



Sensitivity Study Report

for

VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test

	Position	Signature/ Date
Coordinator	R&D Technician	Zore Zhao / Oct 23, 2021
Reviewed by	R&D Supervisor	John Fan / Oct 23, 2021

1. Purpose

The purpose of this testing is to summarize the sensitivity study results of VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test. The VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test is for the rapid, qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in human. It is for self-testing.

2. Scope

It is applicable to VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test.

3. References

CLSI EP17-A2 Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline -Second Edition.

Food and Drug Administration issued Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised).

4. Responsibilities

R&D Supervisor (John Pan) is responsible for the study.

R&D Technicians (Cherish Jiang, Jamie Zhou) are responsible for testing.

R&D Technician (Aura Guo) and Quality Manager (Lily Hu) are responsible as investigators.

R&D Technician (Zore Zhao) is responsible as coordinator.

5. Material and Equipment

5.1. Three (3) VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test lots (Lot 1: T2006007, Lot 2: T2006008, Lot 3: T2006009) (REF: VCD16-10-011)

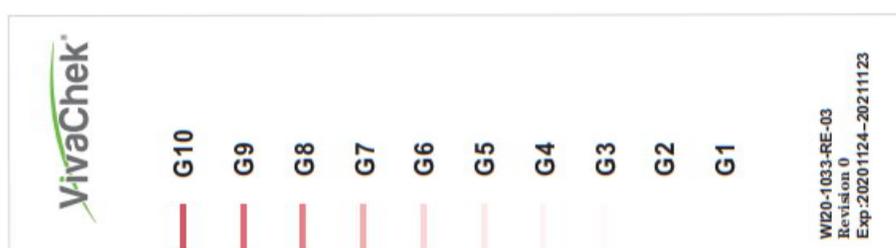
5.2. Novel Coronavirus (2019-nCoV) Real Time Multiplex RT-PCR Kit, -Shanghai ZJ Bio-Tech Co., Ltd.

5.3. Recombinant SARS-CoV-2 antigen (Lot: A20041703)

5.4. Pipettes

5.5. Timer

5.6. Intensity Grading Card (WI20-1033-RE-03): A card with gradient color blocks is used to semi-quantitate the different color intensities of the test line and the control line. Color intensities higher than or equal to G3 are considered as positive results, while color intensities lower than G3 are considered as negative results. A photo of Intensity Grading Card is show below.



6. Acceptance Criteria

6.1. Test Line

Negative results: $T < G3$

Positive results: $T \geq G3$

6.2. Limit of Detection

The limit of detection is the antigen level of 95% or more positive detection rate.

7. Procedure

7.1. Study Site

The sensitivity study is conducted at the VivaChek Biotech (Hangzhou) Co., Ltd.

7.2. Sample Preparation

Prepare negative swab specimen: collect negative anterior nasal swabs from health donors. Each donors are collected three swab specimen and the interval time between specimen collection is at least two hours. These health donors are staff of

VivaChek Biotech (Hangzhou) Co., Ltd. and they are SARS-Cov-2 negative tested by RT-PCR within 7 days.

7.3. LoD Screening

Make a serial dilution of 1:46000, 1:460000, 1:4600000, 1:46000000 for the recombinant SARS-CoV-2 antigen and extraction solution is used as the diluent. Spike 10 µL above dilutions into the anterior nasal swab specimen and they are tested 5 times. The concentration demonstrating 5 of 5 positives is chosen for LoD range finding and as a tentative LoD.

7.4. LoD Confirmation

Once a tentative LoD is established, two (2) doubling dilutions are made of the tentative LoD. Repeat 20 times to established LoD.

7.5. Evaluation Procedure

The evaluation is performed in the following sequence.

- Allow the Test Devices and Extraction Solution to equilibrate to 15-30°C prior to testing.
- Hold the sealed pouch vertically and let all extraction solution flow into the bulb. Break the tip and squeeze the bulb to dispense all extraction solution into the extraction tube.
- Collect specimen.
- Spike 10 µL recombinant SARS-CoV-2 antigen dilution into the anterior nasal swab. Insert the swab with collected specimen into the extraction tube filled with extraction solution. Roll the swab 5 times while pressing the head against the bottom and side of the extraction tube. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Try to release as much liquid as possible.

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,
311100, Zhejiang, China

TF086-002R

Rev: 1.1

- Put on the tube tip.
- Take out a test device from sealed foil pouch and put it on a clean and level surface.
- Apply 3 drops of the extracted specimen into the specimen well. Avoid bubbles during applying.
- Read the test result at 15 minutes. Don't read the result after 20 minutes.

8. Results**8.1. Sensitivity Study Date**

Sensitivity study is performed on Jun 18, 2020.

8.2. Test Results of PCR

SN	Donor Staff Number	Date of PCR Test	Ct Value				PCR Result
			FAM (ORF1ab)	HEX/VIC/JOE (GeneN)	Cal Red 610 (Gene E)	Cy5 (IC)	
1	VCA0008	20200617	UNDET	UNDET	UNDET	30.83	Negative
2	VCA0009	20200617	UNDET	UNDET	UNDET	35.99	Negative
3	VCA0010	20200617	UNDET	UNDET	UNDET	39.47	Negative
4	VCA0011	20200617	UNDET	UNDET	UNDET	38.28	Negative
5	VCA0013	20200617	UNDET	UNDET	UNDET	30.40	Negative
6	VCA0014	20200617	UNDET	UNDET	UNDET	38.29	Negative
7	VCA0015	20200617	UNDET	UNDET	UNDET	27.59	Negative
8	VCA0016	20200617	UNDET	UNDET	UNDET	26.23	Negative
9	VCA0017	20200617	UNDET	UNDET	UNDET	33.88	Negative
10	VCA0018	20200617	UNDET	UNDET	UNDET	27.79	Negative
11	VCA0019	20200617	UNDET	UNDET	UNDET	25.49	Negative
12	VCA0020	20200617	UNDET	UNDET	UNDET	28.53	Negative
13	VCA0021	20200617	UNDET	UNDET	UNDET	29.61	Negative
14	VCA0022	20200617	UNDET	UNDET	UNDET	26.37	Negative
15	VCA0029	20200617	UNDET	UNDET	UNDET	25.27	Negative
16	VCA0032	20200617	UNDET	UNDET	UNDET	35.76	Negative
17	VCA0033	20200617	UNDET	UNDET	UNDET	28.93	Negative
18	VCA0034	20200617	UNDET	UNDET	UNDET	32.96	Negative

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,
311100, Zhejiang, China

TF086-002R

Rev: 1.1

SN	Donor Staff Number	Date of PCR Test	Ct Value				PCR Result
			FAM (ORF1ab)	HEX/VIC/JOE (GeneN)	Cal Red 610 (Gene E)	Cy5 (IC)	
19	VCA0035	20200617	UNDET	UNDET	UNDET	26.22	Negative
20	VCA0036	20200617	UNDET	UNDET	UNDET	34.87	Negative
21	VCA0037	20200617	UNDET	UNDET	UNDET	30.31	Negative
22	VCA0038	20200617	UNDET	UNDET	UNDET	26.98	Negative
23	VCA0039	20200617	UNDET	UNDET	UNDET	30.58	Negative
24	VCA0040	20200617	UNDET	UNDET	UNDET	33.23	Negative
25	VCA0043	20200617	UNDET	UNDET	UNDET	34.41	Negative
26	VCA0044	20200617	UNDET	UNDET	UNDET	28.94	Negative
27	VCA0045	20200617	UNDET	UNDET	UNDET	31.57	Negative
28	VCA0046	20200617	UNDET	UNDET	UNDET	35.73	Negative
29	VCA0047	20200617	UNDET	UNDET	UNDET	28.11	Negative
30	VCA0048	20200617	UNDET	UNDET	UNDET	29.93	Negative
31	VCA0049	20200617	UNDET	UNDET	UNDET	26.54	Negative
32	VCA0053	20200617	UNDET	UNDET	UNDET	30.59	Negative
33	VCA0057	20200617	UNDET	UNDET	UNDET	27.63	Negative
34	VCA0060	20200617	UNDET	UNDET	UNDET	27.77	Negative
35	VCA0063	20200617	UNDET	UNDET	UNDET	31.75	Negative
36	VCA0103	20200617	UNDET	UNDET	UNDET	33.35	Negative
37	VCA0107	20200617	UNDET	UNDET	UNDET	30.54	Negative
38	VCA0108	20200617	UNDET	UNDET	UNDET	34.98	Negative
39	VCA0109	20200617	UNDET	UNDET	UNDET	27.93	Negative
40	VCA0113	20200617	UNDET	UNDET	UNDET	35.35	Negative
41	VCA0114	20200617	UNDET	UNDET	UNDET	28.51	Negative
42	VCA0122	20200617	UNDET	UNDET	UNDET	26.74	Negative
43	VCA0123	20200617	UNDET	UNDET	UNDET	39.56	Negative
44	VCA0134	20200617	UNDET	UNDET	UNDET	32.41	Negative
45	VCA0135	20200617	UNDET	UNDET	UNDET	26.23	Negative
46	VCA0143	20200617	UNDET	UNDET	UNDET	31.93	Negative
47	VCA0145	20200617	UNDET	UNDET	UNDET	29.88	Negative
48	VCA0147	20200617	UNDET	UNDET	UNDET	26.32	Negative
49	VCA0149	20200617	UNDET	UNDET	UNDET	35.86	Negative
50	VCA0152	20200617	UNDET	UNDET	UNDET	31.32	Negative
51	VCA0153	20200617	UNDET	UNDET	UNDET	27.11	Negative
52	VCA0154	20200617	UNDET	UNDET	UNDET	25.76	Negative

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,
311100, Zhejiang, China

TF086-002R

Rev: 1.1

SN	Donor Staff Number	Date of PCR Test	Ct Value				PCR Result
			FAM (ORF1ab)	HEX/VIC/JOE (GeneN)	Cal Red 610 (Gene E)	Cy5 (IC)	
53	VCA0155	20200617	UNDET	UNDET	UNDET	31.52	Negative
54	VCA0159	20200617	UNDET	UNDET	UNDET	34.51	Negative
55	VCA0166	20200617	UNDET	UNDET	UNDET	30.85	Negative
56	VCA0168	20200617	UNDET	UNDET	UNDET	28.49	Negative
57	VCA0171	20200617	UNDET	UNDET	UNDET	35.28	Negative
58	VCA0176	20200617	UNDET	UNDET	UNDET	27.98	Negative
59	VCA0177	20200617	UNDET	UNDET	UNDET	33.31	Negative
60	VCA0179	20200617	UNDET	UNDET	UNDET	34.63	Negative
61	VCA0181	20200617	UNDET	UNDET	UNDET	26.86	Negative
62	VCA0183	20200617	UNDET	UNDET	UNDET	32.15	Negative
63	VCA0184	20200617	UNDET	UNDET	UNDET	28.04	Negative
64	VCA0185	20200617	UNDET	UNDET	UNDET	33.98	Negative
65	VCA0188	20200617	UNDET	UNDET	UNDET	31.27	Negative
66	VCA0189	20200617	UNDET	UNDET	UNDET	32.13	Negative
67	VCA0197	20200617	UNDET	UNDET	UNDET	30.04	Negative
68	VCA0198	20200617	UNDET	UNDET	UNDET	30.92	Negative
69	VCA0200	20200617	UNDET	UNDET	UNDET	33.47	Negative
70	VCA0201	20200617	UNDET	UNDET	UNDET	26.59	Negative
71	VCA0203	20200617	UNDET	UNDET	UNDET	32.89	Negative
72	VCA0204	20200617	UNDET	UNDET	UNDET	34.96	Negative
73	VCA0208	20200617	UNDET	UNDET	UNDET	31.51	Negative
74	VCA0210	20200617	UNDET	UNDET	UNDET	26.34	Negative
75	VCA0211	20200617	UNDET	UNDET	UNDET	30.23	Negative
76	VCA0212	20200617	UNDET	UNDET	UNDET	26.64	Negative
77	VCA0213	20200617	UNDET	UNDET	UNDET	25.53	Negative
78	VCA0214	20200617	UNDET	UNDET	UNDET	31.23	Negative
79	VCA0215	20200617	UNDET	UNDET	UNDET	30.91	Negative
80	VCA0217	20200617	UNDET	UNDET	UNDET	28.85	Negative
81	VCA0218	20200617	UNDET	UNDET	UNDET	25.81	Negative
82	VCA0219	20200617	UNDET	UNDET	UNDET	29.05	Negative
83	VCA0220	20200617	UNDET	UNDET	UNDET	30.29	Negative
84	VCA0223	20200617	UNDET	UNDET	UNDET	32.83	Negative
85	VCA0226	20200617	UNDET	UNDET	UNDET	29.59	Negative
86	VCA0227	20200617	UNDET	UNDET	UNDET	26.81	Negative

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,
311100, Zhejiang, China

TF086-002R

Rev: 1.1

SN	Donor Staff Number	Date of PCR Test	Ct Value				PCR Result
			FAM (ORF1ab)	HEX/VIC/JOE (GeneN)	Cal Red 610 (Gene E)	Cy5 (IC)	
87	VCA0228	20200617	UNDET	UNDET	UNDET	34.13	Negative
88	VCA0229	20200617	UNDET	UNDET	UNDET	29.23	Negative
89	VCA0232	20200617	UNDET	UNDET	UNDET	31.69	Negative
90	VCA0234	20200617	UNDET	UNDET	UNDET	31.09	Negative
91	VCA0235	20200617	UNDET	UNDET	UNDET	29.74	Negative
92	VCA0237	20200617	UNDET	UNDET	UNDET	25.37	Negative
93	VCA0239	20200617	UNDET	UNDET	UNDET	32.51	Negative
94	VCA0240	20200617	UNDET	UNDET	UNDET	33.04	Negative
95	VCA0241	20200617	UNDET	UNDET	UNDET	27.96	Negative
96	VCA0244	20200617	UNDET	UNDET	UNDET	30.66	Negative
97	VCA0245	20200617	UNDET	UNDET	UNDET	29.03	Negative
98	VCA0246	20200617	UNDET	UNDET	UNDET	28.57	Negative
99	VCA0248	20200617	UNDET	UNDET	UNDET	26.43	Negative
100	VCA0250	20200617	UNDET	UNDET	UNDET	29.04	Negative

8.3. Test Results of Establishing a Tentative LoD

Lot	T2006007			
Sample	1/46000	1/460000	1/4600000	1/46000000
Concentration (ng/mL)	50	5	0.5	0.05
Results				
Rep.1	G10	G7	G4	G1
Rep.2	G10	G7	G4	G1
Rep.3	G10	G7	G4	G1
Rep.4	G10	G7	G4	G1
Rep.5	G10	G7	G4	G1
Positive Rate%	5 100%	5 100%	5 100%	0 0%

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,
311100, Zhejiang, China

TF086-002R

Rev: 1.1

Lot	T2006008			
Sample	1/46000	1/460000	1/4600000	1/46000000
Concentration (ng/mL)	50	5	0.5	0.05
Results				
Rep.1	G10	G7	G4	G1
Rep.2	G10	G7	G4	G1
Rep.3	G10	G7	G4	G1
Rep.4	G10	G7	G4	G1
Rep.5	G10	G7	G4	G1
Positive	5	5	5	0
Rate%	100%	100%	100%	0%

Lot	T2006009			
Sample	1/46000	1/460000	1/4600000	1/46000000
Concentration (ng/mL)	50	5	0.5	0.05
Results				
Rep.1	G10	G7	G4	G1
Rep.2	G10	G7	G4	G1
Rep.3	G10	G7	G4	G1
Rep.4	G10	G7	G4	G1
Rep.5	G10	G7	G4	G1
Positive	5	5	5	0
Rate%	100%	100%	100%	0%

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,
311100, Zhejiang, China

TF086-002R

Rev: 1.1

8.4. Test Results of Confirming LoD

Lot	T2006007					
Sample	1/4600000		1/9200000		1/18400000	
Concentration (ng/mL)	0.5		0.25		0.12	
Line	C	T	C	T	C	T
Rep.1	G9	G4	G9	G3	G9	G2
Rep.2	G9	G4	G9	G3	G9	G3
Rep.3	G9	G4	G9	G3	G9	G3
Rep.4	G9	G4	G9	G3	G9	G2
Rep.5	G9	G4	G9	G3	G9	G3
Rep.6	G9	G4	G9	G3	G9	G3
Rep.7	G9	G4	G9	G2	G9	G3
Rep.8	G9	G4	G9	G3	G9	G3
Rep.9	G9	G4	G9	G3	G9	G3
Rep.10	G9	G4	G9	G3	G9	G2
Rep.11	G9	G4	G9	G3	G9	G3
Rep.12	G9	G4	G9	G3	G9	G3
Rep.13	G9	G4	G9	G3	G9	G3
Rep.14	G9	G4	G9	G3	G9	G3
Rep.15	G9	G4	G9	G3	G9	G2
Rep.16	G9	G4	G9	G3	G9	G3
Rep.17	G9	G4	G9	G3	G9	G2
Rep.18	G9	G4	G9	G3	G9	G3
Rep.19	G9	G4	G9	G3	G9	G3
Rep.20	G9	G4	G9	G3	G9	G3
Positive Rate%	20 100%		19 95%		15 75%	

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,
311100, Zhejiang, China

TF086-002R

Rev: 1.1

Lot	T2006008					
Sample	1/4600000		1/9200000		1/18400000	
Concentration (ng/mL)	0.5		0.25		0.12	
Line	C	T	C	T	C	T
Rep.1	G9	G4	G9	G3	G9	G3
Rep.2	G9	G4	G9	G3	G9	G3
Rep.3	G9	G4	G9	G3	G9	G2
Rep.4	G9	G4	G9	G2	G9	G3
Rep.5	G9	G4	G9	G3	G9	G3
Rep.6	G9	G4	G9	G3	G9	G3
Rep.7	G9	G4	G9	G3	G9	G2
Rep.8	G9	G4	G9	G3	G9	G3
Rep.9	G9	G4	G9	G3	G9	G3
Rep.10	G9	G4	G9	G3	G9	G2
Rep.11	G9	G4	G9	G3	G9	G3
Rep.12	G9	G4	G9	G3	G9	G3
Rep.13	G9	G4	G9	G3	G9	G3
Rep.14	G9	G4	G9	G3	G9	G2
Rep.15	G9	G4	G9	G3	G9	G3
Rep.16	G9	G4	G9	G3	G9	G3
Rep.17	G9	G4	G9	G3	G9	G3
Rep.18	G9	G4	G9	G3	G9	G3
Rep.19	G9	G4	G9	G3	G9	G2
Rep.20	G9	G4	G9	G3	G9	G3
Positive Rate%	20 100%		19 95%		15 75%	

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd., Yuhang Economy Development Zone, Hangzhou,
311100, Zhejiang, China

TF086-002R

Rev: 1.1

Lot	T2006009					
Sample	1/4600000		1/9200000		1/18400000	
Concentration (ng/mL)	0.5		0.25		0.12	
Line	C	T	C	T	C	T
Rep.1	G9	G4	G9	G3	G9	G3
Rep.2	G9	G4	G9	G3	G9	G3
Rep.3	G9	G4	G9	G3	G9	G3
Rep.4	G9	G4	G9	G3	G9	G3
Rep.5	G9	G4	G9	G3	G9	G3
Rep.6	G9	G4	G9	G3	G9	G3
Rep.7	G9	G4	G9	G3	G9	G2
Rep.8	G9	G4	G9	G2	G9	G3
Rep.9	G9	G4	G9	G3	G9	G2
Rep.10	G9	G4	G9	G3	G9	G3
Rep.11	G9	G4	G9	G3	G9	G2
Rep.12	G9	G4	G9	G3	G9	G3
Rep.13	G9	G4	G9	G3	G9	G3
Rep.14	G9	G4	G9	G3	G9	G3
Rep.15	G9	G4	G9	G3	G9	G3
Rep.16	G9	G4	G9	G3	G9	G3
Rep.17	G9	G4	G9	G3	G9	G2
Rep.18	G9	G4	G9	G3	G9	G3
Rep.19	G9	G4	G9	G3	G9	G3
Rep.20	G9	G4	G9	G3	G9	G2
Positive Rate%	20 100%		19 95%		15 75%	

9. Conclusion

The results show that the positive detection rate for 0.25 ng/mL control is 95%, 0.12 ng/mL control is less than 95%. Therefore, the sensitivity of the VivaDiag™ Pro SARS-CoV-2 Ag Rapid Test is 0.25 ng/mL.