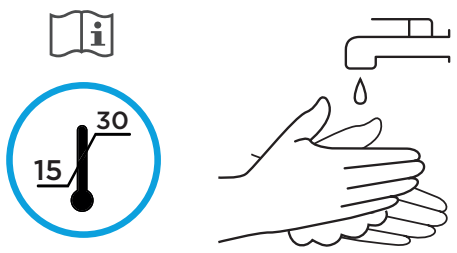
# COVID-19 Antigen Detection Kit Self-test

NEWGENE Bioengineering

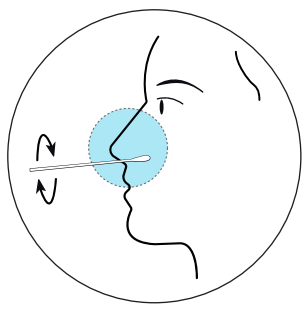
**BEFORE TESTING:** Read the instructions carefully. The test detects SARS-CoV-2 antigen in the nasal secretions collected by a sterile nasal swab. For people who cannot perform the test themselves, the test should be performed by an adult or guardian. Make sure you have enough light to interpret the test results. Use the timekeeping function on a phone or clock to read the result within the correct time interval.

**AFTER TESTING: In case of positive results, contact a health care provider as soon as possible. Even a very faint line counts. Additional testing may be required to confirm viral infection or to initiate infection tracing.** A negative result cannot completely exclude the risk of infection. Low virus load or incorrect sampling can cause false negative results. Always follow local and governmental recommendations. Disinfect used products and samples or place in a sealed waste bag before discarding in household waste. Wash your hands thoroughly after the test.

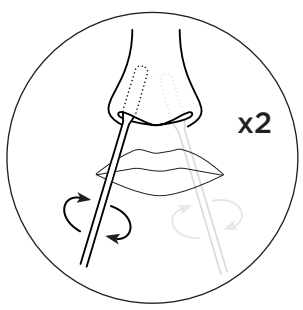
## SAMPLING



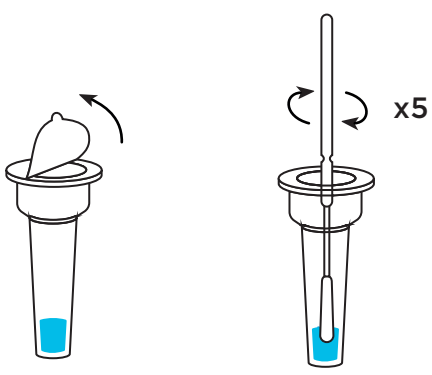

**1** Read the instructions before performing the test. Perform at room temperature. Wash your hands thoroughly.



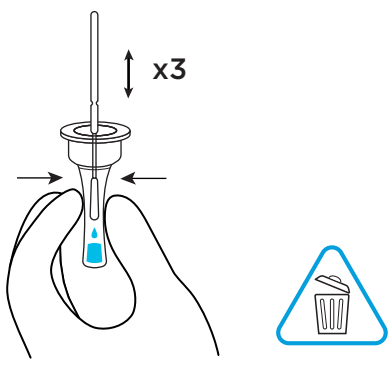
**2** Open the package with the sampling swab. Gently insert the top of the swab into one nostril, 2-3 cm. Do not force.



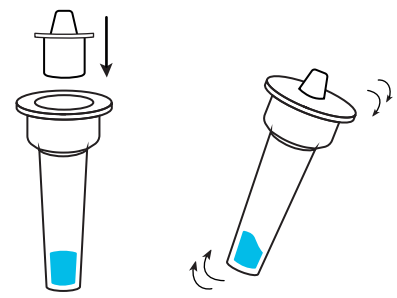

**3** Press the swab against the nasal wall and rotate for about 20 seconds. Repeat in the other nostril.




**4** Remove the sample extraction tube seal and insert the swab. Press it against the sides and rotate for 10 seconds.

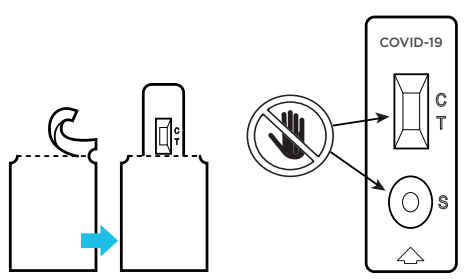



**5** Squeeze the sides of the tube to expel sample solution from the swab. Disinfect used products and samples or place in a sealed waste bag before discarding in household waste.

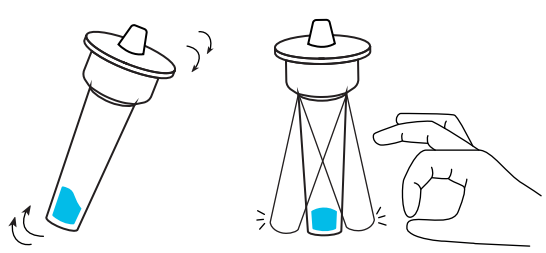


**6** Place the tube cap firmly onto the tube. Avoid touching the top of the tube cap. Shake the tube and then let it rest for 1 minute to release viral antigens.

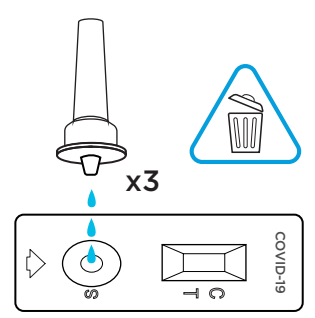
## TEST PROCEDURE




**7** Remove the test cartridge from its package. Place it on a flat surface. Avoid touching the well and window of the test cartridge.

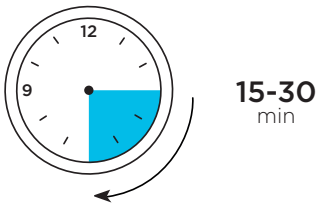


**8** Shake, turn and tap the test tube to mix the liquid again. Avoid touching the top of the tube cap.



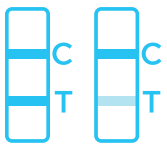

**9** Squeeze the tube to expel 3 drops of sample solution into the loading well. Disinfect used products and samples or place in a sealed waste bag before discarding in household waste.

## RESULTS




**10** Test result is displayed 15-30 minutes after the liquid is expelled into the well. After 30 minutes, the result is invalid.

**POSITIVE**

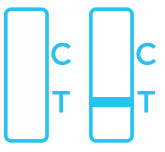



Line at both C and T, regardless of how faint.

**NEGATIVE**


Line at C only. See Limitations.

**INVALID**




Without a line at C. Retest with another test card.

# COVID-19 Antigen Detection Kit Self-test

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## PACKAGE INSERT & INSTRUCTIONS FOR USE

**TYPE:** Nasal sampling, self-test for public use

**PACKAGING:** 25 tests, 5 tests or 1 test

**VERSION:** EN-v02-NS-HT

**DATE:** 2021-06

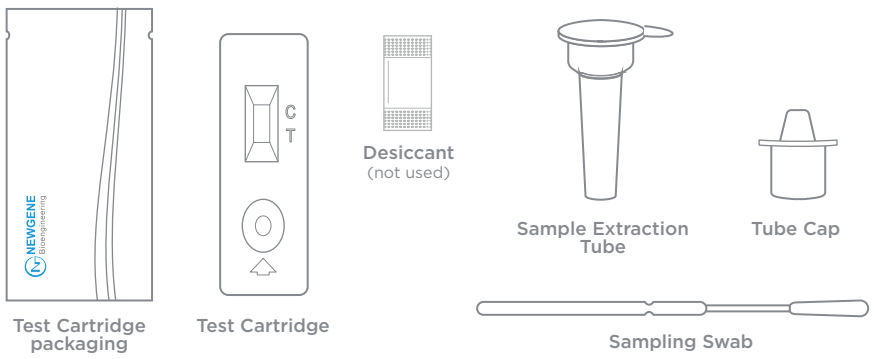
**CAT:** COVID-19-NG08 (manufacturer)

**REF:** REF 5101, 5105, 5125 (importer)

### SUMMARY

COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic virus carriers can also be infectious sources. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are also found in some cases.

### PRODUCT COMPONENTS




### PRINCIPLE

The COVID-19 Antigen Detection Kit is an immunochromatographic membrane assay that uses highly sensitive monoclonal antibodies to detect nucleocapsid protein from SARS-CoV-2. The test strip is composed of the following parts: namely sample pad, reagent pad, reaction membrane, and absorbing pad. The reagent pad contains the colloidal-gold conjugated with the monoclonal antibody against the nucleocapsid protein of SARS-CoV-2; the reaction membrane contains the secondary antibodies for nucleocapsid protein of SARS-CoV-2. The whole strip is fixed inside a plastic device. When the sample is added into the sample well, conjugates absorbed in the reagent pad are dissolved and migrate along with the sample. If SARS-CoV-2 antigen is present in the sample, the complex of the anti-SARS-CoV-2 conjugate and the virus will be captured by the specific anti-SARS-CoV-2 monoclonal antibodies coated on the test line region (T). Absence of the T line suggests a negative result. To serve as a procedural control, a red line will always appear in the control line region (C) indicating that proper volume of sample has been added and membrane wicking effect has occurred.

### WARNINGS AND PRECAUTIONS

This product is applicable for nasal sampling, other test samples may result in incorrect or invalid test results. Keep out of reach of children. Children under the age of 14 should be tested by their parents or guardians. Carry out the analysis within two hours after sampling. Outdated and stale samples can cause erroneous results. Make sure the correct amount of sample is used for testing; too much or too little can cause incorrect results. Test result is displayed 15-30 minutes after the liquid is expelled into the well. After 30 minutes, the result is invalid. If the test line or control line is outside the test window, do not use the test cartridge as the test result is invalid. Retest the sample with another test cartridge. This product is for single use only. Contact a health care provider if your nose is damaged during the procedure. Do not recycle used components. Disinfect used products and samples with surface disinfectant (containing 5%-9% sodium hypochlorite) or place in a sealed waste bag before discarding in household waste. Wash your hands thoroughly after the test.

### EXEMPTION

Self-tests, such as this product, need to be reviewed by a notified body before it can be CE marked by its manufacturer. The CE marking guarantees that the product is reliable and has a sufficient level of safety; that it is safe to use and that the intended user can handle the product, to read and interpret the results correctly. This product is CE marked as a rapid test for professional use in healthcare. The Swedish Medical Products Agency has granted a temporary exemption to use this product as a medical device for in vitro diagnostics with intended use for self-testing by the general public.

### PRODUCT PERFORMANCE

**Limit of detection** for this product is about 0,05 ng/ml SARS-CoV-2 nucleocapsid protein solution.

| **CROSS-REACTIVITY WITH OTHER PATHOGENS** No cross-reactivity observed with pathogens listed below: | | **INTERFERENCE TEST**: No interference observered with substances listed below: | | No interference observed with respiratory pathogens listed below : | |
|---|---|---|---|---|---|
| *Staphylococcus aureus* | $1x10^5$ CFU/mL | Abidol | 20 µg/mL | *Staphylococcus aureus* | $1x10^5$ CFU/mL |
| *Streptococcus pneumoniae* | $1x10^5$ CFU/mL | Aluminium hydroxide | 20 µg/mL | *Streptococcus pneumoniae* | $1x10^5$ CFU/mL |
| Measles virus | $1x10^6$ pfu/mL | Azithromycin | 20 µg/mL | Measles virus | $1x10^6$ pfu/mvL |
| Mumps virus | $1x10^6$ pfu/mL | Beclomethasone | 20 µg/mL | Adenovirus type 3 | $1x10^6$ pfu/mL |
| Adenovirus typ 3 | $1x10^6$ pfu/mL | Bilirubin | 20 µg/mL | *Mycoplasma pneumoniae* | $1x10^5$ CFU/mL |
| *Mycoplasma pneumoniae* | $1x10^5$ CFU/mL | Budesonide | 20 µg/mL | Parainfluenza virus 2 | $1x10^6$ pfu/mL |
| Parainfluenza virus 2 | $1x10^6$ pfu/mL | Ceftriaxone | 20 µg/mL | Metapneumovirus | $1x10^6$ pfu/mL |
| Metapneumovirus | $1x10^6$ pfu/mL | Dexamethasone | 20 µg/mL | SARS-CoV | $1x10^6$ pfu/mL |
| SARS-CoV | $1x10^6$ pfu/mL | Flunisolide | 20 µg/mL | MERS-CoV | $1x10^6$ pfu/mL |
| MERS-CoV | $1x10^6$ pfu/mL | Fluticasone | 20 µg/mL | Human coronavirus OC43 | $1x10^6$ pfu/mL |
| Human coronavirus OC43 | $1x10^6$ pfu/mL | Hemoglobin | 20 µg/mL | Human coronavirus 229E | $1x10^6$ pfu/mL |
| Human coronavirus 229E | $1x10^6$ pfu/mL | Histamine hydrocloride | 20 µg/mL | Human coronavirus NL63 | $1x10^6$ pfu/mL |
| Human coronavirus NL63 | $1x10^6$ pfu/mL | Levofloxacin | 20 µg/mL | Human coronavirus HKU1 | $1x10^6$ pfu/mL |
| Human coronavirus HKU1 | $1x10^6$ pfu/mL | Lopinavir | 20 µg/mL | Influenza B virus (Victoria Lineage) | $1x10^6$ pfu/mL |
| *Bordetella parapertussis* | $1x10^5$ CFU/mL | Meropenem | 20 µg/mL | Influenza B virus (strain B/Yamagata/16/1988) | $1x10^6$ pfu/mL |
| Influenza B virus (Victoria Lineage) | $1x10^6$ pfu/mL | Mometasone | 20 µg/mL | 2009 pandemic influenza A (H1N1) virus | $1x10^6$ pfu/mL |
| Influenza B virus (strain B/Yamagata/16/1988) | $1x10^6$ pfu/mL | Mucin | 20 µg/mL | Influenza A (H3N2) virus | $1x10^6$ pfu/mL |
| 2009 pandemic influenza A (H1N1) virus | $1x10^6$ pfu/mL | Oseltamivir | 20 µg/mL | Avian influenza A (H7N9) virus | $1x10^6$ pfu/mL |
| Influenza A (H3N2) virus | $1x10^6$ pfu/mL | Oxymetazoline | 20 µg/mL | Avian influenza A (H5N1) virus | $1x10^6$ pfu/mL |
| Avian influenza A (H7N9) virus | $1x10^6$ pfu/mL | Paramivir | 20 µg/mL | Epstein-Barr virus | $1x10^6$ pfu/mL |
| Avian influenza A (H5N1) virus | $1x10^6$ pfu/mL | Phenylephrine | 20 µg/mL | Enterovirus CA16 | $1x10^6$ pfu/mL |
| Epstein-Barr virus | $1x10^6$ pfu/mL | Ribavirin | 20 µg/mL | Rhinovirus | $1x10^6$ pfu/mL |
| Enterovirus CA16 | $1x10^6$ pfu/mL | Ritonavir | 20 µg/mL | Respiratory syncytical virus | $1x10^6$ pfu/mL |
| Rhinovirus | $1x10^6$ pfu/mL | Sodium bicarbonate | 20 µg/mL | | |
| *Neisseria meningitidis* | $1x10^5$ CFU/mL | Sodium chloride | 20 µg/mL | | |
| Respiratory syncytical virus | $1x10^6$ pfu/mL | Tobramycin | 20 µg/mL | | |
| | | Triamcinolone acetonide | 20 µg/mL | | |
| | | Zanamivir | 20 µg/mL | | |
| | | α-interferon | 20 µg/mL | | |

**Sensitivity, Specificity and Total Accuracy**: The product performance was evaluated with clinical specimens, taking commercial RT-PCR kit as the gold standard.

| NASAL SWAB | | RT-PCR | | Total |
|---|---|---|---|---|
| | | Positive | Negative | |
| COVID-19 Antigentest | Positive | 168 | 2 | 170 |
| | Negative | 5 | 262 | 267 |
| | Total | 173 | 264 | 437 |
| | | Sensitivity | Specificity | Total Accuracy |
| | | 97.1% | 99.2% | 98.4% |
| | | 95.0% CI [93.4%-99.1%] | 95% CI [97.3%-99.9%] | 95% CI [96.7%-99.4%] |

### LIMITATIONS

This product is intended for self-diagnosis of COVID-19. The final diagnosis should be determined by a physician after evaluation of clinical signs and results of other examinations. A **negative result** indicates that there is no virus in the sample, or that the virus load is below the detection limit for this product. The possibility of viral infection cannot be completely ruled out. A **positive result** indicates that the tested sample has a viral load that is higher than the detection limit of this product. The color intensity of the test line does not correspond to the severity of infection or disease progression in the person. The amount of viral antigens in the sample will decrease with the duration of the disease. Samples taken one week after the onset of symptoms are more likely to show false negative results. The use of a liquid other than the supplied extraction buffer solution will invalidate the test.

### FREQUENTLY ASKED QUESTIONS

**When can I test myself?** You can always test yourself, regardless of symptoms. Follow the instructions from authorities to repeat the test on a regular basis. **I'm unsure of the test results. What should I do?** Take a photo of the test result and the instructions for use. Contact your healthcare provider for help. **The result is invalid. What should I do?** Follow the instructions carefully and repeat the test with a new test kit. If the result is still invalid, contact the importer via the website www.gibsonmedical.se. **I have symptoms which resemble COVID-19, but the result is negative. What should I do?** A negative result can not completely rule out the risk of viral infection. If you have symptoms such as headache, migraine, fever, loss of sense of smell and taste; contact your healthcare provider for a position for further investigation. You can also take a new sample and repeat the test with a new test package. Always follow local and governmental recommendations.

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- Manufacturer of the device
- Date of manufacture
- Use-before date
- EC REP — European representative
- LOT — Manufacturer's batch code
- Read the instructions for use
- Do not use a damaged product
- Do not re-use
- Keep dry
- Keep away from sunlight
- Σ — Number of tests in the package
- IVD — Medical device for in vitro diagnostics
- 2°C – 30°C — Store between 2–30°C

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PRODUCT INFO