

LvtangBio	CE Technical File	File No: LT-TF-14-1.1
	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method)	Rev.No: A/3

SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method) Analytical Inclusivity Study Report



Product Name: SARS-CoV-2Antigen Detection Kit (Colloidal Gold Method)

Model No.: CovAg-N

Document No.: _____

Version: A/3

Complied by: Huayi. Lan Date: 2022.10.11

Reviewed by: Pascal. Hu Date: 2022.10.11

Authorized by: Maia. Wang Date: 2022.10.11

Revision History

Revision Content	Revision Reason	Revision Date	Revised By	Document No. & Version	Remark

LvtangBio	CE Technical File	File No: LT-TF-14-1.1
	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method)	Rev.No: A/3

1. Objective

The inclusivity study aims to determine the analytical reactivity of the SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method) to SARS-CoV-2 variants and the lowest detectable concentration (LOD) for each variant.

2. Testing Time, Location, Personnel and Materials

2.1 Testing Date: May-2021-21-October-2022

2.2 Testing Location

NINGBO LVTANG BIOTECHNOLOGY CO., LTD.

Address: No.9 Dongpu Road, Chengdong Industrial Area, Daxu Town, Xiangshan County,
Ningbo City, Zhejiang Province, China

2.3 Testing Personnel

- Jiang Yang, Ph.D (Research Scientist)
- Huangli Li, Ph.D (Lab Director, Principal Investigator)

2.4 Materials Supplied by the manufacturer.

SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method) used:

LOT: 20231017

MFG: 20220218

EXP: 20240217

3. Acceptance Criteria

For each of the SARS-CoV-2 variant type, its initial LOD range is considered as the lowest concentration at which each of the triplicated specimens are positive.

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4. Test Procedures and Results

Variants	Nucleoprotein recombinant protein	Concentration(mg/ml)
Delta	P80R	2.3
Alpha	ncov-PS-Ag37	1.2
Beta	ncov-PS-Ag40	1.6
Gamma 7	ncov-PS-Ag42	1.1
Delta	ncov-PS-Ag76	1
Omicron	ncov-PS-Ag150	1.6
Lambda	ncov-PS-Ag105	1.8
B.1.640	ncov-PS-Ag151	1.1
XBB	ncov-PS-Ag155	1.1
BA.4.6	ncov-PS-Ag159	1.5
BQ.1.1	ncov-PS-Ag184	2.1
D3L, G204P, P383L, R203K, S235F	ncov-PS-Ag189	1.2
G204R, R203K, S235F	ncov-PS-Ag190	1.1
M234I, S413I, T205I	ncov-PS-Ag191	1.1
P151S, G204R, P13L, R203K	ncov-PS-Ag192	1.1
BF.7	ncov-PS-Ag193	1.4

4.1.1 To establish the initial LOD range for SARS-CoV-2 (2019-nCoV) Nucleocapsid (P80R) Protein, ncov-PS-Ag37, ncov-PS-Ag40, ncov-PS-Ag42, ncov-PS-Ag76, ncov-PS-Ag105, ncov-PS-Ag150, ncov-PS-Ag151, ncov-PS-Ag155, ncov-PS-Ag159, ncov-PS-Ag184, ncov-PS-Ag189, ncov-PS-Ag190, ncov-PS-Ag191, ncov-PS-Ag192, ncov-PS-Ag193 spike in the protein to negative sample matrix in Eppendorf tubes using dilution factors as in Table 1~16. The highest concentration of SARS-CoV-2 Nucleocapsid (P80R) Protein tested will be 1µg/mL, ncov-PS-Ag37 will be 1µg/mL, ncov-PS-Ag40 will be 1µg/mL, ncov-PS-Ag42 will be 1µg/mL, ncov-PS-Ag76 will be 1µg/mL, ncov-PS-Ag105 will be 1µg/mL, ncov-PS-Ag150 will be 1µg/mL, ncov-PS-Ag151 will be 1µg/mL, ncov-PS-Ag155 will be 1µg/mL, ncov-PS-Ag159 will be 1µg/mL, ncov-PS-Ag184 will be 1µg/mL, ncov-PS-Ag189 will be 1µg/mL, ncov-PS-Ag190 will be 1µg/mL, ncov-PS-Ag191 will be 1µg/mL, ncov-PS-Ag192 will be 1µg/mL, ncov-PS-Ag193 will be 1µg/mL. Then 10-fold serial dilutions will be made to obtain the lowest SARS-CoV-2 Nucleocapsid (P80R) Protein or ncov-PS-Ag37, ncov-PS-Ag40, ncov-PS-Ag42, ncov-PS-Ag76, ncov-PS-Ag105, ncov-PS-Ag150, ncov-PS-Ag151, ncov-PS-Ag155, ncov-PS-Ag159, ncov-PS-Ag184, ncov-PS-Ag189, ncov-PS-Ag190, ncov-PS-Ag191, ncov-PS-Ag192, ncov-PS-Ag193 concentration (Table 1~16).

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Table 1: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) Nucleocapsid (P80R) Protein (His Tag).

Sample ID	Test ID	Serial Dilution Factor	Concentration of Nucleocapsid (P80R) Protein (His Tag)	LFA results (P/N)	Test results (Positive/3)
A-1	5	serial dilutions(the total ratio is 1:2.3×10 ³)	1µg/mL	P	3/3
A-2	1		1µg/mL	P	
A-3	2		1µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	4	1:10	10 ng/mL	P	3/3
C-2	10	1:10	10 ng/mL	P	
C-3	7	1:10	10 ng/mL	P	
D-1	11	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	11	1:10	100 pg/mL	P	3/3
E-2	8	1:10	100 pg/mL	P	
E-3	12	1:10	100 pg/mL	P	
F-1	11	1:10	10 pg/mL	N	0/3
F-2	8	1:10	10 pg/mL	N	
F-3	12	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 2: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag37.

Sample ID	Test ID	Serial Dilution Factor	Concentration of Nucleocapsid ncov-PS-Ag37	LFA results (P/N)	Test results (Positive/3)
A-1	15	serial dilutions(the total ratio is 1:1.2×10 ³)	1µg/mL	P	3/3
A-2	1		1µg/mL	P	
A-3	2		1µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	17	1:10	10 ng/mL	P	3/3
C-2	14	1:10	10 ng/mL	P	
C-3	13	1:10	10 ng/mL	P	
D-1	11	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	18	1:10	100 pg/mL	P	3/3
E-2	16	1:10	100 pg/mL	P	
E-3	5	1:10	100 pg/mL	P	
F-1	4	1:10	10 pg/mL	N	0/3
F-2	10	1:10	10 pg/mL	N	

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F-3	7	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 3: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV)ncov-PS-Ag40.

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag40	LFA results (P/N)	Test results (Positive/3)
A-1	15	serial dilutions(the total ratio is 1:1.6×10 ³)	1 µg/mL	P	3/3
A-2	1		1 µg/mL	P	
A-3	2		1 µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	17	1:10	10 ng/mL	P	3/3
C-2	14	1:10	10 ng/mL	P	
C-3	13	1:10	10 ng/mL	P	
D-1	11	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	18	1:10	100 pg/mL	P	3/3
E-2	16	1:10	100 pg/mL	P	
E-3	5	1:10	100 pg/mL	P	
F-1	4	1:10	10 pg/mL	N	0/3
F-2	10	1:10	10 pg/mL	N	
F-3	7	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 4: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag42 .

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag42	LFA results (P/N)	Test results (Positive/3)
A-1	4	serial dilutions(the total ratio is 1:1.1×10 ³)	1 µg/mL	P	3/3
A-2	2		1 µg/mL	P	
A-3	5		1 µg/mL	P	
B-1	1	1:10	100 ng/mL	P	3/3
B-2	16	1:10	100 ng/mL	P	
B-3	14	1:10	100 ng/mL	P	
C-1	7	1:10	10 ng/mL	P	3/3
C-2	8	1:10	10 ng/mL	P	
C-3	3	1:10	10 ng/mL	P	
D-1	15	1:10	1 ng/mL	P	3/3
D-2	17	1:10	1 ng/mL	P	
D-3	11	1:10	1 ng/mL	P	
E-1	13	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	6	1:10	100 pg/mL	P	
F-1	9	1:10	10 pg/mL	N	0/3
F-2	10	1:10	10 pg/mL	N	

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F-3	12	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 5: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag76

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag76	LFA results (P/N)	Test results (Positive/3)
A-1	5	serial dilutions(the total ratio is 1:10 ³)	1 µg/mL	P	3/3
A-2	1		1 µg/mL	P	
A-3	2		1 µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	4	1:10	10 ng/mL	P	3/3
C-2	10	1:10	10 ng/mL	P	
C-3	7	1:10	10 ng/mL	P	
D-1	11	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	15	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	13	1:10	100 pg/mL	P	
F-1	14	1:10	10 pg/mL	N	0/3
F-2	17	1:10	10 pg/mL	N	
F-3	16	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 6: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag105

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag105	LFA results (P/N)	Test results (Positive/3)
A-1	1	serial dilutions(the total ratio is 1:1.8×10 ³)	1 µg/mL	P	3/3
A-2	2		1 µg/mL	P	
A-3	3		1 µg/mL	P	
B-1	4	1:10	100 ng/mL	P	3/3
B-2	5	1:10	100 ng/mL	P	
B-3	6	1:10	100 ng/mL	P	
C-1	7	1:10	10 ng/mL	P	3/3
C-2	8	1:10	10 ng/mL	P	
C-3	9	1:10	10 ng/mL	P	
D-1	10	1:10	1 ng/mL	P	3/3
D-2	11	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	14	1:10	100 pg/mL	P	3/3
E-2	13	1:10	100 pg/mL	P	
E-3	16	1:10	100 pg/mL	P	
F-1	15	1:10	10 pg/mL	N	0/3
F-2	17	1:10	10 pg/mL	N	

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F-3	18	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 7: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag150

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag150	LFA results (P/N)	Test results (Positive/3)
A-1	18	serial dilutions(the total ratio is 1:1.6×10 ³)	1 μg/mL	P	3/3
A-2	15		1 μg/mL	P	
A-3	1		1 μg/mL	P	
B-1	12	1:10	100 ng/mL	P	3/3
B-2	14	1:10	100 ng/mL	P	
B-3	2	1:10	100 ng/mL	P	
C-1	3	1:10	10 ng/mL	P	3/3
C-2	4	1:10	10 ng/mL	P	
C-3	6	1:10	10 ng/mL	P	
D-1	9	1:10	1 ng/mL	P	3/3
D-2	17	1:10	1 ng/mL	P	
D-3	8	1:10	1 ng/mL	P	
E-1	5	1:10	100 pg/mL	P	3/3
E-2	11	1:10	100 pg/mL	P	
E-3	13	1:10	100 pg/mL	P	
F-1	7	1:10	10 pg/mL	N	0/3
F-2	10	1:10	10 pg/mL	N	
F-3	16	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 8: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag151.

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag151	LFA results (P/N)	Test results (Positive/3)
A-1	5	serial dilutions(the total ratio is 1:1.1×10 ³)	1 μg/mL	P	3/3
A-2	1		1 μg/mL	P	
A-3	2		1 μg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	4	1:10	10 ng/mL	P	3/3
C-2	10	1:10	10 ng/mL	P	
C-3	7	1:10	10 ng/mL	P	
D-1	11	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	15	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	13	1:10	100 pg/mL	P	
F-1	14	1:10	10 pg/mL	P	3/3
F-2	17	1:10	10 pg/mL	P	

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F-3	16	1:10	10 pg/mL	P	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 9: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV)ncov-PS-Ag155 .

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag155	LFA results (P/N)	Test results (Positive/3)
A-1	5	serial dilutions(the total ratio is 1:103))	1µg/mL	P	3/3
A-2	6		1µg/mL	P	
A-3	2		1µg/mL	P	
B-1	4	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	1	1:10	10 ng/mL	P	3/3
C-2	10	1:10	10 ng/mL	P	
C-3	7	1:10	10 ng/mL	P	
D-1	11	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	15	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	13	1:10	100 pg/mL	P	
F-1	14	1:10	10 pg/mL	N	0/3
F-2	17	1:10	10 pg/mL	N	
F-3	16	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 10: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag159 .

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag159	LFA results (P/N)	Test results (Positive/3)
A-1	5	serial dilutions(the total ratio is 1:1.5×10 ³)	1µg/mL	P	3/3
A-2	9		1µg/mL	P	
A-3	2		1µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	11	1:10	100 ng/mL	P	
C-1	14	1:10	10 ng/mL	P	3/3
C-2	10	1:10	10 ng/mL	P	
C-3	7	1:10	10 ng/mL	P	
D-1	1	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	15	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	13	1:10	100 pg/mL	P	
F-1	4	1:10	10 pg/mL	N	0/3
F-2	16	1:10	10 pg/mL	N	

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F-3	17	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 11: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag184 .

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag184	LFA results (P/N)	Test results (Positive/3)
A-1	4	serial dilutions(the total ratio is 1:2.1×10 ³)	1µg/mL	P	3/3
A-2	1		1µg/mL	P	
A-3	2		1µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	15	1:10	100 ng/mL	P	
B-3	16	1:10	100 ng/mL	P	
C-1	13	1:10	10 ng/mL	P	3/3
C-2	10	1:10	10 ng/mL	P	
C-3	17	1:10	10 ng/mL	P	
D-1	11	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	3	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	5	1:10	100 pg/mL	P	
F-1	14	1:10	10 pg/mL	N	0/3
F-2	7	1:10	10 pg/mL	N	
F-3	9	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 12: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag189.

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag189	LFA results (P/N)	Test results (Positive/3)
A-1	2	serial dilutions(the total ratio is 1:1.2×10 ³)	1µg/mL	P	3/3
A-2	1		1µg/mL	P	
A-3	4		1µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	13	1:10	10 ng/mL	P	3/3
C-2	16	1:10	10 ng/mL	P	
C-3	7	1:10	10 ng/mL	P	
D-1	14	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	15	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	5	1:10	100 pg/mL	P	
F-1	11	1:10	10 pg/mL	N	0/3
F-2	10	1:10	10 pg/mL	N	

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F-3	17	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 13: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag190.

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag190	LFA results (P/N)	Test results (Positive/3)
A-1	5	serial dilutions(the total ratio is 1:1.1×10 ³)	1µg/mL	P	3/3
A-2	1		1µg/mL	P	
A-3	2		1µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	4	1:10	10 ng/mL	P	3/3
C-2	10	1:10	10 ng/mL	P	
C-3	7	1:10	10 ng/mL	P	
D-1	11	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	15	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	13	1:10	100 pg/mL	P	
F-1	14	1:10	10 pg/mL	P	0/3
F-2	17	1:10	10 pg/mL	P	
F-3	16	1:10	10 pg/mL	P	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 14: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag191.

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag191	LFA results (P/N)	Test results (Positive/3)
A-1	5	serial dilutions(the total ratio is 1:1.1×10 ³)	1µg/mL	P	3/3
A-2	1		1µg/mL	P	
A-3	2		1µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	4	1:10	10 ng/mL	P	3/3
C-2	10	1:10	10 ng/mL	P	
C-3	7	1:10	10 ng/mL	P	
D-1	11	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	15	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	13	1:10	100 pg/mL	P	
F-1	14	1:10	10 pg/mL	P	0/3
F-2	17	1:10	10 pg/mL	P	

LvtangBio	CE Technical File			File No: LT-TF-14-1.1	
	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method)			Rev.No: A/3	
F-3	16	1:10	10 pg/mL	P	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 15: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag192.

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag192	LFA results (P/N)	Test results (Positive/3)
A-1	5	serial dilutions(the total ratio is 1:1.1×10 ³)	1 µg/mL	P	3/3
A-2	1		1 µg/mL	P	
A-3	2		1 µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	4	1:10	10 ng/mL	P	3/3
C-2	10	1:10	10 ng/mL	P	
C-3	7	1:10	10 ng/mL	P	
D-1	11	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	15	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	13	1:10	100 pg/mL	P	
F-1	14	1:10	10 pg/mL	P	0/3
F-2	17	1:10	10 pg/mL	P	
F-3	16	1:10	10 pg/mL	P	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

Table 16: Test Results of Finding Initial LOD Range for SARS-CoV-2 (2019-nCoV) ncov-PS-Ag193.

Sample ID	Test ID	Serial Dilution Factor	Concentration of ncov-PS-Ag193	LFA results (P/N)	Test results (Positive/3)
A-1	2	serial dilutions(the total ratio is 1:1.2×10 ³)	1 µg/mL	P	3/3
A-2	1		1 µg/mL	P	
A-3	4		1 µg/mL	P	
B-1	6	1:10	100 ng/mL	P	3/3
B-2	3	1:10	100 ng/mL	P	
B-3	9	1:10	100 ng/mL	P	
C-1	13	1:10	10 ng/mL	P	3/3
C-2	16	1:10	10 ng/mL	P	
C-3	7	1:10	10 ng/mL	P	
D-1	14	1:10	1 ng/mL	P	3/3
D-2	8	1:10	1 ng/mL	P	
D-3	12	1:10	1 ng/mL	P	
E-1	15	1:10	100 pg/mL	P	3/3
E-2	18	1:10	100 pg/mL	P	
E-3	5	1:10	100 pg/mL	P	
F-1	11	1:10	10 pg/mL	N	0/3
F-2	10	1:10	10 pg/mL	N	

LvtangBio	CE Technical File			File No: LT-TF-14-1.1	
	SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method)			Rev.No: A/3	
F-3	17	1:10	10 pg/mL	N	
Testing Date	10/10/ 2022				
Operator	Jiang Yang				
Reader	Huangli Li				

5. Conclusions

Based on the results above, the SARS-CoV-2 Antigen Detection Kit (Colloidal Gold Method) is capable of detecting all these types of SARS-CoV-2 variants evaluated, with the lowest detectable concentration (LOD) for each variant recombinant SARS-CoV-2 nucleocapsid protein were 100pg/mL.