金标说明书(SARS-CoV-2 Ag Test)N
尺寸:297x210mm
材质:70g双胶纸
双面黑白印刷(对折)
01.05.14.121-220402

CMYK:0/0/0/100

CMYK:0/0/0/10

InTec PRODUCTS, INC.

REF ITP16030-TC25
ITP16030-TC7
ITP16030-TC5
ITP16030-TC2
ITP16030-TC1

Rapid SARS-CoV-2 Antigen Test

For Self-testing Use.
For in vitro diagnostic use only. IVD
Please read the instructions for use carefully prior to use and strictly follow the instructions.
User should not take any decision of medical relevance without first consulting his or her medical practitioner.

INTENDED USE

The Rapid SARS-CoV-2 Antigen Test is a colloidal gold enhanced, rapid immunochromatographic assay for qualitative detection of SARS-CoV-2 antigens in the nasal specimen collected by swabs from individuals who are suspected of having COVID-19. The test is used as an aid in the diagnosis of SARS-CoV-2 infection.
This test is for self-testing.
The test is for self-test with self-collected anterior nasal swab samples. It is indicated for the use of individuals aged 18 years or older with symptoms of COVID-19 within the first seven (7) days of symptom onset.
Testing of individuals without symptoms should be limited to contacts of confirmed or probable cases or to other epidemiological reasons to suspect a COVID-19 infection and should be followed by additional confirmatory testing with a molecular test.

SUMMARY

COVID-19 is a SARS-CoV-2 (also known as 2019-nCoV) associated pneumonia. A few patients have developed severe pneumonia, pulmonary oedema, ARDS, or multiple organ failure and have died. The Rapid SARS-CoV-2 Antigen Test is based on immunochromatography for detection of SARS-CoV-2 antigen in the specimen collected by the swab. It is simple, visual qualitative and presents the result within 20 minutes.

TEST PRINCIPLE

Gold conjugated mouse anti-SARS-CoV-2 N-protein IgG and gold conjugated rabbit nonspecific IgG are pre-coated on the sample pad. SARS-CoV-2 antigen (N protein) can react with the gold conjugated mouse SARS-CoV-2 specific IgG and form an immune complex. The specimen will move forward along the test strip. If the specimen contains SARS-CoV-2 antigen (N protein) and the concentration is above the minimum detection limit, the complex will be captured by the mouse anti-SARS-CoV-2 N-protein IgG pre-coated at the test band region, and form a purplish red band. If the specimen does not contain SARS-CoV-2 antigen or the concentration is below the minimum detection limit, there will be no purplish red band shown at the test band region.
Regardless of whether the analyte exist in the specimen, the gold conjugated rabbit nonspecific IgG will be captured by the goat anti-rabbit IgG. A purplish red band will appear at the control band region.
Only when the control band appears, the correlated result is valid.

STORAGE CONDITIONS AND STABILITY

The Rapid SARS-CoV-2 Antigen Test shall be stored at 2-30°C.The shelf life of the kit is 24 months. Please kindly refer the accurate expired date as indicated on the outer package. Test cassette should be used within 1 hour upon opening the foil pouch.

WARNINGS AND PRECAUTIONS

The warnings and precautions are included, but not limited to the following:

Warnings ⚠

This product is for in vitro diagnosis of the infection of SARS-CoV-2 only; other diseases cannot be analyzed with any component of this kit.
All specimens with positive results must be confirmed using an appropriate test such as RT-PCR or equivalent.

Precautions ⚠

- Do not use expired reagents or test cassettes.
- Do not use the kit if any of the components is damaged or missing.
- Do not reuse the cassette, swab or test tube.
- If bleeding occurs, it may affect the test results. If blood is seen on the nasal swab, stop collecting the specimen and dispose the used swab. Please repeat the test with new test kit after the bleeding has stopped.
- Do not touch or drink the liquid inside the buffer tube. Do not allow it to come into contact with your skin, your eyes or any external surface.
- If the solution makes contact with your skin, immediately wash your skin with water.
- If the solution gets into your eyes, immediately wash them with water.
- If you experience any symptoms after contact with the liquid, seek medical help immediately.
- If the liquid inside the buffer tube is spilled, clean it using gloves and absorbent tissue.
- Do not store the specimen in test tube; it is only used for specimen processing.
- Do not use pooled specimens or specimens other than specified(i.e.urine, blood).
- Do not interchange reagents among kits of different batch number or even products.
- Do not perform the test under environment which leads to rapid evaporation(e.g.＞40°C and ＜40% RH,close to a running fan or air conditioner).
- Clean and disinfect all the areas that may be contaminated by spills of specimens or reagents with appropriate disinfectant to control infectious risks.
- Children and adolescents under the age of 18 or people who cannot understand the instructions of use correctly should only take the test under the supervision of an adult or someone who can fully understands the instructions of use correctly.
- Refer to the local regulations in force regarding the disposal of the testing materials.
- If you experience pain when taking a sample, pull the swab out immediately, otherwise injury may result.
- In the event of a positive result, you are advised to immediately contact the local health department or a doctor for further diagnosis and treatment. It is essential that you comply with all local regulations on self-isolation.
- If the test result is negative, a COVID-19 infection cannot be ruled out. Continue to comply with all applicable rules regarding contact with others and protective measures. If you experience any of the typical COVID-19 symptoms such as fever, cough, body aches, tiredness, runny nose or diarrhea or have had direct contact with a person who tested positive, you should immediately consult a doctor for further diagnosis and treatment and contact the local one Adhere to the rules of conduct recommended by local health authorities.

Reagents and materials provided

Table1 Reagents and materials provided

Component	25 tests (ITP16030-TC25)	7 tests (ITP16030-TC7)	5 tests (ITP16030-TC5)	2 tests (ITP16030-TC2)	1 test (ITP16030-TC1)
Buffer tube	350μL×25 pieces	350μL×7 pieces	350μL×5 pieces	350μL×2 pieces	350μL×1 piece
Cassette	1×25 pieces	1×7 pieces	1×5 pieces	1×2 pieces	1×1 piece
Disposable swab	1×25 pieces	1×7 pieces	1×5 pieces	1×2 pieces	1×1 piece
Instructions for use	1×1 piece	1×1 piece	1×1 piece	1×1 piece	1×1 piece
Tube holder	1×1 piece	1×1 piece	1×1 piece	stand hold of the package	stand hold of the package
Quick operation guide	1×1 piece	1×1 piece	1×1 piece	1×1 piece	1×1 piece

Note: Information of the disposable swab

Accessory	Manufacturer	Authorized Representative	CE mark
Disposable Swabs	Jiangsu Changfeng Medical Industry Co.,Ltd. TouqiaoTown,Guangling District Yang zhou,225109 Jiangsu,P.R.China	Llins Service&Consulting GmbH Obere Seegasse 34/2,69124 Heidelberg,Germany	STERILE EO CE 0197

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer, clock or stopwatch
- plastic waste bag

TEST PROCEDURE

Preparation

1. Wash your hands and make sure they are dry before starting the test.
2. Carefully read the instructions for use prior to use Rapid SARS-CoV-2 Antigen Test.
3. Check the expiry date on the foil pouch. Do not use the kit if expiry date has passed.
4. Allow all reagents and specimens to reach room temperature (10-30°C) before use.
5.Please refer to illustrations in the Quick operation guide .

⚠ Do not eat or smoke while handling specimens.
Do not open the pouch until ready to perform a test.
Use the test under low environment humidity within 1 hour.

Collection

1. Peel off the foil from the top of the buffer tube.
2. Set the buffer tube on the stand hole of the package.
3. Open the swab package at stick end, take out the swab.

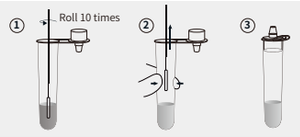
⚠ Do not touch the fabric tip of the swab.

4. Insert the swab into the nostril cavity, gently turn and push the swab into the nasal cavity until it is blocked at the turbinate (about 2.0cm- 2.5cm from the nostril). Rotate the swab 5 times against the wall of the nasal cavity and remove the swab. Use the same swab to sample the other nostril in the same way to ensure that you get enough samples.

⚠ A nasal swab specimen can be self-collected by an individual aged 18 years and older. For young people under 18 years should be tested by an adult. If you experience pain when taking a sample, pull the swab out immediately, otherwise injury may result. If bleeding occurs, it may affect the test results. If blood is seen on the nasal swab, stop collecting the specimen and repeat the test with new kit after the bleeding has stopped.

Specimen treatment

1. Insert the fabric tip of the swab into the solution in the buffer tube, and rotate it against the inner wall of the buffer tube about 10 times to dissolve the specimen in the solution as much as possible.
2. Squeeze the tip of the swab along the inner wall of the buffer tube to keep the liquid in the tube as much as possible, then remove and discard the swab.
3. Press the nozzle cap tightly onto the buffer tube to avoid any leaks.



Specimen addition

1. Unseal the foil punch and put the cassette on a clean, dry and level surface.
2. Add 5 drops (~100μL) of treated specimen into "S" well of the cassette.
3. Wait at least 15 minutes (and 20 minutes at most) to interpret the result.

RESULT INTERPRETATION

Negative: Colored band only appears on control band area indicates a negative result.
A negative result gives the absence of SARS-CoV-2 antigens. A negative result from a self-test is not 100% reliable. A negative result does not rule out a recent infection with SARS CoV-2. If you think you have contact with the virus (with infected person) in the last days before the test is carried out, we recommend that you take a Laboratory Test at the hospitals. Keep following the corona rules; keep your distance, wear mouth mask, wash your hands often and keep watching for complaints. If you have complaints or have had contact with infected person, have yourself tested at the hospital as soon as possible.

Positive: Colored bands appear at both the test band area (even though very weak) and the control band area indicates a positive result.
Why a retest?
A self-test is less reliable than the professional test at the hospitals. Therefore, there is a chance that your positive result is a false alarm. If the retest at the hospital is negative then you may be released from isolation.
Invalid: Colored band appears at neither the control band area nor the test band area of the cassette.
The test is not valid, do a new test. Reread the procedure and repeat the test with a new cassette. The most likely reasons for the control line not appearing are inadequately sample volume or improper procedural techniques (improper specimen collection, temperature and humidity conditions for performing the test), or tests left open for more than one hour or even expired.

In the event of a positive result, you are advised to immediately contact the local health department or a doctor for further diagnosis and treatment. It is essential that you comply with all local regulations on self-isolation. If the test result is negative, a COVID-19 infection cannot be ruled out. Continue to comply with all applicable rules regarding contact with others and protective measures. Should you experience any of the typical COVID-19 symptoms such as fever, cough, body aches, tiredness, runny nose or diarrhea or have had direct contact with a person who tested positive, you should immediately consult a doctor for further diagnosis and treatment and contact the local one adhere to the rules of conduct recommended by local health authorities. If the test did not work and is considered Invalid. This may be the result of an incorrect test procedure and the test should be repeated. Please perform a new test with a new sample and a new test.

Performance Characteristics

Clinical Evaluation Report

Clinical performance of Rapid SARS-CoV-2 Antigen Test was determined by testing 110 positive and 470 negative specimens for SARS-CoV-2 antigen to have a sensitivity of 93.64% and specificity of 100.00%. Clinical specimens were confirmed to be positive or negative using an RT-PCR reference method.

		PCR		
		Positive	**Negative**	**Total**
Rapid SARS-CoV-2 Antigen Test	**Positve**	103	0	103
	Negative	7	470	477
	Total	110	470	580

Results analysis:

Sensitivity (Positive coincidence rate) : 103/110=93.64% (95%CI: 87.33%-97.40%)
Specificity (Negative coincidence rate) : 470/470=100.00% (95%CI: 99.22%-100.00%)
Total coincidence rate: 573/580=98.79% (95%CI: 97.53%~99.51%)
*CI: Confidence Interval

Limit of Detection (LoD)

The LoD for Rapid SARS-CoV-2 Antigen Test was 4.25 x10^2 $TCID_{50}$/mL. The LoD is established using limiting dilutions of heat-inactivated SARS-CoV-2 antigen.

Cross-Reactivity

Rapid SARS-CoV-2 Antigen Test does not cross with the following common respiratory pathogens.

S.N.	Potential Cross-Reactant	Species	Concentration	S.N.	Potential Cross-Reactant	Species	Concentration
1	Coronavirus 229E	VR -740	10^6pfu/mL	15	Legionella	33152	10^7cfu/mL
2	Coronavirus NL63	COV-NL63	10^6pfu/mL	16	Streptococcus pneumoniae	CGMCC 1.8722	10^7cfu/mL
3	Coronavirus OC43	VR -1558	10^6pfu/mL	17	Enterovirus A	CV-A10	10^6pfu/mL
4	Coronavirus HKU1	COV-HKU1	10^6pfu/mL	18	Enterovirus B	Echovirus 6	10^6pfu/mL
5	Seasonal H1N1 influenza	A-H1N1	10^6pfu/mL	19	Staphylococcus aureus	CGMCC 1.2910	10^7cfu/mL
6	H3N2 influenza virus	A-H3N2	10^6pfu/mL	20	Human metapneumovirus	HMPV	10^6pfu/mL
7	H7N9 avian influenza virus	A-H7N9	10^6pfu/mL	21	H5N1 influenza virus	A-H5N1	2.44 X 10^5 $TCID_{50}$/mL
8	Influenza B Yamagata	B-Yamagata	10^6pfu/mL	22	Influenza B V	B/Shand ong/7/97	6.97 X 10^4 $TCID_{50}$/mL
9	Mycoplasma pneumoniae	39505	10^7cfu/mL	23	Adenovirus type 3	QSE77A210	2.99 X 10^5 $TCID_{50}$/mL
10	Chlamydia pneumoniae	VR-2282	10^7cfu/mL	24	Mumps virus	HQ416906-S79-A	6.96 X 10^4 $TCID_{50}$/mL
11	Coronavirus MERS	MERS	10^8 pfu/mL	25	Measles virus	Shanghai-191	8.6 X 10^4 $TCID_{50}$/mL
12	Parainfluenza virus type 1	HPIVs-1	10^6pfu/mL	26	Coxsackie virus 16		13.44 μg/mL
13	Mycobacterium tuberculosis	25177	10^7cfu/mL	27	Enterovirus Type 71		4.7 μg/mL
14	Respiratory syncytial virus	RSV-A2	10^6pfu/mL				

Interfering Substances

The following potentially interfering substances have no impact on Rapid SARS-CoV-2 Antigen Test . The final test concentrations of the interfering substances are documented in the table below.

S.N.	Substance Name	Concentration	S.N.	Substance Name	Concentration	S.N.	Substance Name	Concentration
1	Hemoglobin	2 g/L	9	Levofloxacin	2 mg/mL	17	Triamcinolone acetonide	100 mg/mL
2	Mucoprotein	20 mg/mL	10	Azithromycin	500 mg/mL	18	Budesonide	2 mg/mL
3	Zanamivir	50 mg/mL	11	Ceftriaxone	1 g/mL	19	Mometasone	1 mg/mL
4	Ribavirin	2 g/mL	12	Tobramycin	2 g/mL	20	Fluticasone	10 mg/mL
5	Oseltamivir	200 mg/mL	13	Oxymetazoline	1 g/mL	21	Biotin	1.2μg/mL
6	Peramivir	1 g/mL	14	Beclazone	0.5 mg/mL	22	NaCl	18mg/mL
7	lopinavir	1 g/mL	15	Dexamethasone	20 mg/mL	23	Sodium citrate	9mg/mL
8	Ritonavir	250 mg/mL	16	Flunisolide	5 mg/mL			

Hook Effect

There is no Hook effect under concentration of 3.40 x10^5 $TCID_{50}$/mL. The Hook effect was established using limiting dilutions of heat-inactivated SARS-CoV-2 antigen.

Repeatability and reproducibility

The internal study results showed that the product has a good repeatability and reproducibility by within-run, between-run and batch-to-batch studies using in-house control panel as acceptance criteria.

Limitations

- The kit is designed to detect SARS-CoV-2 antigen in nasals pecimen collected by the provided swab. Other types of specimens may not supply accurate results and the device will not notify this kind of misuse to the user.
- The intensity of test band does not necessarily correlate to the titer of antigen in specimen.
- The presence of the control band only indicates the flow of the conjugate.
- This product is intended to detect SARS-CoV-2 antigen from individuals, clinical diagnosis on SARS-CoV-2 infection should not be made only based on the results of the product.
- A negative result should not exclude the possibility of infection caused by SARS-CoV-2. A negative result can also occur in the following circumstances:
  - Recently acquired SARS-CoV-2 infection.
  - Low levels of antigen below the detection limit of the test.
  - SARS-CoV-2 antigen in the patient failed to react with specific antibody utilized in the assay configuration, in exceptional cases this may lead to observation of negative results.
  - Specimens are not properly stored.
  - Extremely high concentration of a particular analyte.
  - Recently discovered type or subtype of SARS-CoV-2.
- For reasons above, care should be taken in interpreting negative results. Other clinical data(e.g.,symptoms or risk factors) should be introduced in conjunction with the test results.
- Specimen with positive results should be retested with other technological method such as PCR under the guidance of local regulations before the clinical diagnosis is made.
- Positive test results do not rule out co-infections with other pathogens.
- The product is not validated on specimens from infants, children, or patients on anti-retroviral treatment.

FREQUENTLY ASKED QUESTIONS (FAQ)

1. What is the Rapid SARS-CoV-2 Antigen Test used for?
Rapid antigen tests are commonly used in the diagnosis of respiratory illnesses. In this case, the rapid antigen detection test looks for proteins produced by the SARS-CoV-2 virus, which is the virus that causes the disease called COVID-19. Antigen tests are immunoassays that detect the presence of a specific viral antigen, which means they identify people who currently have a viral infection.

2. Where can I get Rapid SARS-CoV-2 Antigen Test?
Rapid SARS-CoV-2 Antigen Test are available either by prescription or over the counter in a pharmacy or retail store without a prescription.

3. How quickly are results for Rapid SARS-CoV-2 Antigen Test available?
Turnaround time for results is usually very quick.In this case, you can get the result within 15-20 minutes.

4. How does the test kit work?
The N protein of the SARS-CoV-2 virus reacts with the stripe-like coating of the test line and if present, results in a color change purplish red line appears. Therefore, if the sample does not contain any viral proteins or antigens, there will be no purplish red appearing on test (T) line.

5. When should/can I test myself?
You can test yourself whether you have symptoms or not. Antigen rapid tests are most likely to perform well in patients with high viral loads which usually appear in the pre-symptomatic (1-3 days before symptom onset) and early symptomatic phases of their illness (within the first 5-7 days of illness).

6. What can affect my test result? What should I pay attention to?
Be sure to visibly collect sample material (nasal secretions). Perform the test immediately after taking the sample. Follow the instructions for use carefully. Apply the drops of extraction buffer only to the sample well (S). Too many or too few drops of extraction solution can lead to an invalid or incorrect test result.

7. What should I do, if there is no C (Control) line appearing?
Your test result is invalid. Repeat the test according to the instructions for use.

8. How to interpret the results?
Purplish red bands appearing at both test band area (even though very weak) and control band area indicates a positive result.
Purplish red band only appearing on control band area indicates a negative result.
If you are still unsure about the results, contact the nearest health facility according to the recommendations of your local authorities.

9. What should I do with the positive or negative results?
If your result is positive, you should contact the medical facility as recommended by your local authorities. Your test result may be double-checked and the authority or facility will explain the appropriate next steps.
·If your result is negative, this may mean that no virus is detected or the viral load is too low to be detected. If you experience symptoms (headache, fever, migraine, loss of sense of smell or taste, etc.), please consult your primary care physician in the nearest health care facility as recommended by your local authorities. If you are not sure, you can repeat the test.

10. How can I dispose of the testing materials?
Please refer to the local regulations in force regarding the disposal of the testing materials.

KEY TO SYMBOLS USED

	CAUTION		KEEP DRY		DO NOT REUSE		USE-BY DATE
	KEEP AWAY FROM SUNLIGHT		CONSULT INSTRUCTIONS FOR USE		CONTAINS SUFFICIENT FOR (N) TESTS	STERILE EO	STERILIZED USING ETHYLENE OXIDE
2℃ 30℃	TEMPERATURE LIMITATION (2~30°C)	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE		DO NOT USE IF PACKAGE IS DAMAGED	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
LOT	BATCH CODE	REF	CATALOGUE NUMBER	CE	EUROPEAN CONFORMITY	DATE OF MANUFACTURE	MANUFACTURER

BIBLIOGRARHY

Susan R. Weiss, Julian L. Leibowitz, Coronavirus Pathogenesis, Advances in Virus Research, Band 81: 85-164 Shuo Su, Gary Wong, Weifeng Shi, et al. Epidemiology, Genetic recombination, and pathogenesis of coronaviruses. Trends in Microbiology, Juni 2016, Band 24, Nr. 6: 490-502

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