

TEST PROCEDURE

Check Instructions for Use for complete procedure

1



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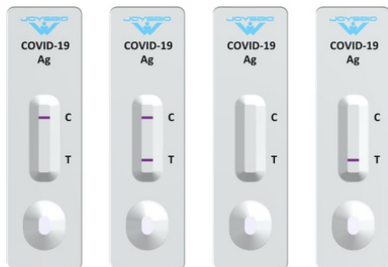
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CONTACT US

JOYSBIO (Tianjin) Biotechnology CO., LTD.

Headquarters: Tianjin International Joint Academy of
Biotechnology & Medicine 9th floor, No.220,
Dongting Road, TEDA 300457 Tianjin China

Website: <https://en.joysbio.com/>

Email: bd@joysbio.com

Tel: +86-130-7204-9899 (ENGLISH)

+86-22-5851-5062 (中文)

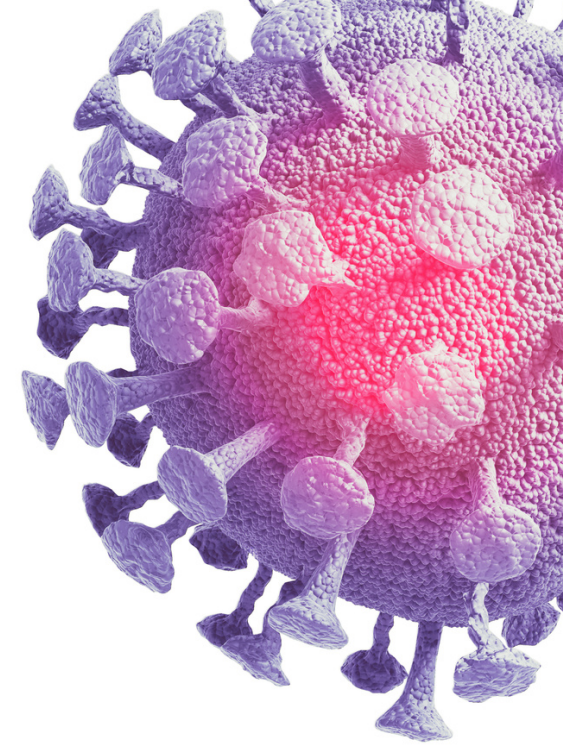
WhatsApp: +86-130-7204-9899

ORDER INFORMATION

JOYSBIO SARS-COV-2 Antigen Rapid Test Kit
(Colloidal Gold)

CATALOG NUMBER: COV-AG-20/G10313

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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 Apollosa (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.