# SARS-CoV-2 Antigen Self Test Nasal

## For Self Testing

| CAT | | SYSTEM | IVD |
|---|---|---|---|
| 99COV130J-ML04 | 5 | visual reading | For in vitro diagnostic use |

**English**
**Intended use**

SARS-CoV-2 Antigen Self Test Nasal is a lateral flow immunoassay intended for qualitative detection of SARS-CoV-2 nucleocapsid protein antigen in self-collected nasal swab samples from individuals aged 14 years or older or adult collected nasal swab samples from individuals aged two years or older. This test is intended for individuals with symptoms of COVID-19 within the first 6 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and for individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests.

Persons who test positive with the SARS-CoV-2 Antigen Self Test Nasal should seek follow up care with their physician or health care provider as additional testing and public health reporting may be necessary. Positive results do not rule out bacterial infection or co-infection with other viruses.

Persons who test negative and continue to experience COVID-19 like symptoms of fever, cough and/or shortness of breath may still have SARS-CoV-2 infection and should seek follow-up care with their physician or health care provider. Negative results are presumptive. All test results will be reported to health care providers and relevant public health authorities in accordance with local provincial and federal requirements.

This test is intended for home use.

**Summary**
At the end of 2019, a novel virus was discovered in a cluster of pneumonia cases.[1] This virus belongs to the large family of *Coronaviruses*, and has been named SARS-CoV-2 because its genetic sequence is closely related to the virus that caused the SARS outbreak in 2013.[2] The disease caused by SARS-CoV-2 is called COVID-19 (COronaVIrus Disease 2019).[3,4] The course of SARS-CoV-2 infections can vary widely. Some infected individuals do not have any symptoms, others experience relatively mild symptoms such as fever, cough, loss of taste or smell, or diarrhea. But it can also cause more serious symptoms such as difficulty in breathing or even death.[5,6] Usually, it takes 5 - 6 days for symptoms to develop after an exposure to SARS-CoV-2, but sometimes it can take as long as 14 days.[6]

**Reagents**

- mAb anti-COVID-19 antibody
- mAb anti-chicken-IgY
- mAb anti-COVID-19 antibody-gold conjugate
- purified chicken-IgY-gold conjugate

**Precautions and warnings**

- Use the test kit once only.
- Remove the test device from the sealed pouch only when you are ready to perform the test.
- Do not use the test kit if the pouch is damaged.
- In the event of a spillage, ensure that it is cleaned thoroughly using a suitable disinfectant.
- Use only the components of this test kit.
- Inadequate or improper sample collection may lead to inaccurate or false results.
- If you suspect the presence of blood on the swab, discard the swab and repeat the test with a fresh one.
- Avoid contact with skin and eyes. In case of accidental contact, rinse well with copious amounts of water in order to avoid skin irritations. Do not dip the swab into provided solution or other liquid before inserting the swab into the nose. In case of concerns, consult your doctor.
- The buffer liquid (0.35mL) contains 0.2% sodium azide which may be toxic if ingested. The buffer liquid also contains ProClin® 300 and polidocanol which may be hazardous to the skin and eye and are harmful if swallowed. Keep the test kit away from children and pets to reduce the risk of accidentally drinking the buffer liquid or swallowing small parts.
- Do not use any of the test components in the body with the exception of the swab included in the kit. Do not swallow any of the components.
- Please consult a medical expert to discuss your test result and to find out whether additional tests are needed. Please also consult a doctor if you have any concerns about your health, if you are experiencing prolonged symptoms, or if your symptoms are worsening.
- Even if your test result is negative, continue to observe all applicable hygiene and safety measures.
- Dispose all waste materials in accordance with local rules. Prevent release into the environment, drainage system or water bodies.

**Storage and stability**
Store the kit at 2 - 30 °C / 36 - 86 °F and protect from direct sunlight. The expiry date of the materials is indicated on the external packaging.
Do not freeze the kit.

**Materials provided**

- Test device (packaged in foil pouch 1 including desiccant package)
- Tube with liquid and nozzle cap (packaged in foil pouch 2)
- Sterile swab[a)]
- Tube holder
- Instructions for Use and Quick Reference Guide

**Materials required (but not provided)**

- Timer

**Test preparation and sample collection**
Carefully read the Instructions for Use of the SARS-CoV-2 Antigen Self Test Nasal. Please also see the enclosed Quick Reference Guide (with illustrations) before performing the test.

**Preparing for a test**
Prior to starting the procedure, the test device and reagents must be equilibrated to operating temperature (15 - 30 °C / 59 - 86 °F).

1. Wash your hands with soap and water or use a hand sanitizer before performing the test.
2. Check the expiry date on the back of the foil pouches. Do not use the test if the expiry date has passed.
3. Open one of the foil pouches 1 by tearing along the tear-line and take out the test device and the desiccant package. Use the test immediatedly after opening the pouch.
4. Ensure that the test device is intact and that there are no green beads in the desiccant package. Do not open the desiccant package.

**Collecting and preparing a nasal sample**

1. Open the foil pouch 2 by tearing along the tear-line and take out one of the tubes with the liquid and one nozzle cap and place them on the table.
2. Open the seal of the tube carefully without spilling the liquid inside the tube. Place the tube in the tube holder.
3. Remove the swab from the packaging. Ensure that you only touch the handle of the swab and not the soft pad at the tip.
4. Slightly tilt your head backwards.
5. Insert the swab with the soft pad at the front into your left nostril. Slowly slide the swab approx. 2 cm forward (parallel to the roof of your mouth - not upwards) until you encounter resistance. Do not apply any pressure.
6. Rotate the swab 4 times (for a total of approx. 15 seconds) against the lining of the nasal wall before removing it from the nostril.
7. Repeat steps 5 and 6 in your right nostril using the same swab.
8. Insert the swab into the tube until the soft pad is in the liquid. Squeeze the tube at the bottom and hold it tight. Stir the swab more than 10 times to transfer the biological material from the swab to the liquid.
9. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab. Dispose the swab and seal the tube securely with the nozzle cap.

The same swab is used to collect samples from both nostrils.

**Performing the test**

1. Place the test device on a flat surface.
2. Hold the tube upright above the circular well on the test device (not over the rectangular result window).
3. Drop exactly 4 drops onto the circular well. Gently squeeze the sides of the tube together if necessary.
   **Note:** You can continue with the test even if you accidentally drop 5 drops onto the test device.
4. Set the timer and read the result after 15 to 30 minutes. Do not touch or move the test device until the result can be read.
5. Wash your hands with soap and water or use a hand sanitizer after performing the test.

⚠ WARNING! Failure to squeeze the tube can lead to incorrect results due to insufficient elution of the material into the buffer or excess buffer in the swab.
⚠ Test results that are read before 15 minutes or after 30 minutes may be incorrect.
⚠ Place the test device on a flat surface.
⚠ Dispense the specimen at 90 degree angle to allow for free falling drops and avoid bubbles.

**Interpreting the test results**

- **Invalid test result:**
  If a control line (C) is not visible, the result must be considered invalid. The test is not working correctly and you should perform another test using a different test kit. You may have performed the test incorrectly. Carefully read the Instructions for Use and repeat the test. If your test result is still invalid, please contact your doctor or a COVID-19 test center.
- **Positive test result:**
  If a test line (T) is visible together with a control line (C), this means that the result is positive. Look carefully at the result: The test should be considered positive if two lines are visible -even if they are faint. A positive test result means it is very likely that you have COVID-19.
  Please contact your doctor/primary care physician or your local health authority immediately and adhere to the local guidelines regarding self-isolation. Your doctor may require you to undergo a PCR test to confirm the result.
- **Negative test result:**
  If a control line (C) is visible (regardless of how faint it is) and a test line (T) is not visible, this means that the result is negative. It is unlikely that you have COVID-19. However, even if your test is negative, continue to observe all hygiene and safety measures.
  If you suspect that you have an infection (i.e., if you have prolonged symptoms or if your symptoms are worsening), contact your doctor/primary care physician. You may have another infection, or your test result may be false.

A negative result does not rule out COVID-19 and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be treated as presumptive and confirmed with a molecular assay, if necessary, for patient management.
If you receive a negative test, follow the instructions below:

• If you have COVID-19 symptoms, test again 48 hours after the first negative test, for a total of at least two tests.
• If you do not have COVID-19 symptoms and believe you have been exposed to COVID-19, test again 48 hours after the first negative test, then 48 hours after the second negative test, for a total of at least three tests.
• If any of the repeat tests are positive, you most likely have COVID-19 and should follow current Public Health measures. You do not need to perform repeat testing if you have a positive result at any time.
• If all repeat tests are negative and you are concerned you have COVID-19, you may choose to test again using an antigen test or consult with your health care provider regarding molecular testing.

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results.

| Status on First Day of Testing | First Result Day 1 | Second Result Day 3 | Third Result Day 5 | Interpretation |
|---|---|---|---|---|
| With Symptoms | Positive | N/A | N/A | Positive for COVID-19 |
| | Negative | Positive | N/A | Positive for COVID-19 |
| | Negative | Negative | N/A | Negative for COVID-19 |
| Without Symptoms | Positive | N/A | N/A | Positive for COVID-19 |
| | Negative | Positive | N/A | Positive for COVID-19 |
| | Negative | Negative | Positive | Positive for COVID-19 |
| | Negative | Negative | Negative | Negative for COVID-19 |

Results should be considered in the context of an individual's recent exposures, history, and the presence of clinical signs and symptoms consistent with COVID-19.

**Limitations of the procedure**

- The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
- The test should be used for the detection of SARS-CoV-2 antigen in human nasal swab samples.
- This is a qualitative test, therefore quantitative values of SARS-CoV-2 antigen concentration cannot be determined.
- Certain user groups (e.g. elderly individuals, children under the age of 14, individuals with impaired mobility and/or vision) may have to perform the test under supervision or with assistance from another person if they are not able to fully understand the instructions for use and/ or perform the test independently.
- False negative test results (i.e., an existing infection is falsely not detected) may occur if the antigen level in the specimen is less than the minimum detection limit of the test.
- False negative test results may occur if the specimen was collected incorrectly.
- False negative test results may occur if the specimen swab is not mixed well in the tube (step 8 in the test procedure section).
- Antigen can generally be detected using front nasal swab samples during the acute phase of infection.
- The immune response cannot be evaluated using this test. Other test methods are required for that purpose.
- Positive results indicate the presence of viral antigens. However, a clinical correlation with the case history and other diagnostic information are required to determine the status of the infection.
- Positive results do not exclude the possibility that a bacterial infection or a co-infection with another virus is present.
- False positive results may occur in the presence of SARS-CoV (from the 2003 outbreak) infections.
- Negative results should be viewed as provisional and a PCR test should be performed as confirmation if necessary.
- Negative results do not rule out a SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including decisions about infection control. Individuals who have tested negative and continue to show COVID-19-like symptoms should contact their doctor/primary care physician.
- The performance of the device has not been assessed on specimens from individuals who have been infected with emerging variants of SARS-CoV-2 of public health concern.

**Serial Testing Information and Limitations**

- Serial testing (i.e., testing every other day) is more likely to detect COVID-19, both when you do or do not have any symptoms.
- Symptomatic individuals that test negative should repeat testing at least twice over three days with at least 48 hours between tests and at least three times over five days with at least 48 hours between tests if they are asymptomatic.
- All COVID-19 antigen test negative results are presumptive and confirmation with a molecular assay may be necessary. If you continue to have symptoms of COVID-19, and both your first and second tests are negative, you may not have COVID-19, however you should follow-up with a healthcare provider.
- The performance of this test was not clinically validated for serial testing in patients with or without symptoms consistent with COVID-19. Serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the FDA.

**Specific performance data**
**Clinical evaluation**
The clinical performance of the SARS-CoV-2 Antigen Self Test Nasal was evaluated in a prospective, all-comer's study at 5 clinical sites in the United States. Symptomatic patients suspected of having COVID-19 (or legal guardians of underaged patients above 2 years of age) were approached to participate in the study. Patients were excluded if their symptoms had lasted longer than 7 days. Patients aged 14 years or older followed the instructions provided in the test kit to self-collect a nasal swab sample and performed the test themselves. Patients younger than 14 years of age were sampled and tested by an adult participant. A nasal swab sample was also taken from each study participant by a healthcare professional for testing on a high-sensitivity PCR method as the comparator.

In total, 168 participants between the age of 2 and 80, were included in this study, including 44 pediatric participants below the age of 14. Valid results were obtained for 158 participants. The SARS-CoV-2 Antigen Self Test Nasal correctly identified 41 out of 44 SARS-CoV-2-positive individuals, and 114 out of 114 SARS-CoV-2-negative individuals. The relative diagnostic sensitivity and specificity of SARS-CoV-2 Antigen Self Test Nasal were 93.2 % (95 % CI: 81.8 % - 97.7 %) and 100.0 % (95 % CI: 96.7 % - 100.0 %), respectively.

| | Positives Antigen / PCR | Negatives Antigen / PCR | PPA (95 % CI*) | NPA (95 % CI*) |
|---|---|---|---|---|
| Self Test | 41 out of 44 | 114 out of 114 | 93.2 % (81.8 - 97.7 %) | 100.0 % (96.7 - 100.0 %) |

*95 % confidence intervals (CI) were calculated using the exact Clopper-Pearson method.

This clinical performance data reflects the accuracy of the test when testing once. This test was not clinically validated for serial testing. The serial testing recommendations are supported by the study conducted by the National Institutes for Health (NIH) and the University of Massachusetts Chan Medical School in collaboration with the US FDA.

**Serial-testing clinical performance**
A prospective clinical study was conducted between January 2021 and May 2022 as a component of the Rapid Acceleration of Diagnostics (RADx) initiative from the National Institutes of Health (NIH). A total of 7,361 individuals were enrolled via a decentralized clinical study design, with a broad geographical representation of the United States. Per inclusion criteria, all individuals were asymptomatic upon enrollment in the study and at least 14 days prior to it and did not have a SARS-CoV-2 infection in the three months prior to enrollment. Participants were assigned to one of three EUA authorized SARS-CoV-2 OTC rapid antigen tests to conduct serial testing (every 48 hours) for 15 days. If an antigen test was positive, the serial-antigen testing result is considered positive.

At each rapid antigen testing time point, study subjects also collected a nasal swab for comparator testing using a home collection kit (using a 15-minute normalization window between swabs). SARS-CoV-2 infection status was determined by a composite comparator method on the day of the first antigen test, using at least two highly sensitive EUA RT-PCRs. If results of the first two molecular test were discordant a third highly sensitive EUA RT-PCR test was performed, and the final test result was based upon the majority rule. Study participants reported symptom status throughout the study using the MyDataHelps app. Two-day serial antigen testing is defined as performing two antigen tests 36 – 48 hours apart. Three-day serial antigen testing is defined as performing three antigen tests over five days with at least 48 hours between each test.

Out of the 7,361 participants enrolled in the study, 5,609 were eligible for analysis. Among eligible participants, 154 tested positive for SARS-CoV-2 infection based on RT-PCR, of which 97 (62%) were asymptomatic on the first day of their infection, whereas 57 (39%) reported symptoms on the first day of infection. Pre-symptomatic subjects were included in the positive percent agreement (PPA) of asymptomatic individuals, if they were asymptomatic on the first day of antigen testing, regardless of whether they developed symptoms at any time after the first day of testing.

Performance of the antigen test with serial testing in individuals is described in the table below.

Data establishing PPA of COVID-19 antigen serial testing compared to the molecular comparator single day testing throughout the course of infection with serial testing. Data is from all antigen tests in study combined.

| DAYS AFTER FIRST PCR POSITIVE TEST RESULT | ASYMPTOMATIC ON FIRST DAY OF TESTING<br>Ag Positive/PCR Positive (Antigen Test Performance % PPA) | | | SYMPTOMATIC ON FIRST DAY OF TESTING | | |
|---|---|---|---|---|---|---|
| | 1 Test | 2 Tests | 3 Tests | 1 Test | 2 Tests | 3 Tests |
| 0 | 9/97 (9.3%) | 35/89 (39.3%) | 44/78 (56.4%) | 34/57 (59.6%) | 47/51 (92.2%) | 44/47 (93.6%) |
| 2 | 17/34 (50.0%) | 23/34 (67.6%) | 25/32 (78.1%) | 58/62 (93.5%) | 59/60 (98.3%) | 43/43 (100%) |
| 4 | 16/21 (76.2%) | 15/20 (75.0%) | 13/15 (86.7%) | 55/58 (94.8%) | 53/54 (98.1%) | 39/40 (97.5%) |
| 6 | 20/28 (71.4%) | 21/27 (77.8%) | 16/18 (88.9%) | 27/34 (79.4%) | 26/33 (78.8%) | 22/27 (81.5%) |
| 8 | 13/23 (56.5%) | 13/22 (59.1%) | 4/11 (36.4%) | 12/17 (70.6%) | 12/17 (70.6%) | 7/11 (63.6%) |
| 10 | 5/9 (55.6%) | 5/8 (62.5%) | | 4/9 (44.4%) | 3/7 (42.9%) | |

1 Test= one (1) test performed on the noted days after first PCR positive test result. Day 0 is the first day of documented infection with SARS-CoV-2.
2 Tests= two (2) tests performed an average of 48 hours apart. The first test performed on the indicated day and the second test performed 48 hours later.
3 Tests= three (3) tests performance an average of 48 hours apart. The first test performed on the indicated day, the second test performed 48 hours later, and a final test performed 48 hours after the second test.

**Analytical performance**

**1. Cross-reactivity & microbial interference:**
There was no cross-reactivity and interference with the following microbes:
Human coronavirus 229E, Human coronavirus OC43, Human coronavirus NL63, Human coronavirus HKU1, SARS-coronavirus, MERS-coronavirus, Adenovirus Type 1, Adenovirus Type 2, Adenovirus Type 5, Adenovirus Type 6, Adenovirus Type 7A, Adenovirus Type 11, Adenovirus Type 14, Adenovirus Type 40, Human Metapneumo-virus 3 Type B1, Human Metapneumo-virus 16 Type A1, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4A, Influenza A H1N1 pdm/Michigan/45/15, Influenza A H1N1 Brisbane/59/07, Influenza A H3N2 Singapore/NFIMH-16-0019/16, Influenza A H3N2 South Australia/55/14, Influenza A H3N2 Hong Kong/8/68, Influenza A H3N2 Victoria/361/11, Influenza B Massachusetts/2/12, Influenza B Malaysia/2506/04, Influenza B Lee/40, Influenza B Yamagata/16/88, Influenza B Victoria/2/87, Influenza B Texas/6/11, Influenza B Colorado/6/17, Influenza B Florida/02/06, Enterovirus Type 68 09/2014 Isolate 4, Respiratory syncytial virus A, Respiratory syncytial virus B, Rhinovirus 1A, Rhinovirus A16, Rhinovirus B42, *Haemophilus influenzae* (NCCP 13815), *Haemophilus influenzae* (NCCP 13819), *Haemophilus influenzae* (NCCP 14581), *Haemophilus influenzae* (NCCP 14582), *Streptococcus pneumoniae* Type 1 (KCCM 41568), *Streptococcus pneumoniae* Type 2 (KCCM 40410), *Streptococcus pneumoniae* Type 3 (KCCM 41569), *Streptococcus pneumoniae* Type 5 (KCCM 41570), *Streptococcus pyogenes* (ATCC 12344), *Candida albicans* (ATCC 10231), *Bordetella pertussis* (NCCP 13671), *Mycoplasma pneumoniae* (ATCC 15531), *Chlamydia pneumoniae* (ATCC VR-2282), *Legionella pneumophila* (ATCC 33155), *Staphylococcus aureus* (NCCP 14647), *Staphylococcus epidermidis* (KCCM 35494).
**Note:** SARS-coronavirus and Human coronavirus HKU1 were tested using recombinant nucleocapsid protein. No cross-reactivity and interference was observed. Cross-reactivity was observed using live samples of SARS-coronavirus at high concentrations.

**2. Studies of exogenous / endogenous interference substances studies:**
There was no interference with the following substances at indicated concentrations:
Chloraseptic (Menthol/Benzocaine) (1.5 mg/mL), Naso GEL (NeilMed) (5 % v/v), CVS Health Nasal Drops (Phenylephrine) (15 % v/v), Afrin (Oxymetazoline) (15 % v/v), CVS Health Oxymetazoline (15 % v/v), CVS Health Nasal Spray (Cromolyn) (15 % v/v), Zicam (5 % v/v), Homeopathic (Alkalol) (10 % v/v), Sore Throat Phenol Spray (15 % v/v), Tobramycin (4 µg/mL), Mupirocin (10 mg/mL), CVS Health Fluticasone Propionate (5 % v/v), Tamiflu (Oseltamivir Phosphate) (5 mg/mL), Soap (Sodium Lauroyl Isethionate) (5 % w/v), Facial wash (Disodium Laureth Sulfosuccinate, Sodium Laureth-6 Carboxylate) (5 % w/v), Hand Sanitizer (Ethyl alcohol) (5 % v/v), Shampoo (Sodium Laureth Sulfate, Sodium Myreth Sulfate) (5 % v/v), Toothpaste (Sodium Lauryl Sulfate, Hydrogen Peroxide, Sodium Monofluorphosphate) (5 % w/v), Dish-washing liquid (Sodium Laureth Sulfate, Lauryl / Myristyl Glucoside) (5 % v/v), Laundry Detergent (Sodium Laureth Sulfate, C12-15 alcohols ethoxylated (or C12-16), Sodium C10-16 alkylbenzenesulfonate, Disodium distyrylbiphenyl disulfonate, C12-13 pareth-2, Sodium hydroxide) (5 % v/v), Bleach (Sodium percarbonate) (5 mg/mL), Surface cleaner for multiple use (Sodium Laureth Sulfate) (5 % v/v), Surface cleaner for bathroom (Sodium hypochlorite) (5 % v/v), Body lotion (5 % w/v), Hand lotion (5 % w/v), Facial suncream SPF 50+ (5 % w/v), Whole Blood (4 % v/v), Mucin (0.5 % w/v).

**3. Limit of Detection:**
The SARS-CoV-2 positive specimen was prepared by spiking inactivated SARS-CoV-2 (2019-nCOV) NCCP 43326/2020/Korea strain to SARS-CoV-2 negative nasal swab confirmed with PCR. LoD is determined as 1.30 x $10^1$ $TCID_{50}$/mL for direct nasal swab by testing serially diluted positive specimens.

**4. Variants of concern:**
Lab testing showed that the SARS-CoV-2 Antigen Self Test Nasal can qualitatively detect major variants of concern including Delta and Omicron variants. Emerging variants are continuously monitored.

A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

**References**


1 Wu et al. Nature. 2020. 579:265–9.
2 Coronaviruses. European Centre for Disease Prevention and Control. https://www.ecdc.europa.eu/en/covid-19/latest-evidence/coronaviruses. Accessed 6 Jan 2021.
3 Coronaviridae Study Group of the International Committee on Taxonomy of Viruses. Nat Microbiol. 2020. 5:536–44.
4 https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-%28covid-2019%29-and-the-virus-that-causes-it.
5 WHO. https://www.who.int/publications-detail-redirect/diagnostic-testing-for-sars-cov-2. Accessed 6 Jan 2021.
6 Centers for Disease Control and Prevention. https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/symptoms.html. Accessed 6 Jan 2021.


**Symbols**

| | |
|---|---|
| REF | Reference number |
| LOT | Batch code |
| IVD | In vitro diagnostic medical device |
| GTIN | Global Trade Item Number |
| UDI | Unique Device Identifier |
| SN | Serial Number |
| SYSTEM | Systems on which reagents can be used |
| CE | This product fulfills the requirements of the European Directive 98/79/EC |
| | Consult instructions for use |
| | Caution |
| | Warning |
| Σ | Contains sufficient for <n> tests |
| | Use-by date |
| | Temperature limit |
| | Do not re-use |
| | Do not use if package is damaged |
| | Date of manufacture |
| | Manufacturer |
| | Keep away from sunlight |
| | Keep product dry |
| EC REP | European Authorized Representative |
| | Distributor |

Additions, deletions or changes are indicated by a change bar in the margin.



a) Swab manufacturers of potentially included swabs:

**[1]** Model No. 96000G: Miraclean Technology Co., Ltd. Room 301, Building A, No.18, Rongshuxia Industrial Zone, Tongxin Community, Baolong Street, Longgang District, Shenzhen, 518116 Guangdong, P.R. China — CE 0197, acc. 93/42/EEC
EC REP Swab Authorized Representative: Share Info Consultant Service LLC, Repräsentanzbüro Heerdter Lohweg 83, 40549 Düsseldorf, Germany

**[2]** Model No. FASP10: FA INC., 10-5, Myeonghaksandanseo-ro, Yeondong-myeon, Sejong-si, 30068, Republic of KOREA — CE 1639, acc. 93/42/EEC
EC REP Swab Authorized Representative: MT Promedt Consulting GmbH, Altenhofstrasse 80, 66386 St. Ingbert, Germany

**[3]** Model No. NSA-T3: WIZCHEM CO., LTD., Bio Venture Town 401-404, Daejeon Techno-Park, 1662, Yuseong-daero, Yuseong-gu, Daejeon, 34054, Republic of KOREA — CE 1023, acc. 93/42/EEC
EC REP Swab Authorized Representative: Intermundien-Lemon Europe GmbH, Brueckstrasse 47, 44787 Bochum, Germany

**[4]** Model No. MFS-93000KQ: Medico Technology Co., Ltd., Room 201 of Building 14th and Building 17th, Hengyi Lane, Yuanhu Road, Zhangbei Industrial Park, Longcheng Street, Longgang district, Shenzhen, Guangdong, China — CE 0413, acc. 93/42/EEC
EC REP Swab Authorized Representative: Wellkang Ltd., Enterprise Hub, NW Business Complex, 1 Beraghmore Road, Derry, BT48 8SE, Northern Ireland, UK

**[5]** Model No. G-015: Jiangsu HanHeng Medical Technology Co., Ltd., 16-B4, #1 North Qingyang Road, Tianning District, 213017 Changzhou, Jiangsu, China — CE 0197, acc. 93/42/EEC
EC REP Swab Authorized Representative: Luxus Lebenswelt GmbH, Kochstrasse 1, 47877 Willich, Germany

For all questions about the SARS-CoV-2 Antigen Self Test Nasal that are not answered in this package insert, there is a FAQ document available on the Roche Canada website (www.rochecanada.com). Please look for the documentation section via the search engine on the website. Please contact Roche Care Center for technical questions at 1-877-273-3433.
The SARS-CoV-2 Antigen Self Test is distributed in Canada by:
Roche Diagnostics
201 Armand-Frappier Boulevard
Laval, Quebec (Canada) H7V 4A2

| | |
|---|---|
| | **SD BIOSENSOR**<br>Head office: C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690 REPUBLIC OF KOREA<br>Manufacturing site: 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161 REPUBLIC OF KOREA<br>www.sdbiosensor.com |
| **Distribution by:** | Roche Diagnostics GmbH, Sandhofer Strasse 116, D-68305 Mannheim<br>www.roche.com<br>Roche order number: 09445323 |
| EC REP Authorized Representative | MT Promedt Consulting GmbH, Altenhofstrasse 80, 66386 St. Ingbert, Germany |

**For additional information on the test, and digital solutions, please visit the website below.**

**https://www.diagnostics.roche.com/covidqr-patients**

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