# SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)
# Instructions for Use (IFU)

CE

【PRODUCT NAME】
SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

【PACKAGE AND SPECIFICATION】
20 Tests/Box (1 Test/Pouch×20 Pouches) ,40 Tests/Box (1 Test/Pouch×40 Pouches)

【INTENDED USE】
For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasal (NS) swab specimens directly from individuals who are suspected of COVID-19 by their healthcare provider within the first 5 days after onset of symptoms. This test is only provided for use by clinical laboratories or to healthcare workers for point-of-care testing, not for at-home testing.
Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is an enveloped non-segmented positive-sense RNA virus. It is the cause of coronavirus disease (COVID-19), which is contagious in humans. SARS-CoV-2 has several structural proteins including spike (S), envelope (E), membrane (M), and nucleocapsid (N).
The antigen is generally detectable in upper respiratory samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
Negative results should be treated as presumptive, which 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. 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 COVID-19, and confirmed with a molecular assay, if necessary, for patient management.
*For in vitro diagnostic use only. For professional use only*

【TEST PRINCIPLE】
JOYSBIO Biotechnology's SARS-CoV-2 Antigen Rapid Test Kit uses an immunocapture method, it is designed to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in respiratory samples from patients with signs and symptoms of infection who are suspected of COVID-19.
Key components: the anti-nucleocapsid protein antibody and chicken IgY labeled by colloidal gold, the nitrocellulose membrane coated with anti-nucleocapsid protein antibody, and goat anti-chicken IgY antibody.
When specimens are processed and added to the test device, SARS-CoV-2 antigens present in the specimen bind to antibodies conjugated to colloidal gold in the test strip. The antigen-conjugate complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the membrane. A color band will show up when antigen-conjugate is deposited at the Test "T" position and the Control "C" position on the device.

【COMPONENT】
Materials provided:

| Component | 20 Tests/Box | 40 Tests/Box | Main Components |
|---|---|---|---|
| Test Device | 20 Tests/Box (1 Test/Pouch ×20 Pouches) | 40 Tests/Box (1 Test/Pouch ×40 Pouches) | The anti-nucleocapsid protein antibody and chicken IgY labeled by colloidal gold, the nitrocellulose membrane coated with anti-nucleocapsid protein antibody and goat anti-chicken IgY antibody. |
| Desiccant | 20 Packs | 40 Packs | Silica Gel |
| Buffer | 20 single-use bottles, each with 350 µL extraction buffer | 40 single-use bottles, each with 350 µL extraction buffer | Detergent Solution |
| Extraction Tube | 20 single-use reaction tubes, each with 1x nozzle cap | 40 single-use reaction tubes, each with 1x nozzle cap | / |
| Specimen Sampling Swabs | 20 sterile, single-use specimen sampling swabs | 40 sterile, single-use specimen sampling swabs | / |

Materials required but not provided with the kit:

| | | |
|---|---|---|
| SARS-CoV-2 (+) Control Swab | 1 each – individually wrapped for single-use | Non-infectious, recombinant viral protein antigen with less than 0.1% sodium azide. |
| SARS-CoV-2 (–) Control Swab | 1 each – individually wrapped for single-use | Buffer with less than 0.1% sodium azide. |

【STORAGE AND STABILITY】
1.Store at 2~30°C in the sealed pouch up to the expiration date and the validity is tentatively 24 months. Do not freeze.
2.The test cassette should be used within 1 hour after taking out from the aluminum foil bag.
3.Keep away from sunlight, moisture, and heat.

【SPECIMEN COLLECTION AND HANDLING】
1.Specimen Collection and Preparation
Acceptable specimens for testing with this kit include nasal swab specimens obtained by the dual nares collection method. Correct specimen collection and preparation methods must be followed. Specimens obtained early during symptom onset will contain the highest viral titers; specimens obtained after five days of symptoms are more likely to produce negative results when compared to an RT-PCR assay. Inadequate specimen collection, improper specimen handling and/or transport may yield a falsely negative result; therefore, training in specimen collection is highly recommended due to the importance of specimen quality for generating accurate test results.
2.Specimen Transport and Storage
Freshly collected specimens should be processed as soon as possible, but no later than one hour after specimen collection. Correct specimen collection and preparation methods must be followed.
3.Nasal Swab Specimen Collection

a. 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.

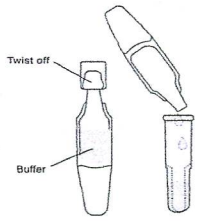
b. Using the same swab, repeat this process for the other nostril to ensure that an adequate sample is collected from both nasal cavities.

c. Withdraw the swab from the nasal cavity. The sample is now ready for processing using the kit.

4.DOs and DON'Ts of Sample Collection
Do collect samples as soon as possible after the onset of symptoms.
Do test samples immediately.
Use only swabs provided with the kit.
Do not place the swab back into the swab packaging sleeve after specimen collection.

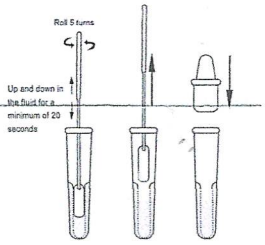
【TEST PROCEDURE】
1.The test kit, the specimen must be at room temperature (15~30°C) for before testing. The kit is only intended for nasal swab specimens that are collected and tested directly (i.e., swabs that have **NOT** been placed in transport media). The kit includes a pre-diluted processing reagent in a ready to use buffer bottle. This kit **IS NOT INTENDED** for testing liquid samples such as a wash or aspirate samples or swabs in transport media as results can be compromised by over dilution.
2.Freshly collected specimens should be processed within 1 hour.

•Step 1:
Twist off the top of the buffer bottle, slowly dispense all of the buffer into the extraction Tube.



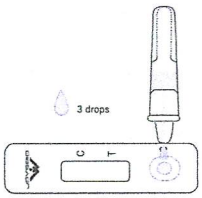

•Step 2:
After collection of nasal (NS) swab specimen, insert the swab into the tube and plunge the swab up and down in the fluid for a minimum of **20 seconds**, then hold the swab against the bottom of the tube and **roll 5 turns**, taking care not to splash contents out of the tube.

•Step 3:
Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.




•Step 4:
Press the nozzle cap firmly onto the extraction tube containing the processed sample (threading or twisting is not required). Mix thoroughly by swirling or flicking the bottom of the tube.Place the extraction tube(s) in a rack in the designated area of the workspace.

•Step 5:
Tear off the foil pouch, take out the test strip/cassette and place the test kit on a clean and level surface. Label the test device and one extraction tube for each specimen or control to be tested.

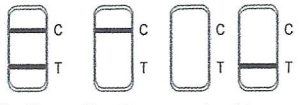



•Step 6:
Gently squeeze the ridged body of the tube, dispensing **three (3) drops** of the processed specimen into the sample well.

•Step 7:
Read the test results between **15 and 20 minutes**. Do not read the results after **20 minutes**.

NOTE: Do not use tubes or tips from any other product, or from other manufacturers.

【INTERPRETATION OF TEST RESULTS】
1.**POSITIVE:** Two lines appear. A colored line should be in the control line region (C), a colored line appears in the test line (T) region. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.
2.**NEGATIVE:** Only one colored control line appears. 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 be confirmed by a molecular testing method, if necessary, for patient management.
3.**INVALID:** Control line fails to appear. Insufficient buffer volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the procedure with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
4.**Result determination time:** The result should be judged within **15~20 minutes** after the sample is added into the sample well, and the result displayed after **20 minutes** is invalid.




Positive Negative Invalid
(The picture is for reference only)

JOYSBIO(Tianjin)Biotechnology Co., Ltd.

Address: Tianjin International Joint Academy of Biotechnology& Medicine 9th floor, No.220, Dongting Road, TEDA 300457 Tianjin China
TEL: 86-22-65378415
Web: en.joysbio.com
E-mail: bd@joysbio.com

6/20/2021

# Letter of Declaration

We, JOYSBIO (Tianjin) Biotechnology Co., Ltd. (hereinafter "JOYSBIO"), with the address of Tianjin International Joint Academy of Biotechnology& Medicine 9th floor No.220, Dongting Road TEDA 300457 Tianjin, China, hereby declare that our product "**JOYSBIO SARS-COV-2 Antigen Rapid Test Kit (Colloidal Gold)**" and its variants are compatible with the new virus strain B.1.1.7, 501Y.V2, 501Y.V3 and B.1.617.2.

If you have any questions or concerns, please feel free to contact us.

Sincerely Yours,

JOYSBIO (Tianjin) Biotechnology Co., Ltd.

JOYSBIO(Tianjin) Biotechnology Co., Ltd
正元盛邦(天津)生物科技有限公司