# CoronAg™ RAPID COVID-19 ANTIGEN TEST

**For professional use only.**

REF **DA01A** CE IVD

## PACKAGING
1T/ Set, 5T/ Set, 10T/ Set, 25T/ Set, 50T/ Set

## INTENDED USE
This kit is intended for the qualitative *in vitro* detection of SARS-CoV-2 nucleocapsid (N) antigen in human nasopharyngeal swab specimens. The test is for professional use only, not for home testing. If necessary, positive test results should be confirmed by the nucleic acid amplification tests.

## SUMMARY
SARS-CoV-2 is an acute infectious disease of the respiratory tract. Currently, patients infected with the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, usually 3 to 7 days. The main manifestations are fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia, and diarrhea are also found in some cases.

## PRINCIPLE
The test uses anti-SARS-Cov-2 nucleocapsid (N) protein monoclonal antibody conjugated to colloidal gold coated on the conjugate pad and test line. During detection, the gold-labeled anti-SARS-CoV-2 monoclonal antibody on the conjugate pad binds to the SARS-CoV-2 antigen in the sample to form a complex and the reaction complex moves across the nitrocellulose membrane. The chromatography is picked up by the anti-SARS-CoV-2 monoclonal antibody pre-coated with the detection site (T) on the membrane, and finally a red colored reaction line forms in the T region. Regardless of whether the sample to be tested contains the SARS-CoV-2 antigen or not, a red reaction line always appears in the quality control area (C).

## KIT CONTENT
- Test cassette
- Sterile swab
- Extraction tube with dropper
- Instruction for use

## STORAGE AND STABILITY
- Store at 2-25 °C in closed packaging.
- Do not expose to sunlight.
- Test cassette should be used within 1 hour after opening its foil.
- Test is stable until the expiry date on packaging.
- Do not freeze.

## SAMPLING-NASOPHARYNGEAL SWAB
1. Remove the swab from the package. Do not touch the soft end with your hands.
2. Tilt the patient's head back 70 degrees. Insert swab through the nostril (NOT upwards) parallel to the palate until a resistance is encountered.
3. Rotate the swab gently then leave in place a few seconds.
4. Remove the swab while rotating it.
5. Repeat sampling with the same swab in the other nostril.

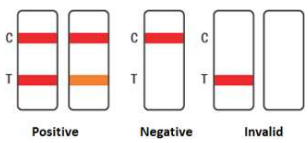
## TEST PROCEDURE
6. Insert the swab into extraction tube and stir the swab more than 10 times while squeezing the tube.
7. Break the swab at the breakpoint and close the tube.
8. Open and place the test cassette on a flat surface.
9. Break off the dropper head and add 3 drops from the tube to the sample well of the test cassette. See the solution migrate through the cassette.
10. Read the test results on the cassette after 15 minutes. Too early and late reads can lead to erroneous results.
11. Test components after use should be treated as medical waste.
12. Wash and disinfect your hands.


## INTERPRETING RESULTS

**Positive result**: If both C and T lines are visible within 15 minutes, the test result is positive and valid. Samples with low antigens may develop different color lines.

**Negative result:** If the test area (T-line) has no color and the control area shows a colored line, the result is negative and valid.

**Invalid result:** if there is no colored line in the control area, the result is invalid. The sample must be re-tested with a new test cassette.




## TEST QUALITY CONTROL
Before the test, test (T) and control (C) lines on the cassette are not visible. After the test, control line (C) must always appear. This shows that the test is working.

## LIMITATIONS
1. Test detects both live and non-living SARS-CoV and SARS-CoV-2.
2. Assay performance depends on the viral load (antigen) in the sample.
3. Test results should not be taken as a confirmed diagnosis but for clinical reference only. If the test results do not match the clinical evidence, additional testing is recommended to confirm the result.
4. Failure to follow the test procedure may affect test performance and/or invalidate the test result.
5. A reaction before 15 minutes can lead to a false negative result, and a reaction after 15 minutes can lead to false positives.

## TEST PERFORMANCE
**1. Clinical Evaluation**
The sensitivity of the test was determined using 100 positive nasopharyngeal swab samples confirmed by RT-qPCR. The specificity of the test was determined using 100 negative nasopharyngeal swab samples confirmed by RT-qPCR. The sensitivity was calculated as 87% (87/100) and specificity as 97% (97/100).

| Test Kit | Comparative RT-qPCR Test Results | |
|---|---|---|
| | Positive (+) | Negative (-) |
| Positive | 87 | 3 |
| Negative | 13 | 97 |
| Total | 100 | 100 |
| **Sensitivity: 87/100 87%, (95% CI: 78.80% to 92.89%)** | | |
| **Specificity: 97/100 97%, (95% CI: 91.48% to 99.38%)** | | |

**2. Limit of Detection (LoD)**
Kit's detection limit is 100 TCID50/ml.

**3. Cross-reactivity**
No cross-reactivity is reported for the samples at given concentrations.

| No. | Samples | Concentrations |
|---|---|---|
| 1 | HCoV-HKU1 | $10^5$ $TCID_{50}$/ml |
| 2 | Staphylococcus aureus | $10^6$ CFU /ml |
| 3 | Streptococcus pyogenes | $10^6$ CFU /ml |
| 4 | Measles virus | $10^5$ $TCID_{50}$/ml |
| 5 | Paramyxovirus parotitis | $10^5$ $TCID_{50}$/ml |
| 6 | Adenovirus 3 | $10^5$ $TCID_{50}$/ml |
| 7 | Mycoplasma pneumonia | $10^5$ $TCID_{50}$/ml |
| 8 | Parainfluenza virus 2 | $10^5$$TCID_{50}$/ ml |
| 9 | Human metapneumovirus (Hmpv) | $10^5$ $TCID_{50}$/ml |
| 10 | Human coronavirus OC43 | $10^5$ $TCID_{50}$/ml |
| 11 | Human coronavirus NL63 | $10^5$ $TCID_{50}$/ml |
| 12 | Human coronavirus 229E | $10^5$ $TCID_{50}$/ml |
| 13 | MERS coronavirus | $10^5$ $TCID_{50}$/ml |
| 14 | Bordetella parapertussia | $10^5$ $TCID_{50}$/ml |
| 15 | Influenza B (Victoria strain) | $10^5$ $TCID_{50}$/ml |
| 16 | Influenza B (Ystrain) | $10^5$ $TCID_{50}$/ml |
| 17 | Influenza A (H1N1 2009) | $10^5$ $TCID_{50}$/ml |
| 18 | Influenza A (H3N2) | $10^5$ $TCID_{50}$/ml |
| 19 | Avian influenza virus (H7N9) | $10^5$ $TCID_{50}$/ml |
| 20 | Avian influenza virus (H5N1) | $10^5$ $TCID_{50}$/ml |
| 21 | Epstein-Barr virus | $10^5$ $TCID_{50}$/ml |
| 22 | Enterovirus CA16 | $10^5$ $TCID_{50}$/ml |
| 23 | Rhinovirus | $10^5$ $TCID_{50}$/ml |
| 24 | Respiratory syncytial virus (RSV) | $10^5$ $TCID_{50}$/ml |
| 25 | Streptococcus pneumoniae | $10^6$ CFU / ml |
| 26 | Candida albicans | $10^6$ CFU / ml |
| 27 | Chlamydia pneumoniae | $10^6$ CFU / ml |
| 28 | Bordetella pertussis | $10^6$ CFU / ml |
| 29 | Pneumocystis jirovecii | $10^6$ CFU / ml |
| 30 | Mycobacterium tuberculosis | $10^6$ CFU / ml |
| 31 | Legionella pneumophila | $10^6$ CFU / ml |

**4. Interfering Substances**
Test results are not affected with the substances at given concentration.

| No. | Substances | Concentrations |
|---|---|---|
| 1 | Whole Blood | 4% |
| 2 | Ibuprofen | 1 mg / ml |
| 3 | Tetracyclines | 3µg / ml |
| 4 | Chloramphenicol | 3µg / ml |
| 5 | Erythromycin | 3µg / ml |
| 6 | Tobramycin | 5% |
| 7 | Throat spray (menthol) | 15% |
| 8 | Mupirocin | 10mg/ml |
| 9 | Throat lozenge (menthol) | 1.5mg/ml |
| 10 | Tamiflu (oseltamivir) | 5mg/ml |
| 11 | Naphthoxoline Hydrochloride nasal drops | 15% |
| 12 | Mucin | 0.50% |
| 13 | Fisherman's Friend | 1.5mg/ml |
| 14 | Compound benzocaine gel | 1.5mg/ml |
| 15 | Cromoglycates | 15% |
| 16 | Sinex (Phenylephrine Hydrochloride) | 15% |
| 17 | Afrin (Oxymetazoline) | 15% |
| 18 | Fluticasone propionate spray | 15% |

**5. High-dose hook effect**
No hook effect was observed when the concentration of inactivated virus stock increased to 4.0x105 TCID50 / ml.

## PRECAUTIONS
1. Do not use the product after the expiry date.
2. Take appropriate precautions in sampling, handling, storage and disposal of the product.
3. Do not reuse the test kit.
4. Do not unpack the test card until you use it.
5. Do not use damaged products.
6. If the reagent solution comes into contact with skin or eyes, rinse with plenty of water.

## SYMBOL

| | | | |
|---|---|---|---|
| IVD | *In vitro* Diagnostics | | Temperature limitation |
| REF | Catalog number | | Use only once |
| | Consult instructions for use | | Keep dry |
| CE | CE marking | | Keep away from sunlight |
| LOT | Batch code | | Do not use if the package is damaged |
| EC REP | Authorized representative in European Community | | Caution |
| | Expire date | | Date of manufacture |

For serious adverse events related to the product, report to Sugenomics Biotechnology and the competent authority where the user and/or patient is located.


## Contact
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