

EDELVITAL Rapid COVID-19 Antigen Test(Colloidal Gold)

Instruction for use

【Product Name】 Rapid COVID-19 Antigen Test(Colloidal Gold)
EDELVITAL 3in1 (KOLLOIDALES GOLD)CORONA ANTIGEN

【Specification】 1 Test/ kit, 10 Tests/ kit, 20 Tests/ kit.

【Intended Use】

The Rapid COVID-19 Antigen Test is a colloidal gold immunochromatography intended for the qualitative detection of nucleocapsid antigens from SARS-CoV-2 in human nasal swabs, throat swabs, anal swabs, nasopharyngeal swab or saliva from individuals who are suspected of COVID-19 by their healthcare provider.

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Test results are for the identification of SARS-CoV-2 nucleocapsid antigen. The antigen is generally detectable in upper respiratory samples or lower respiratory samples during the acute phase of infection. The positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. The positive results do not rule out bacterial infection or co-infection with other viruses. The antigen detected may not be the definite cause of disease. The negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. The negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with SARS-CoV-2 and confirmed with a molecular assay, if necessary for patient management.

【Test Principle】

This reagent is based on colloidal gold immunochromatography assay.

During the test, specimen extracts are applied to the Test Cards. If there are SARS-CoV-2 antigen in the extract, the antigen will bind to the SARS-CoV-2 monoclonal antibody. During lateral flow, the complex will move along the nitrocellulose membrane toward the end of the absorbent paper. When passing the test line (line T, coated with another SARS-CoV-2 monoclonal antibody) the complex is captured by SARS-CoV-2 antibody on test line shows a red line; when passing the line C, colloidal gold-labeled goat anti-rabbit IgG is captured by control line (line C, coated with rabbit IgG) and shows a red line.

【Main components】

The following components are included in the Rapid COVID-19 Antigen Test kit

Materials Provided:

Sample type	Materials
Nasal swabs	1.COVID-19 Antigen Test Card
Throat swabs	2.Extraction Solution
Anal swabs	3.Instruction for Use
Nasopharyngeal swab	4.Swab
Saliva	
Saliva(only)	1.COVID-19 Antigen Test Card
	2.Saliva collection device (with 1ml extraction solution)
	3.Instruction for Use
	4.Disposable dropper

Materials Required but not provided:

- 1.Timer
- 2.Tube rack for specimens
- 3.Any necessary personal protective equipment

【Storage Conditions and Validity】

1. Store the Product at 2-30°C, the shelf life is 24months tentatively.
- 2 Test Card should be used right after opening the pouch.
3. Reagents and devices must be at room temperature (15-30°C) when used for testing.

【Sample Collection Handling】

1. Swab Specimen Collection

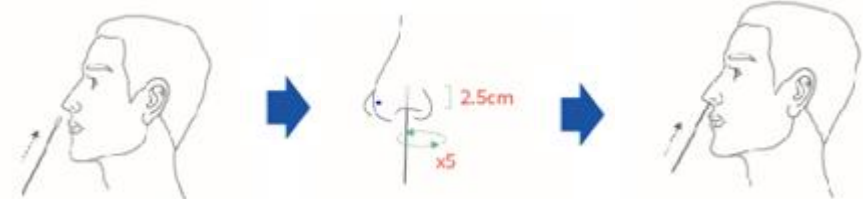
Throat Swab Specimen Collection:

Let the patient's head tilt slightly, mouth open, and make "ah" sounds, exposing the pharyngeal tonsils on both sides. Hold the swab and wipe the pharyngeal tonsils on both sides of the patient with moderate force back and forth for at least 3 time



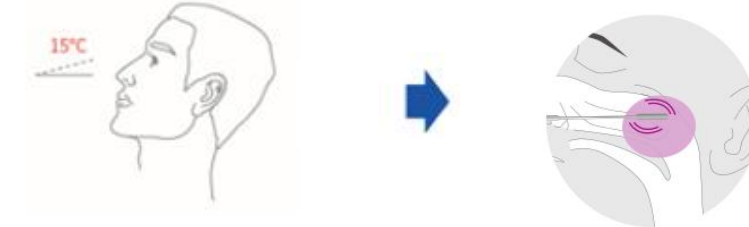
Nasal Swab Specimen Collection

- Insert the swab into one nostril of the patient. The swab tip should be inserted up to 2.5cm (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
- Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities. Withdraw the swab from the nasal cavity.



Nasopharyngeal Swab Specimen Collection

Let the patient's head tilt slightly, Insert a swab into the nostril of the patient, swab over the surface of the posterior nasopharynx. Withdraw the swab from the nasal cavity.



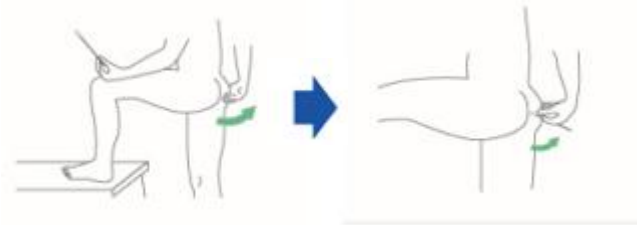
Saliva Specimen Collection by swab

- Cough deeply, make the noise of “kruuuu”
- Place the swab on your tongue
- Hold the swab in your mouth for 10-20s, moisten the swab with saliva



Anal swabs Specimen Collection:

- get in a position that allows you to comfortably access your bum (putting your foot on the step helps)
- pull one bum cheek to the side
- hold the swab tightly and slowly insert the soft tip into anus 3-4cm
- twist the swab slowly for 5-10 seconds and pull it out of your anus



2. The extraction of swab specimen

- Put the swab with collected specimen into the extraction tube, hold and press the swab head against the wall of tube with force while rotating the swab for about 10 seconds (10-15 times) to release the antigen into the extraction solution from the swab head.
- Removing swab: Squeeze the swab head while removing the swab in order to remove as much liquid as possible from the swab. Dispose of swabs according to biohazard waste disposal regulations.
- Screw the nozzle cap onto the extraction tube.

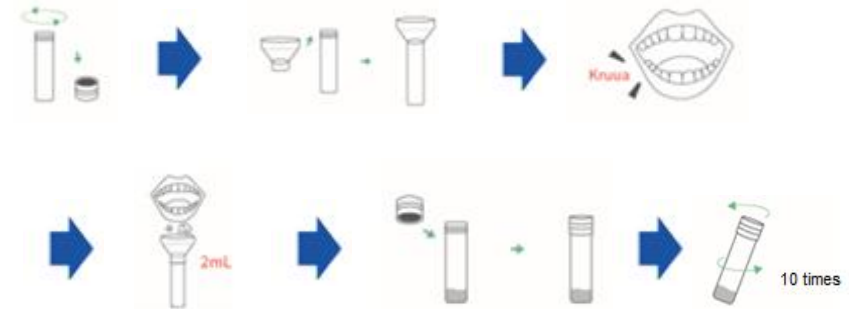


3. Saliva Specimen Collection by Saliva collection device

- Open the lid of the sample tube
- Screw on the salivary funnel



- Cough deeply, make the noise of “kruuuu”
- From the deep throat collect the saliva to 2mL (please note the 2mL mark on the tube)
- Remove the salivary funnel, cover the lid and mix well upside and down for 10 times.



4. Disposable virus sampling tube (VTM, UTM or saline buffer)

For the procedure of collecting samples with disposable virus sampling tubes, see the instructions for the disposable virus sampling tube used.

5. Specimen Transport and Storage

Samples should be tested as soon as possible after collection. Swabs or saliva specimen can be stored in Extraction Solution (include VTM, UTM or saline buffer) for up to 24 hours at room temperature or 2° to 8°C. Do not freeze.

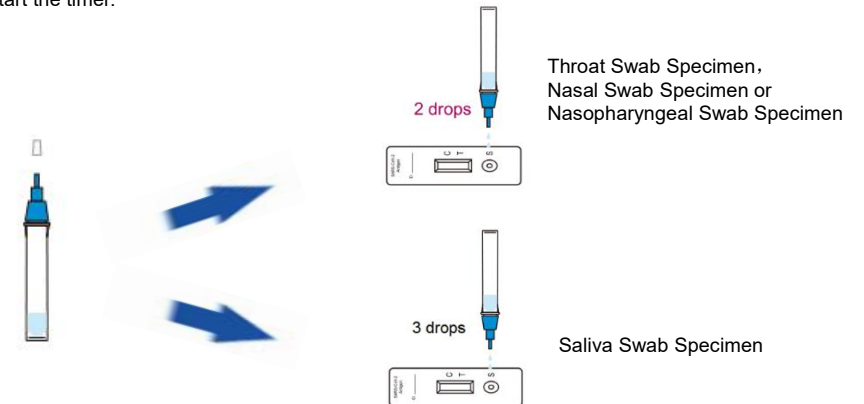
【Test Method】

- The test should be operated at room temperature (15-30°C) .

- Add the specimens

1) Swab specimen:

Open the lid, drip 2 drops of extraction solution (**Throat Swab Specimen** , **Nassal Swab Specimen** or **Anal Swab Specimen**) or 3 drops of extraction solution (**Saliva Specimen**) into the sample well of the Test Card, and start the timer.



2) Saliva Specimen (from Saliva collection device): Open the lid and absorb a tube of liquid with a disposable dropper. drip 3 drops of extraction solution into the sample well of the Test Card, and start the timer.



3) Samples by disposable virus sampling tubes (VTM, UTM or saline buffer): open the lid of the disposable virus sampling tube (VTM, UTM or saline buffer), draw 100µL of liquid with a micropipette, drop into the test card sample wells, and start the timer.



3. Read the results at 15~20 minutes.



【Interpretation of test results】

Negative (-):

There is coloration on line C only showing as following picture, suggesting that there is no SARS-CoV-2 antigen in the specimen.

Positive (+):

There are coloration on both line C and line T showing as follow pictures suggesting that there is SARS-CoV-2 antigen in the specimen.

Invalid:

There is no coloration on line C, as shown in the following pictures. The test is invalid or an error in operation occurred. Repeat the assay with a new cartridge.



Negative



Positive



Invalid

【Reporting Of Results】

Positive Test:

Positive for the presence of SARS-CoV-2 antigen. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The antigen detected may not be the definite cause of disease.

Negative Test :

Negative results are presumptive. Negative test results do not preclude infection and should not be used as the sole basis for treatment or other patient management decisions, including infection control decisions, particularly in the presence of clinical signs and symptoms consistent with COVID-19, or in those who have been in contact with the virus. It is recommended that these results would be confirmed by a molecular testing method, if necessary, for patient management Control.

Invalid:

Do not report results. Repeat the test.

【Limitation of the test】

1. Clinical performance was evaluated with frozen samples, and test performance may be different with fresh samples.
2. Users should test specimens as quickly as possible after specimen collection.
3. Positive test results do not rule out co-infections with other pathogens.
4. Results of SARS-CoV-2 antigen test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.
5. A false-negative test result may occur if the level of viral antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly; therefore, a negative test result does not eliminate the possibility of COVID-19 infection.
6. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness are more likely to be negative compared to a RT-PCR assay.
7. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.
8. The contents of this kit are to be used for the qualitative detection of SARS-CoV-2 antigens from throat, nasal swab, anal swabs or saliva specimens only.
9. The reagent can detect both viable and non-viable SARS-CoV-2 antigen. The detection performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.
10. Negative test results are not intended to rule in other non- SARS-CoV-2 viral or bacterial infections.
11. Positive and negative predictive values are highly dependent on prevalence rates. Positive test results are more likely to represent false positive results during periods of little/no COVID-19 activity when disease prevalence is low. False negative test results are more likely when prevalence of disease caused by SARS-CoV-2 is high.
12. This device has been evaluated for use with human specimen material only.
13. The performance of this test has not been evaluated for use in patients without signs and symptoms of respiratory infection and performance may differ in asymptomatic individuals.



14. The kit was validated with the assorted swabs. Use of alternative swabs may result in false negative results.
15. Users should test specimens as quickly as possible after specimen collection.
16. The validity of Rapid COVID-19 Antigen Test has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.

【Performance Characteristics】

1. Clinical Evaluation Report

Study 1: Nasal swabs

Clinical performance of Rapid COVID-19 Antigen Test(Colloidal Gold) was determined by testing 231 positive and 341 negative specimens for SARS-CoV-2 antigen to have a sensitivity of 99.13% (95% CI: 96.91%-99.89%) and specificity of 100% (95% CI: 98.92%-100%) by nasal swabs. Clinical specimens were determined to be positive or negative using an RT-PCR reference method.

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	229(a)	0(b)	229(a+b)
Antigen Test(Colloidal	Negative	2(c)	341(d)	343(c+d)
Gold) result	Total	231(a+c)	341(b+d)	572(a+b+c+d)
Coincidence rate and 95% confidence interval				
		Coincidence rate	95% confidence interval	
Clinical sensitivity		99.13%	96.91%~99.89%	
Clinical specificity		100%	98.92%~100%	
Total coincidence rate		99.65%	98.74%~99.96%	

Study 2: Throat swabs

Clinical performance of Rapid COVID-19 Antigen Test(Colloidal Gold) was determined by testing 315 positive and 329 negative specimens for SARS-CoV-2 antigen to have a sensitivity of 99.05% (95% CI: 97.24%-99.80%) and specificity of 100% (95% CI: 98.88%-100%) by throat swabs. Clinical specimens were determined to be positive or negative using an RT-PCR reference method.

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	312 (a)	0(b)	312(a+b)
Antigen Test(Colloidal	Negative	3(c)	329(d)	332(c+d)
Gold) result	Total	315(a+c)	329(b+d)	644(a+b+c+d)

Coincidence rate and 95% confidence interval

	Coincidence rate	95% confidence interval
Clinical sensitivity	99.05%	97.24%~99.80%
Clinical specificity	100%	98.88%~100%
Total coincidence rate	99.53%	98.64%~99.90%

Study 3: Saliva

Clinical performance of Rapid COVID-19 Antigen Test(Colloidal Gold) was determined by testing 550 positive and 123 negative specimens for SARS-CoV-2 antigen to have a sensitivity of 99.27% (95% CI: 98.15%-99.80%) and specificity of 100% (95% CI: 97.05%-100%) by saliva specimens. Clinical specimens were determined to be positive or negative using an RT-PCR reference method.

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	546(a)	0(b)	546(a+b)
Antigen Test(Colloidal	Negative	4(c)	123(d)	127(c+d)
Gold) result	Total	550(a+c)	123(b+d)	673(a+b+c+d)
Coincidence rate and 95% confidence interval				
		Coincidence rate	95% confidence interval	
Clinical sensitivity		99.27%	98.15%~99.80%	
Clinical specificity		100%	97.05%~100%	
Total coincidence rate		99.41%	98.49%~99.84%	

Study 4: Anal swabs

Clinical performance of Rapid COVID-19 Antigen Test(Colloidal Gold) was determined by testing 102 positive and 164 negative specimens for SARS-CoV-2 antigen to have a sensitivity of 100% (95% CI: 96.45%-100%) and specificity of 99.39% (95% CI: 96.65%-99.98%) by Anal swabs specimens. Clinical specimens were determined to be positive or negative using an RT-PCR reference method.



		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	102(a)	1(b)	103(a+b)
Antigen Test(Colloidal	Negative	0(c)	163(d)	163(c+d)
Gold) result	Total	102(a+c)	164(b+d)	266(a+b+c+d)
Coincidence rate and 95% confidence interval				
		Coincidence rate	95% confidence interval	
Clinical sensitivity		100%	96.45%~100%	
Clinical specificity		99.39%	96.65%~99.98%	
Total coincidence rate		99.62%	97.92%~99.99%	

Study 5: Nasopharyngeal swabs

Clinical performance of Rapid COVID-19 Antigen Test(Colloidal Gold) was determined by testing 288 positive and 255 negative specimens for SARS-CoV-2 antigen to have a sensitivity of 99.31% (95% CI: 97.51%-99.92%) and specificity of 100% (95% CI: 98.56%-100%) by Nasopharyngeal swabs specimens. Clinical specimens were determined to be positive or negative using an RT-PCR reference method.

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	286(a)	0(b)	286(a+b)
Antigen Test(Colloidal	Negative	2(c)	255(d)	257(c+d)
Gold) result	Total	288(a+c)	255(b+d)	543(a+b+c+d)
Coincidence rate and 95% confidence interval				
		Coincidence rate	95% confidence interval	
Clinical sensitivity		99.31%	97.51%~99.92%	
Clinical specificity		100%	98.56%~100%	
Total coincidence rate		99.63%	98.68%~99.96%	

Study 6: Total

Clinical performance of Rapid COVID-19 Antigen Test(Colloidal Gold) was determined by testing 1486 positive and 1212 negative specimens for SARS-CoV-2 antigen to have a sensitivity of 99.26% (95% CI: 98.68%-99.63%) and specificity of 99.92% (95% CI: 99.54%-100%). Clinical specimens were determined

to be positive or negative using an RT-PCR reference method.

		PCR result		
		Positive	Negative	Total
Rapid COVID-19	Positive	1475(a)	1(b)	1476(a+b)
Antigen Test(Colloidal	Negative	11(c)	1211(d)	1222(c+d)
Gold) result	Total	1486(a+c)	1212(b+d)	2698(a+b+c+d)
Coincidence rate and 95% confidence interval				
		Coincidence rate	95% confidence interval	
Clinical sensitivity		99.26%	98.68%~99.63%	
Clinical specificity		99.92%	99.54%~100%	
Total coincidence rate		99.56%	99.22%~99.77%	

2. Limit of Detection (LoD)

The LOD for Rapid COVID-19 Antigen Test(Colloidal Gold) was 4.25 x10² TCID₅₀/mL. The LOD was established using limiting dilutions of heat-inactivated SARS-CoV-2 antigen.

3. Cross-Reactivity

Rapid COVID-19 Antigen Test(Colloidal Gold) does not cross with the following common respiratory pathogens.

S.N.	Potential Cross-Reactant	Species	Concentration
1	H1N1(2009)	A-H1N1-2009	10 ⁶ pfu/mL
2	Seasonal H1N1 influenza virus	A-H1N1	10 ⁶ pfu/mL
3	H3N2 influenza virus	A-H3N2	10 ⁶ pfu/mL
4	H5N1 avian influenza virus	A-H5N1	10 ⁶ pfu/mL
5	H7N9 avian influenza virus	A-H7N9	10 ⁶ pfu/mL
6	Influenza B Yamagata	B-Yamagata	10 ⁶ pfu/mL
7	Influenza B Victoria	B-Victoria	10 ⁶ pfu/mL
8	Respiratory syncytial virus type A	RSV-A2	10 ⁶ pfu/mL
9	Respiratory syncytial virus type B	RSV-B	10 ⁶ pfu/mL
10	Enterovirus A	CV-A10	10 ⁶ pfu/mL
11	Enterovirus B	Echovirus 6	10 ⁶ pfu/mL
12	Enterovirus C	CV-A21	10 ⁶ pfu/mL
13	Enterovirus D	EV-D68	10 ⁶ pfu/mL



14	Parainfluenza virus type 1	HPIVs-1	10 ⁶ pfu/mL
15	Parainfluenza virus type 2	HPIVs-2	10 ⁶ pfu/mL
16	Parainfluenza virus type 3	HPIVs-3 VR-93	10 ⁶ pfu/mL
17	Rhinovirus A	HRV-9 VR-489	10 ⁶ pfu/mL
18	Rhinovirus B	HRV-52 VR-1162 HRV-3 VR-1113	10 ⁶ pfu/mL
19	Rhinovirus C	HRV-16 VR-283	10 ⁶ pfu/mL
20	Adenovirus type 1	HAdV-1 VR-1	10 ⁶ pfu/mL
21	Adenovirus type 2	HAdV-2 VR-846	10 ⁶ pfu/mL
22	Adenovirus type 3	HAdV-3	10 ⁶ pfu/mL
23	Adenovirus type 4	HAdV-4 VR-1572	10 ⁶ pfu/mL
24	Adenovirus type 5	HAdV-5 VR-1578/1516	10 ⁶ pfu/mL
25	Adenovirus type 7	HAdV-7 VR-7	10 ⁶ pfu/mL
26	Adenovirus type 55	HAdV-55	10 ⁶ pfu/mL
27	Human metapneumovirus	HMPV	10 ⁶ pfu/mL
28	Epstein-Barr virus	HHV-4 VR-1492	10 ⁶ pfu/mL
29	Measles virus	MV VR-24	10 ⁶ pfu/mL
30	Human cytomegalovirus	HHV-5 VR-977	10 ⁶ pfu/mL
31	Rotavirus	RV VR-2018	10 ⁶ pfu/mL
32	Norovirus	NOR	10 ⁶ pfu/mL
33	Mumps virus	MuV VR-106	10 ⁶ pfu/mL
34	Varicella-zoster virus	VZV VR-1367	10 ⁶ pfu/mL
35	Legionella	33152	10 ⁷ cfu/mL
36	Bordetella pertussis	BAA-589	10 ⁷ cfu/mL
37	Haemophilus influenzae	Hib	10 ⁷ cfu/mL
38	Staphylococcus aureus	CGMCC 1.2910	10 ⁷ cfu/mL
39	Streptococcus pneumoniae	CGMCC 1.8722	10 ⁷ cfu/mL
40	Streptococcus pyogenes	CGMCC 1.8868	10 ⁷ cfu/mL
41	Klebsiella pneumoniae	CGMCC 1.1736	10 ⁷ cfu/mL



42	Mycobacterium tuberculosis	25177	10 ⁷ cfu/mL
43	Mycoplasma pneumoniae	39505	10 ⁷ cfu/mL
44	Chlamydia pneumoniae	VR-2282	10 ⁷ cfu/mL
45	Aspergillus fumigatus	AF293	10 ⁷ cfu/mL
46	Candida albicans	SC5314	10 ⁷ cfu/mL
47	Candida glabrata	ATCC 2001	10 ⁷ cfu/mL
48	Cryptococcus neoformans	H99	10 ⁷ cfu/mL
49	Cryptococcus gutii	R265	10 ⁷ cfu/mL
50	Pneumocystis jirovecii (PJP)	CGMCC 1.9054	10 ⁷ cfu/mL
51	Coronavirus229E	VR-740	10 ⁶ pfu/mL
52	CoronavirusOC43	VR-1558	10 ⁶ pfu/mL
53	CoronavirusNL63	COV-NL63	10 ⁶ pfu/mL
54	Coronavirus HKU1	COV-HKU1	10 ⁶ pfu/mL
55	Coronavirus MERS	MERS	10 ⁸ TU/mL
56	Coronavirus SARS	SARS	10 ⁸ TU/mL
57	Pooled human nasal wash	/	10 ⁷ cfu/mL

4. Interfering Substances

The following potentially interfering substances have no impact on Rapid COVID-19 Antigen Test(Colloidal Gold). The final test concentrations of the interfering substances are documented in the Table below.

S.N.	Substance Name	Concentration
1	Whole Blood	4%(v/v)
2	Mucin	0.5%(v/v)
3	Ricola (Menthol)	1.5mg/mL
4	Sucrets (Dyclonin)	1.5mg/mL
5	Sucrets (Menthol)	1.5mg/mL
6	Chloraseptic (Menthol)	1.5mg/mL
7	Chloraseptic (Benzocaine)	1.5mg/mL
8	Naso GEL (NeilMed)	5%(v/v)
9	CVS Nasal Drops (Phenylephrine)	15%(v/v)
10	Afrin (Oxymetazoline)	15%(v/v)
11	CVS Nasal Spray (Cromolyn)	15%(v/v)
12	Nasal Gel (Oxymetazoline)	10%(v/v)
13	Zicam	5%(v/v)
14	Homeopathic (Alkalol)	1:10



15	Fisherman's Friend	1.5mg/mL
16	Sore Throat Phenol Spray	15%(v/v)
17	Tobramycin	4µg/mL
18	Mupirocin	10mg/mL
19	Fluticasone Propionate	5%(v/v)
20	Tamiflu (Oseltamivir Phosphate)	5mg/mL

5. Hook Effect

The concentration is 3.40×10^5 TCID₅₀/mL, the test results are all positive, and there is no HOOK effect.

【Precautions】

- For in vitro diagnostic use.
- This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens.
- Do not use this kit beyond the expiration date printed on the outside carton.
- Do not use the kit to evaluate patient specimens if either the positive control swab or negative control swab fail to give expected results.
- Test results are meant to be visually determined.
- To avoid erroneous results, specimens must be processed as indicated in the assay procedure section.
- Do not reuse any kit components.
- Proper specimen collection, storage and transport are critical to the performance of this test.
- Specific training or guidance is recommended if operators are not experienced with specimen collection and handling procedures. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when specimens are collected and evaluated. Pathogenic microorganisms, including hepatitis viruses and Human Immunodeficiency Virus, may be present in clinical specimens. Standard precautions and institutional guidelines should always be followed in handling, storing, and disposing of all specimens and all items contaminated with blood or other body fluids.
- Dispose of used test kits as biohazardous waste in accordance with federal, state and local requirements.
- For additional information on hazard symbols, safety, handling and disposal of the components within this kit, please refer to the Safety Data Sheet (SDS).
- Wear suitable protective clothing, gloves, and eye/face protection when handling the contents of this kit.

【Instruction Version】

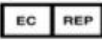
Version:V5.0

Catalogue number : A6061204

【Index of CE Symbols】

	The product is used in vitro, please don't swallow it.		Please don't reuse it
	Validity		Please read the instruction book carefully before using
	Warning, please refer to the instruction in the annex		Manufacturer



	Temperature scope within which the product is reserved		Batch number
	European union authorization representative		Keep dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
	Date of manufacture		Biological risks
	The product meets the basic requirements of European in vitro diagnostic medical devices directive 98/79/EC		

【Basic Information】



Anbio (Xiamen) Biotechnology Co.,Ltd.

Add: No.2016,Wengjiao West Road, Xinyang Street, Haicang District, Xiamen,Fujian,China.

Tel:+86-592-6312399,Email:info@anbio.com



Lotus NL B.V.

Add: Koningin Julianaplein 10, 1e Verd,2595AA,The Hague ,Netherlands.

Email: peter@lotusnl.com

