

**SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold
Immunochromatography)**

Analysis Specificity Investigation Report

Beijing Lepu Medical Technology Co., Ltd.



Contents

1 Overview	2
2 Information about the kit used in this investigation.....	2
3. Investigation method.....	2
3.1 Content of cross-reaction validation.....	3
3.2 Validation information.....	3
3.3 Validation information.....	3
4 Investigational results.....	4
4.1 Test results of nasal swab samples from 20 healthy subjects	4
4.2 Test results of pathogen samples and recombinant N protein	5
4.3 Test results of interferent	8
5 Conclusion.....	12

1 Overview

The Report presents the cross-reaction investigation data on the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography).

2 Information about the kit used in this investigation

For the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) used for validation of cross reaction, the specification is 25 tests/kit and the lot numbers are 20CG2704X-y, 20CG2705X-y and 20CG2706X-y.

3 Investigation method

The substances cross-reacting and interfering with SARS-CoV-2 are collected according to the *Technical Review Points for Registration of SARS-CoV-2 Antigen/Antibody Reagents (Trial)*, and evaluated on cross-reaction using the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) produced by Beijing Lepu Medical Technology Co., Ltd. (the Company for short).

3.1 Content of cross-reaction validation

- (1) Nasal swab samples from 20 healthy subjects came from Aipuyi
- (2) Non-targeted commensal and pathogenic microorganisms

1 Human coronavirus OC43	8 EB virus	15 Human Metapneumovirus (hMPV)
2 Human coronavirus 229E	9 Measles virus	16 Parainfluenza virus 1-4
3 Human coronavirus HKU1	10 Human cytomegalovirus	17 Enterovirus (e.g. EV68)
4 Human coronavirus NL63	11 Rotavirus	18 Rhinovirus
5 Influenza A	12 Norovirus	19 HBV
6 Influenza B	13 Mumps virus	20 HIV
7 Adenovirus (e.g. C1 Ad. 71)	14 Varicella-zoster virus	21 HCV

- (3) Microbial interference by other common respiratory pathogens:

1 Mycoplasma pneumoniae	6 Chlamydia pneumoniae	11 Streptococcus pyogenes
2 Staphylococcus aureus	7 Haemophilus influenzae	12 Bordetella pertussis
3 Staphylococcus epidermis	8 Legionella pneumophila	13 Pneumocystis jiroveci (PJP)
4 Pseudomonas aeruginosa	9 Mycobacterium tuberculosis	14 Candida albicans
5 Streptococcus pneumoniae	10 Staphylococcus salivarius	

- (4) SARS-CoV-2 recombinant N protein: Manufacturer: Feipeng Biological Co., Ltd.

3.2 Interfering substance verification content

Substance	Active ingredient
Endogenous interferents	Human whole blood
	Mucin
Antiviral drug	Quinine, zanamivir, ribavirin, oseltamivir, peramivir, lopinavir, ritonavir, and arbidol
Anti-inflammatory agent	Paracetamol, acetylsalicylate, ibuprofen
Antibiotics	Levofloxacin, azithromycin, ceftriaxone and meropenem
Systemic antibiotics	Tobramycin
Drugs for alleviating allergic symptoms	Histamine hydrochloride
Nasal sprays or nose drops	Phenylephrine, oxymetazoline, and sodium chloride (including preservatives)
Nasal corticosteroids	Beclomethasone, dexamethasone, flunisolide, triamcinolone acetonide, budesonide, mometasone, and fluticasone
Throat lozenge	Strepsils (flurbiprofen 8.75mg), throat lozenge (mint)

3.3 Validation information

Lot numbers: 20CG2704X-y, 20CG2705X-y, 20CG2706X-y

Testers: Zhang Bo, Liu Yanjuan

Interferents information

No.	Type of interferent	Name of Interferent	Low concentration	Medium concentration	High concentration
1	Endogenous interferents	Mucin	1mg/mL	3mg/mL	5mg/mL
		Human whole blood	0.5%	1%	2%
2	Antiviral drug	Quinine	0.5 mg/mL	1 mg/mL	2 mg/mL
3		Zanamivir	5 mg/mL	10 mg/mL	20 mg/mL
4		Ribavirin	2 mg/mL	5 mg/mL	10 mg/mL
5		Oseltamivir	5 mg/mL	10 mg/mL	20 mg/mL
6		Peramivir	0.1 mg/mL	0.15 mg/mL	0.2 mg/mL
7		Lopinavir	5 mg/mL	10 mg/mL	20 mg/mL
8		Ritonavir	0.5 mg/mL	1 mg/mL	2.5 mg/mL
9		Arbidol	0.5 mg/mL	1 mg/mL	2 mg/mL
10		Anti-inflammatory agent	Paracetamol	0.5 mg/mL	1 mg/mL
11	Acetylsalicylate		0.5 mg/mL	1 mg/mL	2 mg/mL

12		Ibuprofen	0.5 mg/mL	1 mg/mL	2 mg/mL
13	Antibiotics	Levofloxacin	5 mg/mL	10 mg/mL	20 mg/mL
14		Azithromycin	5 mg/mL	10 mg/mL	20 mg/mL
15		Ceftriaxone	5 mg/mL	10 mg/mL	25 mg/mL
16		Meropenem	1 mg/mL	2 mg/mL	5 mg/mL
17	Systemic antibiotics	Tobramycin	1 mg/mL	2 mg/mL	5 mg/mL
18	Drugs for alleviating allergic symptoms	Histamine hydrochloride	0.5 mg/mL	1 mg/mL	1.5 mg/mL
19	Nasal sprays or nose drops	Phenylephrine, and	5%	10%	15%
20		Oxymetazoline	5%	10%	15%
21		Sodium chloride (including preservatives)	5 mg/mL	10 mg/mL	30 mg/mL
22	Nasal corticosteroids	Beclomethasone	0.5 mg/mL	1 mg/mL	2 mg/mL
23		Dexamethasone	2 mg/mL	5 mg/mL	10 mg/mL
24		Flunisolide	2 mg/mL	5 mg/mL	10 mg/mL
25		Triamcinolone acetonide	0.5 mg/mL	1 mg/mL	2 mg/mL
26		Budesonide	10 mg/mL	20 mg/mL	40 mg/mL
27		Mometasone	2 mg/mL	5 mg/mL	10 mg/mL
28		Fluticasone	5 mg/mL	10 mg/mL	15 mg/mL
29	Throat lozenge	Strepsils (flurbiprofen 8.75mg)	1%	2%	5%
30		Throat lozenge (mint)	1%	2%	5%

4 Investigational results

4.1 Test results of nasal swab samples from 20 healthy subjects

The test results of nasal swab samples from 20 healthy subjects tested with the SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold Immunochromatography) produced by the Company were negative, as follows:

Sample	20CG2704X-y	20CG2705X-y	20CG2706X-y
1	Negative	Negative	Negative
2	Negative	Negative	Negative
3	Negative	Negative	Negative
4	Negative	Negative	Negative
5	Negative	Negative	Negative
6	Negative	Negative	Negative
7	Negative	Negative	Negative
8	Negative	Negative	Negative
9	Negative	Negative	Negative
10	Negative	Negative	Negative
11	Negative	Negative	Negative
12	Negative	Negative	Negative
13	Negative	Negative	Negative
14	Negative	Negative	Negative
15	Negative	Negative	Negative
16	Negative	Negative	Negative
17	Negative	Negative	Negative
18	Negative	Negative	Negative
19	Negative	Negative	Negative
20	Negative	Negative	Negative

4.2 Test results of pathogen samples and recombinant N protein

(1) Cross-reaction with non-targeted symbionts and pathogenic microorganisms

SN	Type of Pathogen	Pathogen concentration	20CG2704X-y	20CG2705X-y	20CG2706X-y
1	Endemic human coronavirus	10^5 TCID ₅₀ /mL	Negative	Negative	Negative

	OC43				
2	Human coronavirus 229E	10 ^{4.5} TCID ₅₀ /mL	Negative	Negative	Negative
3	Human coronavirus HKU1	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
4	Human coronavirus NL63	10 ⁴ TCID ₅₀ /mL	Negative	Negative	Negative
5	Influenza A	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
6	Influenza B	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
7	Adenovirus 1	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
8	Adenovirus 2	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
9	Adenovirus 3	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
10	Adenovirus 4	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
11	Adenovirus 5	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
12	Adenovirus 7	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
13	EB virus	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
14	Measles virus	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
15	Human cytomegalovirus	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
16	Rotavirus	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
17	Norovirus	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
18	Mumps virus	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
19	Varicella zoster virus	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
20	Metapneumovirus	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
21	Parainfluenza virus 1	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
22	Parainfluenza virus 2	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
23	Parainfluenza virus 3	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
24	Parainfluenza virus 4	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
25	Enterovirus (e.g. EV68)	10 ⁴ TCID ₅₀ /mL	Negative	Negative	Negative
26	Rhinovirus	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
27	HBV	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
28	HIV	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative
29	HCV	10 ⁵ TCID ₅₀ /mL	Negative	Negative	Negative

(2) Cross-react with other common respiratory pathogens

No.	Type of Pathogen	Pathogen concentration	20CG2704X-y	20CG2705X-y	20CG2706X-y
1	Mycoplasma pneumoniae	10 ⁵ CFU/mL	Negative	Negative	Negative
2	Staphylococcus aureus	10 ⁶ CFU/mL	Negative	Negative	Negative
3	Staphylococcus epidermis	10 ⁶ CFU/mL	Negative	Negative	Negative
4	Pseudomonas aeruginosa	10 ⁶ CFU/mL	Negative	Negative	Negative
5	Streptococcus pneumoniae	10 ⁶ CFU/mL	Negative	Negative	Negative
6	Chlamydia pneumoniae	10 ⁵ CFU/mL	Negative	Negative	Negative
7	Haemophilus influenzae	10 ⁵ CFU/mL	Negative	Negative	Negative
8	Legionella pneumophila	10 ⁵ CFU/mL	Negative	Negative	Negative
9	Mycobacterium tuberculosis	10 ⁶ CFU/mL	Negative	Negative	Negative
10	Staphylococcus salivarius	10 ⁵ CFU/mL	Negative	Negative	Negative
11	Streptococcus pyogenes	10 ⁶ CFU/mL	Negative	Negative	Negative
12	Bordetella pertussis	10 ⁶ CFU/mL	Negative	Negative	Negative
13	Pneumocystis jiroveci (PJP)	10 ⁶ CFU/mL	Negative	Negative	Negative
14	Candida albicans	5×10 ⁴ CFU/mL	Negative	Negative	Negative
15	High concentration of new coronavirus N protein (dilution ratio is 1/10 ²)	/	Positive	Positive	Positive
16	High concentration of new coronavirus N protein (dilution ratio is 1/10 ³)	/	Positive	Positive	Positive
17	High concentration of new coronavirus N protein (dilution ratio is 1/10 ⁶)	/	Positive	Positive	Positive
18	High concentration of new coronavirus N protein (dilution ratio is 1/10 ⁷)	/	Negative	Negative	Negative

4.3 Test results of interferent

As listed below:

20CG2704X-y					
SN	Type of interferent	Name of interferent	Low concentration	Medium concentration	High concentration
1	Endogenous interferents	Mucin	Negative	Negative	Negative
		Human whole blood	Negative	Negative	Negative
2	Antiviral drug	Quinine	Negative	Negative	Negative
3		Zanamivir	Negative	Negative	Negative
4		Ribavirin	Negative	Negative	Negative
5		Oseltamivir	Negative	Negative	Negative
6		Peramivir	Negative	Negative	Negative
7		Lopinavir	Negative	Negative	Negative
8		Ritonavir	Negative	Negative	Negative
9		Arbidol	Negative	Negative	Negative
10		Anti-inflammatory agent	Paracetamol	Negative	Negative
11	Acetylsalicylate		Negative	Negative	Negative
12	Ibuprofen		Negative	Negative	Negative
13	Antibiotics	Levofloxacin	Negative	Negative	Negative
14		Azithromycin	Negative	Negative	Negative
15		Ceftriaxone	Negative	Negative	Negative
16		Meropenem	Negative	Negative	Negative
17	Systemic antibiotics	Tobramycin	Negative	Negative	Negative
18	Drugs for alleviating allergic symptoms	Histamine hydrochloride	Negative	Negative	Negative
19	Nasal sprays or	Phenylephrine, and	Negative	Negative	Negative

20	nose drops	Oxymetazoline	Negative	Negative	Negative
21		Sodium chloride (including preservatives)	Negative	Negative	Negative
22	Nasal corticosteroids	Beclomethasone	Negative	Negative	Negative
23		Dexamethasone	Negative	Negative	Negative
24		Flunisolide	Negative	Negative	Negative
25		Triamcinolone acetonide	Negative	Negative	Negative
26		Budesonide	Positive	Positive	Positive
27		Mometasone	Positive	Positive	Positive
28		Fluticasone	Positive	Positive	Positive
29	Throat lozenge	Strepsils (flurbiprofen 8.75mg)	Negative	Negative	Negative
30		Throat lozenge (mint)	Negative	Negative	Negative

20CG2705X-y					
SN	Type of interferent	Name of interferent	Low concentration	Medium concentration	High concentration
1	Endogenous interferents	Mucin	Negative	Negative	Negative
		Human whole blood	Negative	Negative	Negative
2	Antiviral drug	Quinine	Negative	Negative	Negative
3		Zanamivir	Negative	Negative	Negative
4		Ribavirin	Negative	Negative	Negative
5		Oseltamivir	Negative	Negative	Negative
6		Peramivir	Negative	Negative	Negative
7		Lopinavir	Negative	Negative	Negative
8		Ritonavir	Negative	Negative	Negative
9		Arbidol	Negative	Negative	Negative
10		Anti-inflammatory agent	Paracetamol	Negative	Negative
11	Acetylsalicylate		Negative	Negative	Negative

12		Ibuprofen	Negative	Negative	Negative
13	Antibiotics	Levofloxacin	Negative	Negative	Negative
14		Azithromycin	Negative	Negative	Negative
15		Ceftriaxone	Negative	Negative	Negative
16		Meropenem	Negative	Negative	Negative
17	Systemic antibiotics	Tobramycin	Negative	Negative	Negative
18	Drugs for alleviating allergic symptoms	Histamine hydrochloride	Negative	Negative	Negative
19	Nasal sprays or nose drops	Phenylephrine, and	Negative	Negative	Negative
20		Oxymetazoline	Negative	Negative	Negative
21		Sodium chloride (including preservatives)	Negative	Negative	Negative
22	Nasal corticosteroids	Beclomethasone	Negative	Negative	Negative
23		Dexamethasone	Negative	Negative	Negative
24		Flunisolide	Negative	Negative	Negative
25		Triamcinolone acetonide	Negative	Negative	Negative
26		Budesonide	Positive	Positive	Positive
27		Mometasone	Positive	Positive	Positive
28		Fluticasone	Positive	Positive	Positive
29	Throat lozenge	Strepsils (flurbiprofen 8.75mg)	Negative	Negative	Negative
30		Throat lozenge (mint)	Negative	Negative	Negative

20CG2706X-y					
SN	Type of interferent	Name of interferent	Low concentration	Medium concentration	High concentration
1	Endogenous	Mucin	Negative	Negative	Negative

	interferents	Human whole blood	Negative	Negative	Negative
2	Antiviral drug	Quinine	Negative	Negative	Negative
3		Zanamivir	Negative	Negative	Negative
4		Ribavirin	Negative	Negative	Negative
5		Oseltamivir	Negative	Negative	Negative
6		Peramivir	Negative	Negative	Negative
7		Lopinavir	Negative	Negative	Negative
8		Ritonavir	Negative	Negative	Negative
9		Arbidol	Negative	Negative	Negative
10		Anti-inflammatory agent	Paracetamol	Negative	Negative
11	Acetylsalicylate		Negative	Negative	Negative
12	Ibuprofen		Negative	Negative	Negative
13	Antibiotics	Levofloxacin	Negative	Negative	Negative
14		Azithromycin	Negative	Negative	Negative
15		Ceftriaxone	Negative	Negative	Negative
16		Meropenem	Negative	Negative	Negative
17	Systemic antibiotics	Tobramycin	Negative	Negative	Negative
18	Drugs for alleviating allergic symptoms	Histamine hydrochloride	Negative	Negative	Negative
19	Nasal sprays or nose drops	Phenylephrine, and	Negative	Negative	Negative
20		Oxymetazoline	Negative	Negative	Negative
21		Sodium chloride (including preservatives)	Negative	Negative	Negative
22	Nasal corticosteroids	Beclomethasone	Negative	Negative	Negative
23		Dexamethasone	Negative	Negative	Negative
24		Flunisolide	Negative	Negative	Negative
25		Triamcinolone acetonide	Negative	Negative	Negative

26		Budesonide	Positive	Positive	Positive
27		Mometasone	Positive	Positive	Positive
28		Fluticasone	Positive	Positive	Positive
29	Throat lozenge	Strepsils (flurbiprofen 8.75mg)	Negative	Negative	Negative
30		Throat lozenge (mint)	Negative	Negative	Negative

5 Conclusion

This product does not cross-react with Human Coronavirus OC43, Human Coronavirus 229E, Human Coronavirus HKU1, Human Coronavirus NL63, Influenza A, Influenza B, Adenovirus (1, 2, 3, 4, 5, 7), Epstein Barr Virus, Measles Virus, Human Giant Cellular virus, rotavirus, norovirus, mumps virus, varicella-zoster virus, metapneumovirus, parainfluenza virus 1-4, enterovirus, rhinovirus, hepatitis B virus, HIV, hepatitis C virus, Mycoplasma pneumoniae, Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa, Streptococcus pneumoniae, Chlamydia Streptococcus pneumoniae, Haemophilus influenzae, Legionella pneumophila, Mycobacterium tuberculosis, Staphylococcus salivarius, Streptococcus pyogenes, Pertussis Bordetella, Pneumocystis gibsonii, Candida albicans and high concentration of N protein.

When the mucin concentration $\leq 5\text{mg/mL}$ and human whole blood $\leq 2\%$, it will not interfere with the test results of this product; Quinine, Zanamivir, Ribavirin, Oseltamivir, Peramivir, Lopinavir, Ritonavir, Arbidol, Acetaminophen, Acetylsalicylic Acid, Bulo Fen, levofloxacin, azithromycin, ceftriaxone, meropenem, tobramycin, histamine hydrochloride, phenylephrine, oxymetazoline, sodium chloride (with preservatives), clomethasone, dexamethasone, flunx Shrinks, triamcinolone acetonide, budesonide, mometasone, fluticasone, Strepsils (flurbiprofen 8.75mg), throat lozenges (menthol) have no effect on the test results of this product at the verified concentration.