# COVIOS® AG

**COVID-19 Antigen Rapid Diagnostic Test**

JANUARY 2022

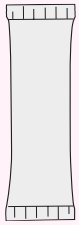
REF 11811125

FOR PROFESSIONAL USE CE

**Global Access Diagnostics**

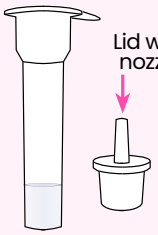
## KIT COMPONENTS (ALL SINGLE USE ONLY)

- Lateral flow device
- Sterile swab
- Swab extraction buffer tube



X1
LATERAL FLOW DEVICE

X1
STERILE SWAB




X1
SWAB EXTRACTION BUFFER TUBE

## MATERIALS REQUIRED BUT NOT PROVIDED

- Tube stand
- Stopwatch/ timer

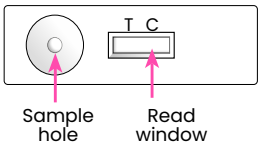
**PLEASE READ IN FULL**

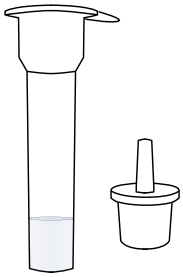
## SPECIMEN COLLECTION AND HANDLING

**1** Open kit components pictured above and lay on a clean, flat surface

Sterile swab

Lateral flow test device

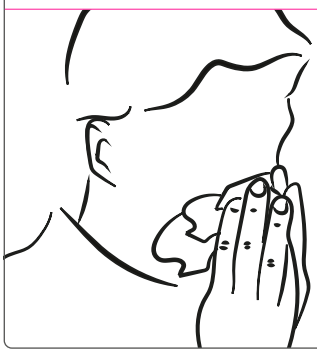


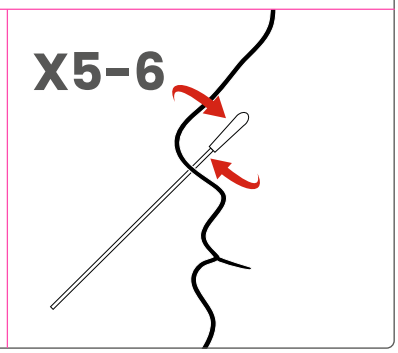



Swab Extraction Buffer Tube

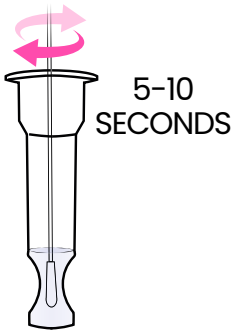
**2** **NASAL SWAB SPECIMEN COLLECTION:**

1. Ask patient to blow their nose thoroughly to remove excess mucus.
2. Insert swab 1-2cm into both nostrils one at a time and rotate the swab against the nasal wall 5-6 times and withdraw.

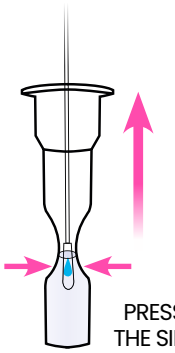




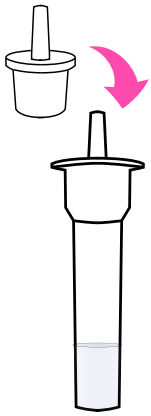

**3** **TUBE:** Peel back and remove the foil, Lower the swab specimen into the tube. Submerge the swab in the buffer and mix thoroughly pressing the swab on the tube sides for 5 to 10 seconds.



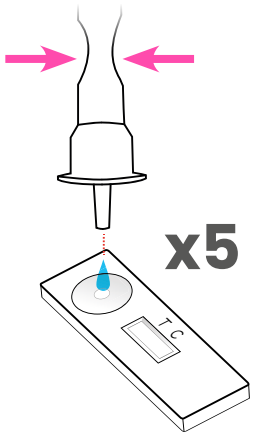

**4** **SQUEEZE:** Extract as much fluid as possible by squeezing and twisting the swab head through your fingers as you draw it out from the tube.




**CLOSE:** Seal the tube by pushing the nozzle in place.



**5** Ensure tube is **VERTICAL** and carefully dispense 5 continuous drops of extract into the sample hole on the lateral flow test device by gently squeezing the tube.





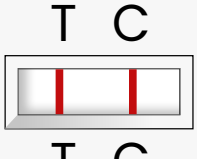
Read the TEST ( T ) visually at 10 minutes.

Discard extraction tube and swab.

## INTERPRETATION OF TEST RESULTS

**DO NOT INTERPRET THE TEST AFTER 15 MINUTES. IF UNSURE, PLEASE REPEAT TEST ON NEW DEVICE AND INTERPRET AT 10 MINUTES**

### POSTIVE




If the test line ( T ) is visible, this indicates a postive SARS-CoV-2 result.


If the test line ( T ) is faint, this indicates a postive SARS-CoV-2 result.

### NEGATIVE


If the test line ( T ) is not visible, this indicates a negative result.

### INVALID


If the control line ( C ) is absent, the test is invalid.

# COVIOS®AG COVID-19 ANTIGEN RAPID DIAGNOSTIC TEST: PERFORMANCE DATA

| Prospective Recruitment | | RT-qPCR | | |
|---|---|---|---|---|
| | | Pos | Neg | Total |
| GAD Rapid Antigen Test | Pos | 173 | 0 | 173 |
| | Neg | 18 | 458 | 476 |
| | Total | 191 | 458 | 649 |

| Performance | Sensitivity | Specificity |
|---|---|---|
| | **90.6%** (85.6% to 94.0%) | **100.0%** (99.2% to 100.0%) |

- GAD COVID-19 Rapid Antigen Test uses a nose only (anterior nares) swab
- RT-qPCR platforms: TibMolbiol and Roche
- Range Ct: 11.7 to 34.7
- FINDDX Ref: https://bit.ly/3nEeoi2

| Sensitivity stratified by RT-PCR cycle threshold value | |
|---|---|
| Ct | Sensitivity |
| <20 | 100.0% (92/92) |
| <25 | 96.4% (160/166) |
| <33 | 92.5% (172/186) |

# COVID-19 MICROBIAL INTERFERENCE AND CROSS REACTIVITY

| Pathogen | Concentration stock $TCID_{50}$ **0r CFU/mL | Reactive |
|---|---|---|
| hCoV-OC-43 | $4.17 \times 10^5$ | No Cross-Reactivity |
| hCoV-229-E | $1.70 \times 10^5$ | No Cross-Reactivity |
| hCoV-NL-63 | $1.41 \times 10^5$ | No Cross-Reactivity |
| Adenovirus 5 | $1.30 \times 10^5$ | No Cross-Reactivity |
| hMPV-16 | $1.26 \times 10^6$ | No Cross-Reactivity |
| Parainfluenza 1 | $5.01 \times 10^5$ | No Cross-Reactivity |
| Parainfluenza 2 | $1.51 \times 10^6$ | No Cross-Reactivity |
| Parainfluenza 3 | $1.70 \times 10^5$ | No Cross-Reactivity |
| Parainfluenza 4A | $4.17 \times 10^5$ | No Cross-Reactivity |
| Influenza A H3N2 | $1.41 \times 10^5$ | No Cross-Reactivity |
| Influenza A H1N1 | $1.41 \times 10^5$ | No Cross-Reactivity |
| Influenza B | $1.26 \times 10^6$ | No Cross-Reactivity |
| Enterovirus type 68 | $1.26 \times 10^6$ | No Cross-Reactivity |
| RSV-A | $5.01 \times 10^5$ | No Cross-Reactivity |
| Rhinovirus type 1A | $1.41 \times 10^5$ | No Cross-Reactivity |
| Haemophilus influenza | $5.43 \times 10^5$ | No Cross-Reactivity |
| Streptococcus pneumoniae | $4.16 \times 10^8$ | No Cross-Reactivity |
| Streptococcus pyogenes | $2.66 \times 10^9$ | No Cross-Reactivity |
| Candida albicans | $4.50 \times 10^8$ | No Cross-Reactivity |
| Bordetella pertussis | $6.43 \times 10^9$ | No Cross-Reactivity |
| Legionella pneumophila | $1.42 \times 10^{10}$ | No Cross-Reactivity |
| Pneumocystis jiroveci | $6.34 \times 10^8$ | No Cross-Reactivity |

Organisms for Testing & Concentrations. **1TCID50/ml = 0.7 pfu/ml

## INTENDED USE

The COVIOS®AG COVID-19 Antigen Rapid Diagnostic Test is a qualitative point of care, lateral Flow immunoassay and is used as an aid to the qualitative detection of SARS-CoV-2 antigens in human nasal swabs from individuals who are at risk or suspected of COVID-19 by their healthcare provider during the acute phase of infection. Test results should be considered in conjunction with other diagnostic and clinical information.

## PRINCIPLES OF THE TEST

Nucleocapsid proteins in the sample are bound by capture reagents in the test lines as they are transported through the lateral flow strip, and made visible by secondary reagents.

A visible test line confirms the presence of the virus or fragment of the virus, indicating that the subject is experiencing COVID-19 infection.

The appearance of the CONTROL line (marked C) confirms that the test has been performed correctly.

## STORAGE

This product is stable at room temperature (2-30°C).

## WARNINGS & PRECAUTIONS

- For in vitro diagnostic use only.
- Single use. Used tests must not be re-used.
- Do not use after the expiry date printed on the packaging.
- Store at room temperature.
- Dispose of used kit components safely in clinical waste.
- Do not open pouch until you are ready to use the test. Use within 10 min of opening.

## LIMITATIONS OF USE

- The COVIOS®AG COVID-19 Antigen Rapid Diagnostic Test is designed for use by medical professionals or trained personnel who are competent in administrating rapid antigen tests. Sample collection by self-swabbing is acceptable
- For reliable results, follow the instructions
- Test results should be used in conjunction with other clinical and patient information
- Positive test results do not rule out co-infections with other pathogens.
- Negative test results may occur if antigen levels extracted in a specimen are below the sensitivity of the test or sampled inappropriately.

If you have any questions or comments, please contact our helpline on +44 1234 619973 during UK office hours, or email info@globalaccessdiagnostics.com

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