

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

Performance Evaluation--Clinical Study Report

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Ver1.1

1. Introduction

VivaDiag™ SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human nasal swab or throat swab specimen.

The test devices contain:

- 1) Conjugate pad: murine anti-SARS-CoV-2 nucleocapsid protein monoclonal antibody labeled with colloidal gold.
- 2) NC membrane: coated with one detection line (T line) and one quality control line (C line). The T line coated with murine anti-SARS-CoV-2 nucleocapsid protein monoclonal antibody. The C line coated with Goat anti-mouse IgG polyclonal antibody.

2. Objective

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

3. Method

3.1 Instruments and Materials

VivaDiag™ SARS-CoV-2 Ag Rapid Test, Lot: T2006001,
SARS-CoV-2 RT-PCR test kit,
CT

3.2 Samples

Total 156 subjects were invited to participate in this comparison study at 3 clinical sites. All 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.

In this study, from 121 negative subjects, 61 are from Nasal swab specimens and 60 are from throat swab specimens. From 35 positive subjects, 20 are from Nasal swab specimens and 15 are from throat swab specimens.

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

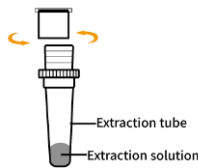
SARS-CoV-2 clinical sample (by RT-PCT & CT)	Quantity
Negative	121
Positive	35
Total	156

Note:

Both nasal swab specimen and throat swab specimen can be used by VivaDiag™ SARS-CoV-2 Ag Rapid Test to detect the presence of SARS-CoV-2 antigen in the specimen. Internal validation studies based on Matrix Equivalency (Report No.TF025-013) were performed on both nasal swab specimens and throat swab specimens, no statistic difference was observed among those specimens.

3.3 Procedure

- 1) Take out a test device from sealed foil pouch and put it on a clean and level surface.
- 2) Gently unscrew the cap of an extraction tube (prefilled with 300uL extraction solution), and place it on tube stand.



- 3) Specimen collection

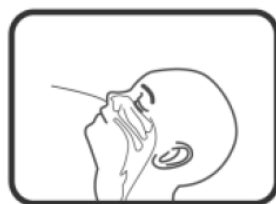
Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.

- Nasal swab specimen

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).

- Throat swab specimen

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

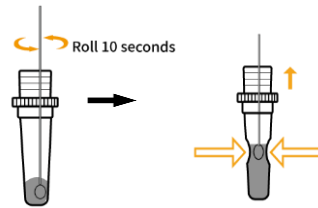


Nasal swab specimen



Throat swab specimen

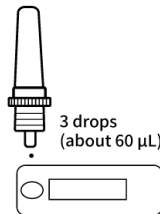
- 4) Insert sterile swab with collected specimen into extraction tube (prefilled with 300uL extraction solution). Roll the swab at least 10 seconds while pressing the head against the bottom and side of the extraction tube. Roll the swab head against the inside of the extraction tube when remove it. Try to release as much liquid as possible. Dispose of the used swab in the biohazard waste.



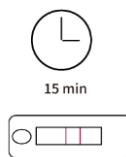
- 5) Insert a filtered nozzle into extraction tube containing extracted specimen.



- 6) Invert extraction tube and apply 3 drops (about 60uL) of extracted specimen onto the specimen well.



- 7) Read the test result at 15 minutes. Don't read the result after 20 minutes.



3.4 Interpretation of Test Results

Positive result:

Both the quality control line C and the detection line T appear.

Negative result:

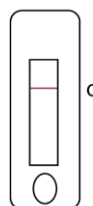
Only the quality control line C appears, with no other line appearing on the detection line.

Invalid result:

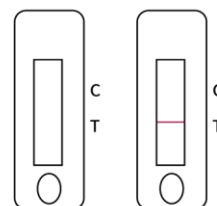
Quality control line C fails to appear indicating the test is invalid, no matter if the detection line appears or not. Collect a new specimen and perform another test with a new test device.



Positive: Both detection line (T) and quality control line (C) appear purplish-red 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 detection (T) line is colored or not.

4. Results and Conclusions

VivaDiag™ SARS-CoV-2 Ag Rapid Test	PCR		
	Positive	Negative	Total
Positive	29	0	29
Negative	6	121	127
Total	35	121	156
Sensitivity	82.86% (29/35, 95%CI, 67.21%~94.72%)		
Specificity	100% (121/121, 95%CI, 97.85%~100%)		
Accuracy	96.15% (150/156, 95%CI, 93.85%~98.90%)		

The VivaDiag™ SARS-CoV-2 Ag Rapid Test showed 82.86% of clinical sensitivity.

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

The VivaDiag™ SARS-CoV-2 Ag Rapid Test showed 96.15% of clinical accuracy.

From the results of 156 negative and positive samples, we can confirm that VivaDiag™ SARS-CoV-2 Ag 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™ SARS-CoV-2 Ag Rapid Test and SARS-CoV-2 RT-PCR and CT

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

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

5.2 Results of positive samples

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

sample	Clinical Site	Sample Type	Date of testing	Days from onset of symptoms	VivaDiag™ SARS-CoV-2 Ag	PCR & CT	VivaDiag™ SARS-CoV-2 Ag coincidence
1	No.1	nasal swab	July 22, 2020	1	Positive	Positive	Yes
2	No.1	nasal swab	July 22, 2020	0	Positive	Positive	Yes
3	No.1	nasal swab	July 22, 2020	1	Positive	Positive	Yes
4	No.1	throat swab	July 22, 2020	1	Positive	Positive	Yes
5	No.1	nasal swab	July 22, 2020	4	Negative	Positive	No
6	No.1	nasal swab	July 22, 2020	1	Positive	Positive	Yes
7	No.1	throat swab	July 22, 2020	2	Positive	Positive	Yes
8	No.1	nasal swab	July 22, 2020	2	Positive	Positive	Yes
9	No.1	throat swab	July 23, 2020	1	Positive	Positive	Yes
10	No.1	nasal swab	July 23, 2020	1	Positive	Positive	Yes
11	No.1	throat swab	July 23, 2020	2	Positive	Positive	Yes
12	No.1	nasal swab	July 23, 2020	1	Positive	Positive	Yes
13	No.1	nasal swab	July 24, 2020	3	Positive	Positive	Yes
14	No.1	nasal swab	July 24, 2020	1	Positive	Positive	Yes
15	No.1	throat swab	July 24, 2020	5	Negative	Positive	No
16	No.2	throat swab	July 25, 2020	1	Positive	Positive	Yes
17	No.2	nasal swab	July 25, 2020	2	Positive	Positive	Yes
18	No.2	throat swab	July 25, 2020	5	Negative	Positive	No
19	No.2	nasal swab	July 25, 2020	1	Positive	Positive	Yes
20	No.2	nasal swab	July 25, 2020	6	Negative	Positive	No
21	No.2	throat swab	July 26, 2020	2	Positive	Positive	Yes
22	No.2	nasal swab	July 26, 2020	3	Positive	Positive	Yes

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

6. 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.