Hoyotek®

CE

Instruction for use
Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)
(ONLY FOR PROFESSIONAL USE)

【*Product name*】

Corona Virus (COVID-19) Antigen Rapid Test (Colloidal Gold)

【*Model code*】

HYT-G01-01: Nasal/ Nasopharyngeal swab

【*Packing specification*】

HYT-G01-01: 30 Tests/ box, 1 Test/ box

【*Intended use*】

The COVID-19 Antigen Rapid Test Kit (Swab) intended for qualitative detection of nucleocapsid protein antigen in direct nasal or nasopharyngeal swab specimens from the human body. It is only used as a supplementary test for the nucleic acid test of novel coronavirus or in cooperation with nucleic acid test in suspected cases. It cannot be used as a basis for the diagnosis and exclusion of pneumonia caused by novel coronavirus infection and is not suitable for general screening. For medical institution use only, and biosecurity protection should be done in laboratory when testing of novel coronavirus. The results of this kit are only for clinical reference. If the test result is positive, further confirmation is needed. If the test result is negative, the possibility of infection cannot be excluded. Comprehensive analysis of the patient's condition should be carried out in combination with clinical symptoms and other laboratory tests.

【*Test principle*】

The COVID-19 Antigen Rapid Test is a lateral flow immunoassay based on the principle of double antibody sandwich technology and the colloidal gold method. The SARS-CoV-2 nucleocapsid protein monoclonal antibody conjugated with colored microparticles is used as a detector and sprayed onto the conjugation pad. During the test, the SARS-CoV-2 antigen in the sample, if present, interacts with the SARS-CoV-2 antibody conjugated with colored microparticles, forming an antigen-antibody-labeled complex. This complex migrates via capillary action on the membrane to the test line, where it is captured by the pre-coated monoclonal SARS-CoV-2 nucleocapsid protein antibody. A colored test line (T) is visible in the results window. The absence of the T-line indicates no SARS-CoV-2 antigen in the sample or a negative result. The control line (C) is used as a procedural control and should always be displayed when the test procedure is being carried out properly.

【*Product components*】

Components	Packing Specifications	Material
Corona Virus (COVID-19) Antigen Rapid Test Card	1 bag/30 bags	Colloidal gold labeled mouse anti-Corona Virus (COVID-19) nucleocapsid protein monoclonal antibody; Mouse anti-Corona Virus (COVID-19) nucleocapsid protein monoclonal antibody; Goat anti-mouse polyclonal antibody;
Sample extraction solution and swab	0.5ml ×1 bottle/0.5ml ×30 bottles	Na_2HPO_4, NaH_2PO_4, NaCl, $C_{56}H_{111}O_{56}$

【*Storage conditions and expiry date*】

1. Storage between 2-30℃, keep away from light, valid for 12 months.
2. The product should be stored in dry condition under 2-30℃ and kept away from direct light. Under the condition of 18-30℃, the humidity is below 60. Therefore, the product has to be used within 1 hour after opening. If the Humidity is above 60%, it should be used immediately.
3. Production date and validity period are shown in the label.

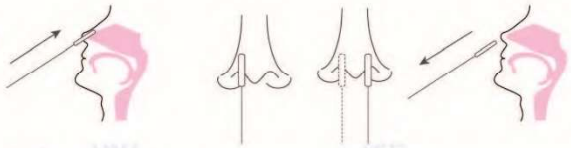
【*Specimen collection and handling*】

Specimen Collection

- Inadequate specimen collection or improper specimen handling may yield a false result.
- Prior to collecting the nasal swab, the patient should be instructed to blow their nose.

• Nasal Swabbing:

1. Insert the swab into one nostril of the patient. 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.
2. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.
3. Withdraw the swab from the nasal cavity.



• *Nasopharyngeal Swabbing:*

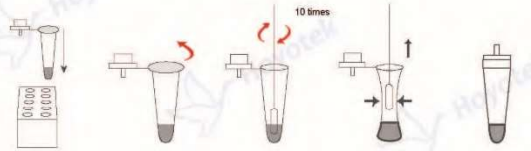
1. Tilt the patient's head back. Insert the swab through the nostril that presents the most secretion under visual inspection.
2. Keep the swab near the septum floor of the nose while gently pushing the swab into the posterior nasopharynx. Rotate the swab several times.
3. Leave the swab in place for several seconds then remove it from the nasopharynx.

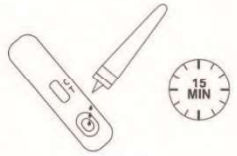
Specimens Transport and Storage:

Specimens should be tested as soon as possible. If transport of the samples is required, the following transport media are recommended, which have been tested and shown not to interfere with the performance of the test: Hank's balance Mkd salt solution, M5 media, or saline. Alternatively, samples may be stored refrigerated (2-8℃) or at room temperature (15-30℃) in a clean, dry and closed container for up to 8 hours before testing.

【*Specimen Preparation*】

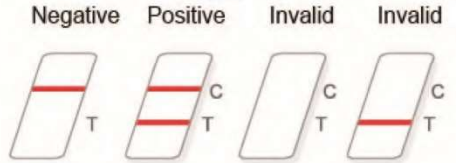
1. Tear off the aluminum foil of the extraction tube and put it on the workstation.
2. Insert the swab into the extraction tube which contains buffer. Rotate the swab at least 10 times while pressing the swab against the bottom and side of the extraction tube.
3. Pinch the extraction tube with fingers and roll the swab head against the inside of the Extraction tube when you remove it to release as much liquid as possible. The extracted solution will be used as test specimen.
4. Insert a dropper tip into the specimen extraction tube tightly.
5. Add four drops of the solution (approx. 100 uL) into the test cassette and then start the timer. Result should be read at 13-15 minutes.





【*Interpretation of assay result*】

1. Positive: Two red lines appear at T-line and C-line. It indicates that COVID-19 antigen is detected in the sample, the patient may be in early stage of infection or is currently infected. The final confirmation should be combined with clinical symptoms.
2. Negative: Only one red quality control line (C) appears in the detection window. It indicates that no COVID-19 antigen is detected in the sample.
3. Invalid results: The control window has no red stripe. If you get an invalid result, please repeat the test again, in strict accordance with the instructions. If the test result is invalid again, please contact local suppliers or customer service with our company for technical consultation.



【*Limitations of the test method*】

1. This product inspection result is only for clinical reference and should not serve as the only basis for clinical diagnosis and treatment. The clinical management of patients should be combined with its symptoms or signs, other medical history and laboratory examination, treatment response and epidemiological information such as the comprehensive consideration.
2. Due to the methodological limitations of antigen detection reagents, the minimum detection limit (analytical sensitivity) is generally below that of nucleic acid reagents. Therefore, experimenters should pay more attention to negative results. Other test results must also be considered in order to make a comprehensive judgment. It is recommended that nucleic acid tests or virus isolation and culture identification methods be used to verify negative results when in doubt. Analysis of the possibility of wrong negative results:

(a) Improper sampling, transport and treatment, and insufficient virus droplets in samples may lead to false negative results.
(b) Genetic variation in the virus may lead to changes in antigenic determinants, resulting in false negative results, which are more likely to occur with monoclonal antibody reagents.
(c) For an emergent novel corona virus, the optimal type of sample to be tested and the optimal sampling time after infection (peak viral titer) may not be confirmed. Therefore, multiple sampling at multiple sites in the same patient will reduce the possibility of false negative results.

【*Product performance indicator*】

1. Smooth appearance, solid material attachment, complete contents, complete packaging no damage, clearly identifiable signs, no visible impurities were found in the sample extract.
2. The moving speed of sample diluent≥10mm per minute.
3. Compliance rate of positive quality control products: inspection 5 positive quality control products, P1~P5 Corona Virus (COVID-19) Antigen is required to be positive; the positive internal quality control compliance rate should be 5/5 (+/+).
4. Compliance rate of negative quality control products: inspection of 10 negative quality control products, N1~N10 Corona Virus (COVID-19) Antigen is required to be negative; the negative internal quality control compliance rate should be 10/10 (-/-).
5. Minimum detection limit: the minimum detection limit of quality control products S1-S5, S1~S4 Corona Virus (COVID-19) Antigen test results should be positive, S5 Corona Virus (COVID-19) Antigen test results should be negative.
6. Repeatability: test 2 internal repeatability quality control products, each test for 10 times, test results should be positive.
7. The cross reaction of the pathogen: there is no reaction with Flu A virus and Flu B virus.

【*Diagnostic performance*】

The performance of the kit was tested on samples from patients with suspected COVID-19 taken between March 2020 and January 2021 during daily clinical practice at the Hunan CDC and Shenyang Sixth People's Hospital (China). The samples were taken by qualified personnel.
500 nasopharyngeal swab samples were taken for molecular diagnosis using RT-PCR for the rapid antigen test. The test was shown to have 96 % diagnostic sensitivity and 99 % diagnostic specificity compared with the RT-PCR results.

Clinical Study Results			
Corona Virus (COVID-19) Antigen	PCR Comparator		Sub total
	Positive	Negative	
Positive	96	4	100
Negative	4	396	400
Sub total	100	400	500

Positive Percent Agreement (PPA)= 96/100(96%) (95%CI: 90.07%~98.9%)
Negative Percent Agreement (NPA)= 396/400 (99%) (95%CI:97.46%~99.73%)

400 nasal swab samples were taken for molecular for molecular diagnosis using RT-PCR for the rapid antigen test, the test was shown to have 95.24 % diagnostic sensitivity and 98.18 % diagnostic specificity compared with the RT-PCR results.

Corona Virus (COVID-19) Antigen	PCR Comparator		Sub total
	Positive	Negative	
Positive	120	5	125
Negative	6	269	275
Sub total	126	274	400

Positive Percent Agreement (PPA)= 120/126(95.24%) (95%CI: 89.92%~98.23%)
Negative Percent Agreement (NPA)= 269/274 (98.18%) (95%CI:95.79%~99.41%)

1.Interference experiment
The following substances were tested at the concentration shown, and no interference was found.

OTC Throat drop (Halls)	15%	Budesonide	2 mg/mL
OTC Throat drop (Ricola)	15%	Menthol	10 mg/mL
OTC Nasal spray (Afrin)	15%	Mucin	10μg/mL
OTC Nasal spray (VicksSinex)	15%	Mometasone	1 mg/mL
Acetyl salicylic acid	10mg/mL	Ibuprofen	3 mM
Acetaminophen	15mg/mL	Flunisolide	120μg/mL
Afrin Nasal Spray (Oxymetazoline)	4%(v/v)	Tobramycin	80μg/mL
Sodium Cromoglycate	12 mg/mL	Fluticasone	0.4ng/mL
Whole Blood	5%(v/v)	Ritonavir	8.0mg/mL
Chlorpheniramine	5 mg/mL	Abidor	420mg/mL
maleate Dexamethason	1 mg/mL	Peramivir	1.0mmol/L
Doxycycline hyclate	50μM	Quinine	150μM

2. Cross-reactivity
There was no cross-reaction and interference with the potential cross-reacting microorganisms listed below:

MERS-Coronavirus	Florida/USA-2_Saudi Arabia_2014	5×10^4 $TCID_{50}$/ml
Influenza A	H1N1 Denwer	2×10^5 $TCID_{50}$/mL
	H1N1 WS/33	1.5×10^5 $TCID_{50}$/ml
	H1N1 Pdm-09	2×10^5 $TCID_{50}$/ml
	H1N1 New Caledonia	1×10^5 $TCID_{50}$/ml
	H1N1 New jersey	2×10^5 $TCID_{50}$/ml
Influenza B	Nevada/03/2011	2×10^5 $TCID_{50}$/ml
	B/Lee/40	5×10^5 $TCID_{50}$/ml
	B/Taiwan/2/62	1×10^5 $TCID_{50}$/ml
Human Coronavirus	229E	1×10^5 $TCID_{50}$/ml
	OC43	1×10^5 $TCID_{50}$/ml
	NL63	1×10^5 $TCID_{50}$/ml
Respiratory syncytial virus	Type A	1×10^5 $TCID_{50}$/ml
	Type B	1×10^5 $TCID_{50}$/ml
Human Metapneumovirus (hMPV)	hMPV 3 Type B1 / Peru2-2002	1×10^5 $TCID_{50}$/ml
	hMPV 16 Type A1 / IA10-2003	1×10^5 $TCID_{50}$/ml
Parainfluenza virus	Type 1	1×10^5 $TCID_{50}$/ml
	Type 2	1×10^5 $TCID_{50}$/ml
	Type 3	1×10^5 $TCID_{50}$/ml
	Type 4A	1×10^5 $TCID_{50}$/ml
Rhinovirus	A16	1×10^5 $TCID_{50}$/ml
	Type B42	1×10^5 $TCID_{50}$/ml
Enterovirus	Type 68	1×10^5 $TCID_{50}$/ml
	(09/2014 isolate 4)	1×10^4 $TCID_{50}$/ml
Mycobacterium tuberculosis	K	1×10^4 $TCID_{50}$/ml
	Erdman	1×10^4 $TCID_{50}$/ml
	HN878	1×10^4 $TCID_{50}$/ml
	CDC1551	1×10^4 $TCID_{50}$/ml
	H37Rv	1×10^4 $TCID_{50}$/ml

Novel Coronavirus Monoclonal Antibody is a protein that recognizes nucleocapsid protein and can detect genetic variants of strains.

【*Cautions*】

1. The test should not be done if the condition of kit and samples are not restored to 18-30℃ , as it will affect the accuracy of the results.
2. The positive samples obtained by the rapid test should be confirmed by other methods.
3. The rapid test should be sealed and kept in dry place. The test cassette should be tested as soon as possible after removal from the packaging. Avoid placing it in the air for too long due to moisture.
4. The deepness of the test line color is not necessarily associated with the titer of the antigen in the sample. The interpretation of the results after 15 minutes are invalid.
5. When COVID-19 antigen content in the sample is very high, the C-line zone may be weakened, which is a normal phenomenon.
6. The results of rapid test are only for clinical reference and should not be the only basis for clinical diagnosis and treatment.
7. Waste samples and test should be treated as potential infectious agents.
8. The appearing time of the Control Line should not be taken as the time basis for judging the results of test line. The color rendering results should be observed and judged within a time limit of 13-15 minutes.
9. The rapid test is only used for in vitro diagnosis.
10. This product must be operated by professionally trained personnel, such as medical staff with clinical experience.

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【*Index of Symbol*】

	Do not reuse	IVD	For in vitro diagnostic use only
2℃ 30℃	Store between 2-30℃		Consult instructions for use
	Use by	LOT	Lot number
	Do not use if package is damaged	Σ	Contains sufficient for <n> tests
	Keep away from sunlight		Keep dry
	Manufacturing date		Manufacturer
EC REP	Authorized representative in the European Community		

Version Number: 02
Effective Date: June 3rd, 2021