result:

Display screen showing a valid positive result for SARS-CoV-2 Ag (antigen detected).

Negative result:

Display screen showing a valid negative result for SARS-CoV-2 Ag (no antigen detected).

Invalid result:

Display screen showing invalid results, should repeat the test.

5. Results and Conclusions

VivaDiag™ SARS-CoV-2 Ag FIA Test	PCR		
	Positive	Negative	Total
Positive	31	0	31
Negative	4	121	125
Total	35	121	156
Sensitivity	88.57% (31/35, 95%CI, 74.05%~95.46%)		
Specificity	100% (121/121, 95%CI, 96.92%~100%)		
Accuracy	97.44% (152/156, 95%CI, 93.59%~98.99%)		

The VivaDiag™ SARS-CoV-2 Ag FIA Test showed 88.57% of clinical sensitivity.

The VivaDiag™ SARS-CoV-2 Ag FIA Test showed 100% of clinical specificity.

The VivaDiag™ SARS-CoV-2 Ag FIA Test showed 97.44% of clinical accuracy.

From the results of 156 negative and positive samples, we can confirm that VivaDiag™ SARS-CoV-2 Ag FIA test has good clinical performance compare with RT-PCR & CT.

6. Testing data

6.1 Results of negative samples

Table 2 - Results of negative samples were tested with VivaDiag™ SARS-CoV-2 Ag FIA Test and SARS-CoV-2 RT-PCR and CT

Sample	Clinical Site	Date of testing	VivaDiag™ SARS-CoV-2 Ag	PCR & CT	VivaDiag™ SARS-CoV-2 Ag coincidence
1	No.1	July 22, 2020	Negative	Negative	Yes
2	No.1	July 22, 2020	Negative	Negative	Yes
3	No.1	July 22, 2020	Negative	Negative	Yes
4	No.1	July 22, 2020	Negative	Negative	Yes
5	No.1	July 22, 2020	Negative	Negative	Yes
6	No.1	July 22, 2020	Negative	Negative	Yes
7	No.1	July 22, 2020	Negative	Negative	Yes
8	No.1	July 22, 2020	Negative	Negative	Yes
9	No.1	July 22, 2020	Negative	Negative	Yes
10	No.1	July 22, 2020	Negative	Negative	Yes
11	No.1	July 22, 2020	Negative	Negative	Yes
12	No.1	July 22, 2020	Negative	Negative	Yes
13	No.1	July 22, 2020	Negative	Negative	Yes
14	No.1	July 22, 2020	Negative	Negative	Yes
15	No.1	July 22, 2020	Negative	Negative	Yes
16	No.1	July 22, 2020	Negative	Negative	Yes
17	No.1	July 22, 2020	Negative	Negative	Yes
18	No.1	July 23, 2020	Negative	Negative	Yes
19	No.1	July 23, 2020	Negative	Negative	Yes
20	No.1	July 23, 2020	Negative	Negative	Yes
21	No.1	July 23, 2020	Negative	Negative	Yes
22	No.1	July 23, 2020	Negative	Negative	Yes

23	No.1	July 23, 2020	Negative	Negative	Yes
24	No.1	July 23, 2020	Negative	Negative	Yes
25	No.1	July 23, 2020	Negative	Negative	Yes
26	No.1	July 23, 2020	Negative	Negative	Yes
27	No.1	July 23, 2020	Negative	Negative	Yes
28	No.1	July 23, 2020	Negative	Negative	Yes
29	No.1	July 23, 2020	Negative	Negative	Yes
30	No.1	July 23, 2020	Negative	Negative	Yes
31	No.1	July 23, 2020	Negative	Negative	Yes
32	No.1	July 23, 2020	Negative	Negative	Yes
33	No.1	July 23, 2020	Negative	Negative	Yes
34	No.1	July 23, 2020	Negative	Negative	Yes
35	No.1	July 23, 2020	Negative	Negative	Yes
36	No.1	July 24, 2020	Negative	Negative	Yes
37	No.1	July 24, 2020	Negative	Negative	Yes
38	No.1	July 24, 2020	Negative	Negative	Yes
39	No.1	July 24, 2020	Negative	Negative	Yes
40	No.1	July 24, 2020	Negative	Negative	Yes
41	No.1	July 24, 2020	Negative	Negative	Yes
42	No.1	July 24, 2020	Negative	Negative	Yes
43	No.1	July 24, 2020	Negative	Negative	Yes
44	No.1	July 24, 2020	Negative	Negative	Yes
45	No.1	July 24, 2020	Negative	Negative	Yes
46	No.1	July 24, 2020	Negative	Negative	Yes
47	No.1	July 24, 2020	Negative	Negative	Yes
48	No.1	July 24, 2020	Negative	Negative	Yes
49	No.1	July 24, 2020	Negative	Negative	Yes
50	No.1	July 24, 2020	Negative	Negative	Yes
51	No.2	July 25, 2020	Negative	Negative	Yes
52	No.2	July 25, 2020	Negative	Negative	Yes
53	No.2	July 25, 2020	Negative	Negative	Yes
54	No.2	July 25, 2020	Negative	Negative	Yes
55	No.2	July 25, 2020	Negative	Negative	Yes
56	No.2	July 25, 2020	Negative	Negative	Yes
57	No.2	July 25, 2020	Negative	Negative	Yes
58	No.2	July 25, 2020	Negative	Negative	Yes
59	No.2	July 25, 2020	Negative	Negative	Yes
60	No.2	July 25, 2020	Negative	Negative	Yes
61	No.2	July 25, 2020	Negative	Negative	Yes
62	No.2	July 25, 2020	Negative	Negative	Yes
63	No.2	July 25, 2020	Negative	Negative	Yes
64	No.2	July 25, 2020	Negative	Negative	Yes
65	No.2	July 25, 2020	Negative	Negative	Yes
66	No.2	July 25, 2020	Negative	Negative	Yes
67	No.2	July 25, 2020	Negative	Negative	Yes
68	No.2	July 25, 2020	Negative	Negative	Yes
69	No.2	July 26, 2020	Negative	Negative	Yes
70	No.2	July 26, 2020	Negative	Negative	Yes
71	No.2	July 26, 2020	Negative	Negative	Yes
72	No.2	July 26, 2020	Negative	Negative	Yes
73	No.2	July 26, 2020	Negative	Negative	Yes
74	No.2	July 26, 2020	Negative	Negative	Yes
75	No.2	July 26, 2020	Negative	Negative	Yes
76	No.2	July 26, 2020	Negative	Negative	Yes
77	No.2	July 26, 2020	Negative	Negative	Yes
78	No.2	July 26, 2020	Negative	Negative	Yes
79	No.2	July 26, 2020	Negative	Negative	Yes
80	No.2	July 26, 2020	Negative	Negative	Yes
81	No.2	July 26, 2020	Negative	Negative	Yes
82	No.2	July 26, 2020	Negative	Negative	Yes
83	No.2	July 26, 2020	Negative	Negative	Yes
84	No.2	July 26, 2020	Negative	Negative	Yes
85	No.2	July 26, 2020	Negative	Negative	Yes
86	No.3	July 27, 2020	Negative	Negative	Yes

87	No.3	July 27, 2020	Negative	Negative	Yes
88	No.3	July 27, 2020	Negative	Negative	Yes
89	No.3	July 27, 2020	Negative	Negative	Yes
90	No.3	July 27, 2020	Negative	Negative	Yes
91	No.3	July 27, 2020	Negative	Negative	Yes
92	No.3	July 27, 2020	Negative	Negative	Yes
93	No.3	July 27, 2020	Negative	Negative	Yes
94	No.3	July 27, 2020	Negative	Negative	Yes
95	No.3	July 27, 2020	Negative	Negative	Yes
96	No.3	July 27, 2020	Negative	Negative	Yes
97	No.3	July 27, 2020	Negative	Negative	Yes
98	No.3	July 27, 2020	Negative	Negative	Yes
99	No.3	July 28, 2020	Negative	Negative	Yes
100	No.3	July 28, 2020	Negative	Negative	Yes
101	No.3	July 28, 2020	Negative	Negative	Yes
102	No.3	July 28, 2020	Negative	Negative	Yes
103	No.3	July 28, 2020	Negative	Negative	Yes
104	No.3	July 28, 2020	Negative	Negative	Yes
105	No.3	July 28, 2020	Negative	Negative	Yes
106	No.3	July 28, 2020	Negative	Negative	Yes
107	No.3	July 28, 2020	Negative	Negative	Yes
108	No.3	July 28, 2020	Negative	Negative	Yes
109	No.3	July 28, 2020	Negative	Negative	Yes
110	No.3	July 28, 2020	Negative	Negative	Yes
111	No.3	July 28, 2020	Negative	Negative	Yes
112	No.3	July 28, 2020	Negative	Negative	Yes
113	No.3	July 28, 2020	Negative	Negative	Yes
114	No.3	July 28, 2020	Negative	Negative	Yes
115	No.3	July 28, 2020	Negative	Negative	Yes
116	No.3	July 29, 2020	Negative	Negative	Yes
117	No.3	July 29, 2020	Negative	Negative	Yes
118	No.3	July 29, 2020	Negative	Negative	Yes
119	No.3	July 29, 2020	Negative	Negative	Yes
120	No.3	July 29, 2020	Negative	Negative	Yes
121	No.3	July 29, 2020	Negative	Negative	Yes

6.2 Results of positive samples

Table 3 - Results of positive samples were tested with VivaDiag™ SARS-CoV-2 Ag FIA Test and SARS-CoV-2 RT-PCR and CT

sample	Clinical Site	Date of testing	Days from onset of symptoms	VivaDiag™ SARS-CoV-2 Ag	PCR & CT	VivaDiag™ SARS-CoV-2 Ag coincidence
1	No.1	July 22, 2020	1	Positive	Positive	Yes
2	No.1	July 22, 2020	0	Positive	Positive	Yes
3	No.1	July 22, 2020	1	Positive	Positive	Yes
4	No.1	July 22, 2020	1	Positive	Positive	Yes
5	No.1	July 22, 2020	4	Positive	Positive	Yes
6	No.1	July 22, 2020	1	Positive	Positive	Yes
7	No.1	July 22, 2020	2	Positive	Positive	Yes
8	No.1	July 22, 2020	2	Positive	Positive	Yes
9	No.1	July 23, 2020	1	Positive	Positive	Yes
10	No.1	July 23, 2020	1	Positive	Positive	Yes
11	No.1	July 23, 2020	2	Positive	Positive	Yes
12	No.1	July 23, 2020	1	Positive	Positive	Yes
13	No.1	July 24, 2020	3	Positive	Positive	Yes
14	No.1	July 24, 2020	1	Positive	Positive	Yes
15	No.1	July 24, 2020	5	Negative	Positive	No
16	No.2	July 25, 2020	1	Positive	Positive	Yes
17	No.2	July 25, 2020	2	Positive	Positive	Yes
18	No.2	July 25, 2020	5	Negative	Positive	No
19	No.2	July 25, 2020	1	Positive	Positive	Yes
20	No.2	July 25, 2020	6	Negative	Positive	No

21	No.2	July 26, 2020	2	Positive	Positive	Yes
22	No.2	July 26, 2020	3	Positive	Positive	Yes
23	No.2	July 26, 2020	5	Positive	Positive	Yes
24	No.3	July 27, 2020	2	Positive	Positive	Yes
25	No.3	July 27, 2020	2	Positive	Positive	Yes
26	No.3	July 27, 2020	6	Negative	Positive	No
27	No.3	July 27, 2020	2	Positive	Positive	Yes
28	No.3	July 27, 2020	3	Positive	Positive	Yes
29	No.3	July 28, 2020	2	Positive	Positive	Yes
30	No.3	July 28, 2020	1	Positive	Positive	Yes
31	No.3	July 28, 2020	2	Positive	Positive	Yes
32	No.3	July 28, 2020	1	Positive	Positive	Yes
33	No.3	July 28, 2020	3	Positive	Positive	Yes
34	No.3	July 29, 2020	0	Positive	Positive	Yes
35	No.3	July 29, 2020	2	Positive	Positive	Yes

7. Reference

WHO - Instructions and requirements for Emergency Use Listing (EUL) submission: In vitro diagnostics detecting SARS-CoV-2 nucleic acid and rapid diagnostics tests detecting SARS-CoV-2 antigens.