

TEST PROCEDURE

Check Instructions for Use for complete procedure

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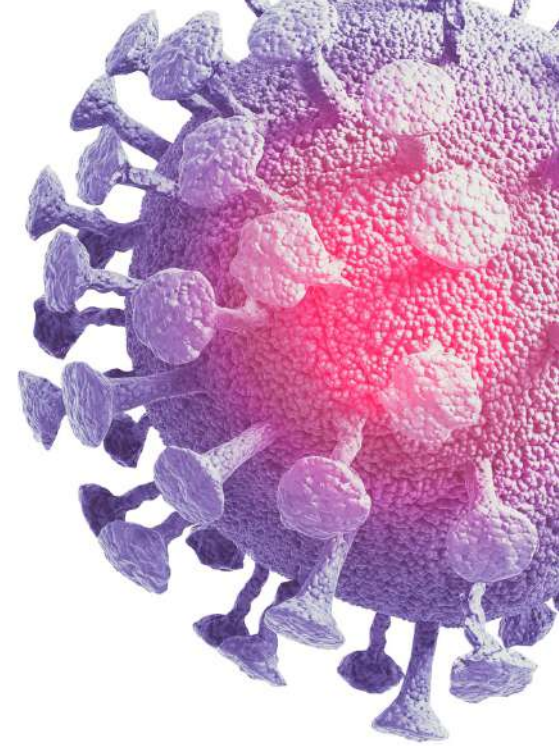
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KASTER
Medical Technology



SARS-COV-2 Antigen Rapid Test Kit

less-invasive COVID-19 testing
with nasal (NS) swab

JOYSBIO (Tianjin) Biotechnology CO., LTD.
Website: <https://en.joysbio.com/>



INTENDED USE

For in vitro qualitative detection of SARS-CoV-2 nucleocapsid antigen in nasal (NS) swab specimens directly from individuals who meet COVID-19 clinical and / or epidemiological criteria. JOYSBIO COVID-19 Antigen Rapid Test Kit is for professional use only and is intended to be used as an aid in the diagnosis of SARS-CoV-2 infection. The product may be used in any laboratory and non-laboratory environment that meets the requirements specified in the Instructions for Use and local regulation.

HIGHLIGHT

- High performance proved by an independent clinical study in Europe
- Rapid detection of SARS-COV-2 nucleocapsid antigen in less than 15 minutes
- Less-invasive sample collection with nasal swabs
- No instrumentation required
- Cost-effective solution for large-scale testing



PRODUCT INFO

PERFORMANCE*:

- **SENSITIVITY:** 98.72% (100% for samples with Ct values ≤ 33)
- **SPECIFICITY:** 97.32%
- **CLINICAL STUDY POPULATION:** 190 individuals, including 78 PCR-positives and 112 PCR-negatives
- **CLINICAL STUDY DATE & LOCATION:** November 2020 Apollonia (Benevento) Italy

SPECIFICATION:

- **TEST TIME:** 15–20 MINUTES
- **STORAGE CONDITION:** 2°C–30°C
- **CE MARK**
- **SAMPLE TYPE:** Nasal (NS) swab
- **SHELF LIFE:** 24 months

CONTENTS:

- 20x Test Devices
- 20x Buffer Bottle (350 μ L/bottle)
- 20x Extraction Tubes and Nozzle Caps
- 20x Sterilized Nasal (NS) Swabs
- 1x Tube Rack
- 1x Instructions for Use
- Positive/Negative Control Swabs (upon request)



*Sensitivity and Specificity vs PCR using Nasopharyngeal swabs.



JOYSBIO Biotechnology's SARS-CoV-2 Antigen Rapid test can detect SARS-CoV-2 with spike (S)-protein mutations

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2, or 2019-nCoV) 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).

JOYSBIO Biotechnology's SARS-CoV-2 Antigen Rapid test 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.

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

SARS-CoV-2 variants with spike (S)-protein D614G mutations now predominate globally

JOYSBIO Biotechnology has confirmed that its SARS-CoV-2 Antigen Rapid test can detect the dominant new variants of the SARS-CoV-2 with spike (S)-protein mutations.