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

**Instructions for Use**

**PRODUCT NAME:** SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)

**PACKAGE AND SPECIFICATION:**

- 20 Tests/box (1 Test/bag <20 Bags), 40 Tests/box (1 Test/bag ≥40 Bags)

**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, or SARS-CoV). It 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 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 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 other 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:**

JOYSHIO Biotechnology’s SARS-CoV-2 Antigen Rapid Test Kit uses immunochromatography technology to detect the presence or absence of SARS-CoV-2 nucleocapsid proteins in respiratory samples from individuals suspected of infection with SARS-CoV-2 as suspected of COVID-19.

Key components:
- The anti-nucleocapsid protein antibody and chicken IgY antibody
- The antigen is coated on the colloidal gold in the test strip.

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-antibody complexes migrate across the test strip to the reaction area and are captured by a line of antibodies bound on the test line. The test line will show up when antigen-antibody is deposited at the Test "T" position and the Control "C" position of the device.

**COMPONENTS:**

- **Test card:** 20 Tests/Kit (≥20 Bags), 40 Tests/Kit (1 Test/bag ≥40 Bags)
- **Anti-nucleocapsid protein antibody and chicken IgY labeled colloidal gold:** 40 tests/kit.

**4Dos 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. **Specimen Collection and Preparation**

   - Collect nasal swab specimen by inserting the swab into the nostril of the patient.
   - The swab tip should be inserted up to 2.5 cm (1 inch) from the side of the nostril. Roll the swab 5 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.

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**

   - 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.

   - Use 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. The sample is now ready for processing using the kit.

**STORAGE AND STABILITY:**

1. Store the test at 2°C to 25°C 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 it out from the aluminum foil bag.
3. Keep away from sunlight, moisture, and heat.

**SPECIMEN COLLECTION AND HANDLING**

1. **Specimen Collection**

   - Specimen collection may be performed by the patient or a healthcare provider.

2. **Specimen Preparation**

   - Swab the nasal swab with only a small amount of nasal fluid.

3. **Sample Preparation**

   - Mix the sample with 1.5 ml of the provided buffer.

4. **Sample Collection**

   - Collect the sample from the nasal swab.

5. **Sample Storage**

   - Store the sample at room temperature (5°C-30°C) for 24 hours.

6. **Sample Transfer**

   - Transfer the sample to another specimen collection tube.

7. **Sample Transport**

   - Transport the sample to the laboratory within 24 hours.

8. **Sample Handling**

   - Handle the sample with care to prevent contamination.

9. **Sample Analysis**

   - Analyze the sample using the SARS-CoV-2 Antigen Rapid Test Kit.

**Materials required but not provided in kit:**

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

**STORAGE:**

- Store the kit at 2°C to 25°C.

**NOTES:**

- Do not use test 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. The clinical correlation with patient history and other diagnostic information is necessary for determining 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 rule out 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 procedure and repeat the procedure with a new test cassette. If the problem persists, contact 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.

**Step 1:** Place the test strip in the test tube rack, then 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 2:** Gently squeeze the ridged body of the tube, dispensing three (3) drops of the processed specimen into the sample well.

**Step 3:** Place the extraction tube(s) in a rack in the designated area of the workspace.

**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.

**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 test tubes or tips from any other product, or from other manufacturers.
The validity of the kit has not been proven for identification/confirmation of tissue culture isolates and should not be used in clinical practice.

**PERFORMANCE CHARACTERISTICS**

1. Clinical Performance

The performance of the kit was established with 150 direct nasal swabs prospectively collected and enrolled from individual symptomatic patients who were suspected of COVID-19. As with all antigen tests, performance may decrease as days since symptom onset increases. Samples were collected by qualified personnel in China.

Nasal swabs were collected following the dual nares method and handled as described in the instruction of the kit. Specimens were frozen within 30 minutes of collection and stored until tested. All specimens within a pre-specified date range were selected and then sequentially tested in a blinded fashion. The performance of the kit was compared to results of a nasopharyngeal or oropharyngeal swab tested with a commercialized molecular assay.

The kit showed 88.9% sensitivity and 99.05% specificity.

**LIMITATIONS OF TEST METHOD**

1. This product is only suitable for a qualitative test and auxiliary diagnosis.

2. The test results are only for clinical reference and should not be the only basis for clinical diagnosis and treatment. The clinical management of patients should be considered in combination with clinical symptoms, physical signs, medical history, other laboratory tests, therapeutic reaction, and epidemiological information.

3. Users should test patients as quickly as possible after specimen collection.

4. Positive test results do not rule out co-infections with other pathogens.

5. Results from the test should be correlated with the clinical history, epidemiological data, and other data available to the clinician evaluating the patient.

6. 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 SARS-CoV-2 infection.

7. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5 of illness may be more likely to be negative compared to an RT-PCR assay.

8. Failure to follow the test procedure may adversely affect test performance and/or invalidate the test result.

9. The contents of this kit are designed to be used for the qualitative detection of SARS-CoV-2 antigens from nasal swab specimens only.

10. The kit performance depends on antigen load and may not correlate with other diagnostic methods performed on the same specimen.

11. Negative test results are not intended to rule out other non-SARS-CoV-2 viral or bacterial infections.

12. Positive and negative predictive values are highly dependent on prevalence. Positive test results are more likely to represent false-positive results during periods of little/no SARS-CoV-2 activity when disease prevalence is low. False-negative test results are more likely when the prevalence of disease caused by SARS-CoV-2 is high.

13. This kit has been standardized for use with human specimen material only.

14. Monoclonal antibodies may fail to detect or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.

15. The performance of this test has not been evaluated for use in patients without symptoms and signs of respiratory infection and performance may differ in asymptomatic individuals.

16. The sensitivity of the test after the first five days of the onset of symptoms has been demonstrated to decrease as compared to an RT-PCR SARS-CoV-2 assay.

17. Negative results should be treated as presumptive and confirmed with an FDA-authorized molecular assay, if necessary, for clinical management, including infection control.

18. Specimen stability recommendations are based upon stability data from influenza testing and performance may be different from SARS-CoV-2. Users should test specimens as quickly as possible after specimen collection, and within one hour after specimen collection.

**In Vitro Diagnostic Use**

See Instruction for Use

Catalog #

Do not reuse

Store between 4~30°C

Keep away from Sunlight

CE Mark

EU Authorized Representive

**BASE INFORMATION**

JOYSBio(Tianjin) Biotechnology Co., Ltd.
Address: Tianjin International Joint Academy of Biotechnology & Medicine 9th floor No.220, Dongfang Road,

**BACKGROUND INFORMATION**

The LOD for the SARS-CoV-2 antigen rapid test kit is 1.6 x 10³ TCID₅₀/mL. The LOD for the SARS-CoV-2 antigen rapid test kit was established using limiting dilutions of a viral sample inactivated by gamma irradiation. The material was supplied at a concentration of 1.3 x 10³ TCID₅₀/mL. In this study, designed to estimate the LOD of the assay when using a direct nasal swab, the starting material was spiked into a volume of veal infusion dilution solution. An initial range-finding study was performed testing devices in triPLICATE using a 10-fold dilution series. At each dilution, 50 μL samples were added to swabs and then tested using the procedure appropriate for patient nasal swab specimens. A concentration was chosen between the last dilution to give positive results and the first to give 3 negative controls. Using this concentration, the LOD was further refined with a 2-fold dilution series. The last dilution demonstrating 100% positivity was then tested in an additional 20 replicates tested in the same way.

**Hooke Effect**

As part of the LOD study, the highest concentration of the sample (1.3 x 10³ TCID₅₀/mL) was tested. There was no hook effect detected.

**Warnings**

1. A negative result can occur if the SARS-CoV-2 virus present in the specimen is below the sensitivity of the kit.

2. Not for the screening of donated blood.

3. Do not store, drink, or eat any part of the kit or any parts of the kit reagents are being handled.

4. Dispose of all specimen and materials used to perform the test as biohazardous waste.

5. Handle the negative and positive controls in the same manner as patient specimens for operator protection.

6. Do not perform the test in a room with strong airflow, i.e. an electric fan or strong air-conditioning.

**EXPLANATION OF LABELS**

**Antigen**

SARS-CoV-2 antigen nasal swab samples were spiked with one of the following substances to specified concentrations and tested in multiple replicates. No false positivity or false negativity was found with the following:

- Malaria
- Dengue
- Human coronavirus NL63
- Human coronavirus 229E
- Streptococcus pneumoniae
- Pneumocystis jirovecii
- Legionella pneumophila
- Chlamydia pneumoniae
- Human Metapneumovirus
- Parainfluenza virus 1
- Parainfluenza virus 2
- Parainfluenza virus 3
- Parainfluenza virus 4
- Rhinovirus
- Mycoplasma pneumoniae
- Bordetella pertussis
- Mycobacterium tuberculosis
- Pooled human nasal wash
- Respiratory syncytial virus
- Enterovirus

**Concentration**

Malaria 2.2 x 10⁴ CFU/mL
Dengue 1.5 x 10⁵ TCID₅₀/mL
Human coronavirus NL63 1.7 x 10⁵ TCID₅₀/mL
Human coronavirus 229E 1.0 x 10⁴ TCID₅₀/mL
Streptococcus pneumoniae 1.1 x 10⁴ CFU/mL
Pneumocystis jirovecii 1.0 x 10⁴ TCID₅₀/mL
Legionella pneumophila 1.4 x 10⁴ CFU/mL
Chlamydia pneumoniae 1.1 x 10⁴ CFU/mL
Human Metapneumovirus 1.0 x 10⁴ TCID₅₀/mL
Parainfluenza virus 1 1.0 x 10⁴ TCID₅₀/mL
Parainfluenza virus 2 1.0 x 10⁴ TCID₅₀/mL
Parainfluenza virus 3 3.5 x 10⁴ TCID₅₀/mL
Parainfluenza virus 4 1.4 x 10⁴ TCID₅₀/mL
Rhinovirus 1.3 x 10⁴ PFU/mL
Mycoplasma pneumoniae 1.8 x 10⁴ CFU/mL
Bordetella pertussis 1.5 x 10⁴ CFU/mL
Mycobacterium tuberculosis 1.0 x 10⁴ CFU/mL
Pooled human nasal wash 100%
Respiratory syncytial virus 1.0 x 10⁴ TCID₅₀/mL

**Interfering substances**

- Whole Blood 5%
- MERS-coronavirus 2.1 x 10⁴ TCID₅₀/mL
- SARS-coronavirus 3.2 x 10⁴ PFU/mL
- Adenovirus C1 1.5 x 10⁴ TCID₅₀/mL
- Adenovirus 71 1.5 x 10⁴ TCID₅₀/mL
- Canicoid adenovirus 4.2 x 10⁴ CFU/mL
- Respiratory syncytial virus 5.1 x 10⁴ TCID₅₀/mL
- Enterovirus 5.4 x 10⁴ TCID₅₀/mL

**Flucetasone Propionate**

4%v/v Mucin 0.54%

**CV’s Nasal Drops (Phenylephrine)**

17%v/v Rital/Menthol 1.0 mg/mL

**Tamf妥(Oseltamivir Phosphate)**

6mg/ml Aftrax(Oxym etidrone) 145v/w

**Sucralfate(Dicyclomine/ Mentholsalicylate)**

0.25% I lotal Mucof in 12 mg/mL

**Chloramphenicol**

1.8 mg/mL Nasal Gels(Oxymetazoline) 12 mg/mL

**Homocysteic Acid**

1:10 dilution Macip rin 12 mg/mL

**Oxytetracycline**

165v/v Tobramycin 5 µg/mL

**Fisherm an’s Friend**

Zicam 4%v/v
LOTUS NL B.V.  

【DATE OF APPROVAL AND AMENDMENT OF IFU】: March-2020