EN REF 9901-NCOV-04G

Roche order number 09365397160

# SARS-CoV-2 Rapid Antigen Test
## Nasal

For prescription use only
For in vitro diagnostic use only

SD BIOSENSOR

PLEASE READ CAREFULLY BEFORE YOU PERFORM THE TEST

## INTENDED USE
The SARS-CoV-2 Rapid Antigen Test is a lateral flow rapid chromatographic immunoassay for the qualitative detection of nucleocapsid antigen to SARS-CoV-2 present in human nasal samples. This test is intended for use as an aid in detection of SARS-CoV-2 infection in individuals suspected of COVID-19 with clinical symptoms onset within 5 days. Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in human nasal swab samples during the acute phase of infection. Positive results indicate the presence of viral antigens, but clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Negative results should be treated as presumptive, and do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19, and confirmed with a molecular assay, if necessary, for patient management. The SARS-CoV-2 Rapid Antigen Test is intended for use in laboratory or POC settings by healthcare professionals, or self-collection under the supervision of a healthcare worker.

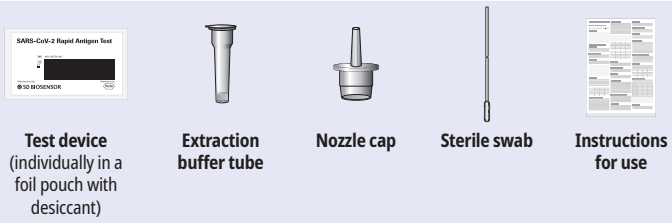
## INTRODUCTION
Coronaviruses can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and dyspnea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome, kidney failure, and even death. In late 2019 a new coronavirus, later named SARS-CoV-2[1], was identifi ed in a cluster of pneumonia cases, and the World Health Organization described the global SARS-CoV-2 situation as pandemic on March 11, 2020[2]. The disease associated with SARS-CoV-2 infection was named COVID-19 (COronaVIrus Disease 2019)[3].

## PRINCIPLE OF THE TEST
The SARS-CoV-2 Rapid Antigen Test has two pre-coated lines: A "C" Control line and a "T" Test line on the surface of the nitrocellulose membrane. Both the control line and test line in the result window are not visible before applying any samples. Mouse monoclonal anti-SARS-CoV-2 antibody is coated on the test line region and mouse monoclonal anti-Chicken IgY antibody is coated on the control line region. Mouse monoclonal anti-SARS-CoV-2 antibody conjugated with color particles are used as detectors for the SARS-CoV-2 antigen device. During the test, the SARS-CoV-2 antigen in the sample interacts with monoclonal anti-SARS-CoV-2 antibody conjugated with color particles making an antigen-antibody color particle complex. This complex migrates on the membrane via capillary action to the test line, where it is captured by the mouse monoclonal anti-SARS-CoV-2 antibody. A colored test line becomes visible in the result window if SARS-CoV-2 antigens are present in the sample.

Even if the test line is very faint or not uniform the test result should be interpreted as a positive result. If SARS-CoV-2 antigens are not present in the sample, no color appears in the test line. The control line is used for procedural control, and always appears if the test result is valid. If no control line is visible the test result should be considered as invalid.

## ACTIVE COMPONENTS
- mAb anti-COVID 19 antibody
- mAb anti-Chicken IgY
- mAb anti-COVID-19 antibody-gold conjugate
- Purified chicken IgY-gold conjugate

## KIT CONTENTS



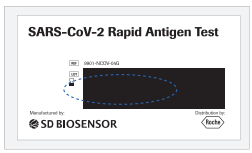

**Test device** (individually in a foil pouch with desiccant) | **Extraction buffer tube** | **Nozzle cap** | **Sterile swab** | **Instructions for use**

## KIT STORAGE AND STABILITY
1. Store the kit at 2-30°C / 36-86°F out of direct sunlight.
2. Kit materials are stable until the expiration date printed on the outer box.
3. Do not freeze the kit.

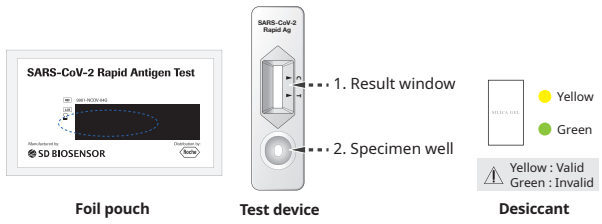
## MATERIALS REQUIRED BUT NOT SUPPLIED
Timer
External controls: SARS-CoV-2 Antigen Control (Roche order number 09338322160)

## WARNINGS AND PRECAUTIONS
1. Equilibrate the kit contents and specimens to operating temperature before testing.
2. Do not re-use the test kit.
3. Do not use the test kit if the pouch is damaged or the seal is broken.
4. Do not use the extraction buffer of another lot.
5. Do not smoke, drink or eat while handling the sample.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
7. Clean up spills thoroughly using an appropriate disinfectant.
8. Handle all samples as if they contain infectious agents.
9. Observe established precautions against microbiological hazards throughout testing procedures.
10. Dispose of all samples and materials used to perform the test as biohazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
11. Desiccant in foil pouch is to absorb moisture and keep humidity from affecting products. If the desiccant beads change from yellow to green, the test device in the pouch should be discarded.

## KIT PREPARATION
1. Carefully read instructions for using the SARS-CoV-2 Rapid Antigen Test.
2. Check the expiry date on the back of the foil pouch. Do not use the test if the expiry date has passed.

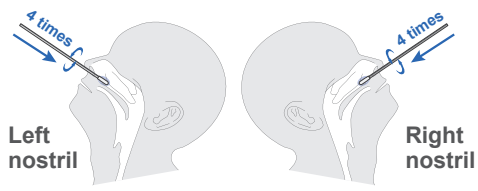



3. Open the foil pouch and remove the test device and the desiccant package. Use the test immediately after opening the pouch.
4. Ensure that the test device is undamaged and that the desiccant status indicator shows valid (yellow).




5. Perform a QC test as recommended in the EXTERNAL QUALITY CONTROL section and according to the Instructions for Use of the QC material.

## SPECIMEN COLLECTION, TRANSPORT AND STORAGE
### Nasal swab




1. Tilt patient's head back slightly
2. While rotating the swab, insert swab approximately one inch (about 2 cm) into nostril until resistance is met at turbinates.
3. Slowly rotate the swab in a circular path against the nasal wall at least 4 times for a minimum of 15 seconds.
4. Repeat in other nostril using the same swab.

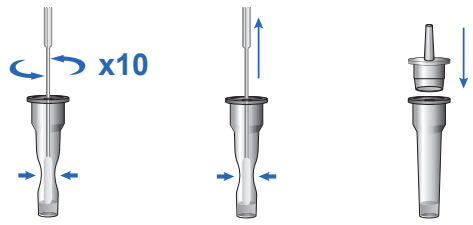
### Transport and storage
Samples should be tested as soon as possible after specimen collection.
Specimens in extraction buffer are stable for up to 1 hour at room temperature (20±5°C), up to four hours when stored refrigerated at 5±3°C. If stored frozen at -20°C, specimens in extraction buffer are stable for only one (1) freeze/thaw cycle.
Dry swab specimens are stable for 1 hour at room temperature (20±5°C).

## TEST PROCEDURE
Prior to starting the procedure, test devices and reagents must be equilibrated to operating temperature (15-30°C/ 59-86°F) for at least 30 minutes prior to the test.

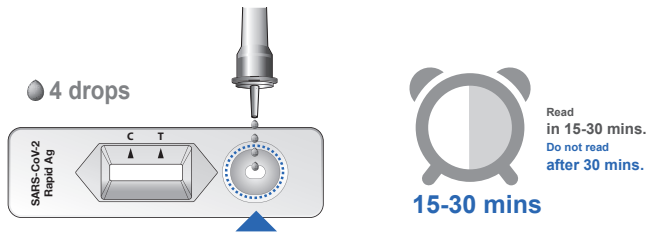
### Preparation
Carefully open extraction buffer tube avoiding spillage.

If buffer is spilled, do not use the tube.

### Fresh specimen
1. Insert the swab from patient into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 10 times.
2. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
3. Press the nozzle cap tightly onto the tube.




4. Apply 4 drops of extracted specimen to the specimen well of the test device.
5. Read test result at 15-30 minutes.




- Place the test device on a flat surface
- Dispense the specimen at a 90 degree angle to allow for free falling drops and avoid bubbles.
- **Do not read test results after 30 minutes. It may give false results.**

## INTERNAL QUALITY CONTROL
A control line is used in the test as a procedural control. A visible control line confirms that the lateral flow of the test is successful but is not the confirmation that the specimen and buffer have been applied properly.

## EXTERNAL QUALITY CONTROL
External positive and negative controls are not included in the SARS-CoV-2 Rapid Antigen Test kit. These controls can be purchased as additional quality control to demonstrate a positive or negative reaction (REF 9901-C-NCOV-01G).

It is recommended that positive and negative controls be run:
- Once for each new lot,
- Once for each untrained operator,
- Once for each new shipment of test kits,
- As required by test procedures in these instructions and in accordance with local, state and federal regulations or accreditation requirements.

## READING AND INTERPRETING RESULTS

| SARS-CoV-2 Antigen Control: Positive | | | |
|---|---|---|---|
| Result | | Interpretation | Follow up |
| Test (T) Line | Control (C) Line | | |
| Positive | Positive | Pass | - |
| Negative | Positive | Fail | Retest* |
| No Control (C) Line | | Invalid | Retest* |

| SARS-CoV-2 Antigen Control: Negative | | | |
|---|---|---|---|
| Result | | Interpretation | Follow up |
| Test (T) Line | Control (C) Line | | |
| Negative | Positive | Pass | - |
| Positive | Positive | Fail | Retest* |
| No Control (C) Line | | Invalid | Retest* |

* Use new test devices and new control for retest.

## INTERPRETATION OF TEST RESULT

| Test result | Example | Description |
|---|---|---|
| Negative* |  | 1. A colored band will appear in the top section of the result window to show that the test is working properly. This band is control line (C). |
| Positive* |   | 2. A colored band will appear in the lower section of the result window. This band is test line of SARS-CoV-2 antigen (T). |
| Invalid |   | 3. An absent control line, indicates an invalid test result. In case of an invalid result, perform QC and repeat test. |

* Even if the control line or test line is faint or not uniform, the test should be considered to be performed properly and the test result should be interpreted.

## LIMITATIONS
1. The test procedure, precautions and interpretation of results for this test must be followed strictly when testing.
2. The test should be used for the detection of SARS-CoV-2 antigen in human nasal swab samples.
3. This test cannot be used for quantifying SARS-CoV-2 antigen concentration.
4. Failure to follow the test procedure and interpretation of test results may adversely affect test performance and/or produce invalid results.
5. The immune response cannot be assessed with this test and needs other testing methods.
6. The test result should not be used as a sole basis for treatment or patient management decisions, and should be considered in the context of the patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.
7. A negative result may occur if the concentration of antigen in a sample is below the detection limit of the test or if the sample was collected or transported improperly. Therefore a negative test result does not eliminate the possibility of SARS-CoV-2 infection, and should be confirmed by a molecular assay, if necessary for patient management.
8. Positive test results do not rule out co-infections with other pathogens.
9. Positive test results do not differentiate between SARS-CoV-2 and SARS-CoV.
10. Negative test results are not intended to rule in or rule out other coronavirus infection.
11. The performance of this device has not been assessed in a population vaccinated against COVID-19

## SPECIFIC PERFORMANCE DATA
### Clinical evaluation
Clinical performance of the SARS-CoV-2 Rapid Antigen Test Nasal was evaluated using nasal swab samples from 696 subjects in a prospective study at a clinical center in Germany. The study cohort included adults at high risk for SARS-CoV-2 infection according to clinical suspicion. 311 subjects underwent nasal sampling performed by healthcare professionals and 385 subjects followed instructions to obtain a nasal swab sample by themselves. Self-collection was performed under the supervision of healthcare workers without interference or assistance. Test procedures and result reading were always performed by healthcare professionals. RT-PCR tests (Roche cobas® SARS-CoV-2 and TibMolbiol SARS-CoV-2 E-gene assay) using combined nasopharyngeal/oropharyngeal swab samples were used as the comparator methods. Nasal sampling always preceded the combined NP/OP sampling.

The following tables summarize the patient and performance characteristics of the SARS-CoV-2 Rapid Antigen Test Nasal. The relative sensitivity was 89.6 % (Ct value ≤ 30; 95 % CI: 79.7 % - 95.7 %) for professionally collected samples, and 89.1 % (Ct value ≤ 30; 95 % CI: 78.8 % - 95.5 %) for self-collected samples. For patients for whom days post symptom onset was known, and was 0-5 days, the relative sensitivity in comparison to RT-PCR was 86.7 % (95 % CI: 75.4 % - 94.1 %) for professionally collected nasal samples and 88.9 %(95 % CI: 77.4 % - 95.8 %) for self-collected nasal samples. The relative specificity in comparison to RT-PCR was 99.1 % (95 % CI: 96.9 % -99.9 %) for professionally collected nasal samples and 99.0 % (95% CI: 97.2 % -99.8 %) for self-collected nasal samples.

In total, nasal swab samples from 150 PCR-positive and 546 PCR-negative individuals were evaluated using the SARS-CoV-2 Rapid Antigen Test Nasal. The relative sensitivity and relative specificity were 82.7 % (95 % CI: 75.6 % - 88.4 %) and 99.1 % (95 % CI: 97.9 % - 99.7 %), respectively.

**Summary of sample characteristics and performances:**

| | Overall | HCP-collection | Self-collection |
|---|---|---|---|
| **N** | 696 | 311 | 385 |
| **Asymptomatic, n/N (%)** | 20/696 (2.9 %) | 7/311 (2.3 %) | 13/385 (3.4 %) |
| **Symptomatic, n/N (%)** | 676/696 (97.1 %) | 304/311 (97.7 %) | 372/385 (96.6 %) |
| **DPSO, median (range)** | 3 (0 - 27) | 3 (0 - 15) | 4 (0 - 27) |
| **PCR positive, n/N (%)** | 150/696 (21.6 %) | 77/311 (24.8 %) | 73/385 (19.0 %) |
| **PCR positive symptomatic, n/N (%)** | 147/150 (98.0 %) | 75/77 (97.4 %) | 72/73 (98.6 %) |
| **PCR positive asymptomatic, n/N (%)** | 3/150 (2.0 %) | 2/77 (2.6 %) | 1/73 (1.4 %) |
| **PCR negative, n/N (%)** | 546/696 (78.4 %) | 234/311 (75.2 %) | 312/385 (81.0 %) |
| **PCR sample type** | Combined OP/NP | | |

| **Relative sensitivity, % (95 % CI), N** | **Professional collection** | **Self-collection** |
|---|---|---|
| **Ct[a] ≤ 24** | 97.7 % (CI: 88.0 % - 99.9 %), 44 | 97.9 % (CI: 88.7 % - 99.9 %), 47 |
| **Ct[a] ≤ 27** | 93.1 % (CI: 83.3 % - 98.1 %), 58 | 94.7 % (CI: 85.4 % - 98.9 %), 57 |
| **Ct[a] ≤ 30** | **89.6 % (CI: 79.7 % - 95.7 %), 67** | **89.1 % (CI: 78.8 % - 95.5 %), 64** |
| **Ct[a] ≤ 33** | 87.1 % (CI: 77.0 % - 93.9 %), 70 | 84.5 % (CI: 74.0 % - 92.0 %), 71 |
| **All Ct values** | 83.1 % (CI: 72.9 % - 90.7 %), 77 | 82.2 % (CI: 71.5 % - 90.2 %), 73 |

a) for samples run on **cobas** the Target 2 (E gene) Ct values were used.

| **Relative specificity, % (95 % CI), N** | **Professional collection** | **Self-collection** |
|---|---|---|
| **All Ct values** | 99.1 % (CI: 96.9 % - 99.9 %), 234 | 99.0 % (CI: 97.2 % - 99.8 %), 312 |

**Summary of all nasal samples evaluated and overall performance:**

| | PCR positive | PCR negative | Total |
|---|---|---|---|
| Antigen positive | 124 | 5 | 129 |
| Antigen negative | 26 | 541 | 567 |
| Total | 150 | 546 | 696 |
| Relative sensitivity | **82.7 % (95 % CI: 75.6 % - 88.4 %)** | | |
| Relative specificity | **99.1 % (95 % CI: 97.9 % - 99.7 %)** | | |

## ANALYTICAL PERFORMANCE

### Limit of detection (LoD)

The SARS-CoV-2 positive specimen was prepared by spiking inactivated SARS-CoV-2 (2019-nCOV) NCCP 43326/2020/Korea strain in negative clinical matrix using SARS-CoV-2 negative nasal swab confirmed with PCR. LoD is determined as 9.25 x $10^{1.2}$ $TCID_{50}$/mL (146.6 $TCID_{50}$/mL) for direct nasal swab by testing serially diluted positive specimens.

### Cross-reactivity

No cross-reactivity was observed for the following microorganisms at the indicated concentrations, with the exception of SARS-CoV. All microorganisms were spiked into negative clinical matrix for testing.

| Virus/Bacteria | Concentration | Results |
|---|---|---|
| Extraction buffer with negative nasal matrix[a] | N/A | NEG |
| Human coronavirus 229E[b] | 2.18 X $10^5$ PFU/mL | NEG |
| Human coronavirus OC43[b] | 4.06 X $10^7$ PFU/mL | NEG |
| Human coronavirus NL63[b] | 1.17 X $10^5$ PFU/mL | NEG |
| MERS-coronavirus[b] | 2.87 X $10^5$ PFU/mL | NEG |
| SARS-coronavirus[c] | N/A | POS |
| Adenovirus Type1[b] | 1.77 X $10^8$ PFU/mL | NEG |
| Adenovirus Type2[b] | 7.93 X $10^6$ PFU/mL | NEG |
| Adenovirus Type5[b] | 2.33 X $10^7$ PFU/mL | NEG |
| Adenovirus Type6[b] | 1.34 X $10^7$ PFU/mL | NEG |
| Adenovirus Type7A[b] | 9.74 X $10^4$ PFU/mL | NEG |
| Adenovirus Type11[b] | 1.34 X $10^7$ PFU/mL | NEG |
| Adenovirus Type14[b] | 1.69 X $10^5$ PFU/mL | NEG |
| Adenovirus Type40[b] | 2.62 X $10^6$ PFU/mL | NEG |
| Human Metapneumovirus3 type B1[b] | 1.50 X $10^6$ PFU/mL | NEG |
| Human Metapneumovirus16 type A1[b] | 6.58 X $10^6$ PFU/mL | NEG |
| Parainfluenza virus 1[b] | 2.13 X $10^8$ PFU/mL | NEG |
| Parainfluenza virus 2[b] | 8.68 X $10^5$ PFU/mL | NEG |
| Parainfluenza virus 3[b] | 4.55 X $10^6$ PFU/mL | NEG |
| Parainfluenza virus 4A[b] | 2.62 X $10^6$ PFU/mL | NEG |
| Influenza A H1N1 pdm/Michigan/45/15[b] | 8.68 X $10^5$ PFU/mL | NEG |
| Influenza A H1N1 Brisbane/59/07[b] | 4.99 X $10^5$ PFU/mL | NEG |
| Influenza A H3N2 Singapore/INFIMH-16-0019/16[b] | 3.22 X $10^4$ PFU/mL | NEG |
| Influenza A H3N2 South Australia/55/14[b] | 8.1 X $10^4$ PFU/mL | NEG |
| Influenza A H3N2 Hong Kong/8/68[b] | 3.45 X $10^5$ PFU/mL | NEG |
| Influenza A H3N2 Victoria/361/11[b] | 9.74 X $10^4$ PFU/mL | NEG |
| Influenza B Massachusetts/2/12[b] | 1.69 X $10^5$ PFU/mL | NEG |
| Influenza B Malaysia/2506/04[b] | 2.87 X $10^5$ PFU/mL | NEG |
| Influenza B Lee/40[b] | 1.69 X $10^5$ PFU/mL | NEG |
| Influenza B Yamagata/16/88[b] | 1.69 X $10^5$ PFU/mL | NEG |
| Influenza B Victoria/2/87[b] | 1.28 X $10^4$ PFU/mL | NEG |
| Influenza B Texas6/11[b] | 2.62 X $10^6$ PFU/mL | NEG |
| Influenza B Colorado6/17[b] | 3.22 X $10^4$ PFU/mL | NEG |
| Influenza B Florida/02/06[b] | 2.62 X $10^6$ PFU/mL | NEG |
| Enterovirus type 68 09/2014 Isolate 4[b] | 2.44 X $10^5$ PFU/mL | NEG |
| Respiratory syncytial virus A[b] | 2.62 X $10^6$ PFU/mL | NEG |
| Respiratory syncytial virus B[b] | 3.45 X $10^5$ PFU/mL | NEG |
| Rhinovirus 1A[b] | 2.44 X $10^6$ PFU/mL | NEG |
| Rhinovirus A16[b] | 8.68 X $10^6$ PFU/mL | NEG |
| Rhinovirus B42[b] | 7.24 X $10^5$ PFU/mL | NEG |
| Haemophilus influenzae (NCCP 13815)[a] | N/A | NEG |
| Haemophilus influenzae (NCCP 13819)[a] | N/A | NEG |
| Haemophilus influenzae (NCCP 14581)[a] | N/A | NEG |
| Haemophilus influenzae (NCCP 14582)[a] | N/A | NEG |
| Streptococcus pneumoniae type1 (KCCM 41560)[a] | N/A | NEG |
| Streptococcus pneumoniae type2 (KCCM 40410)[a] | N/A | NEG |
| Streptococcus pneumoniae type3 (KCCM 41569)[a] | N/A | NEG |
| Streptococcus pneumoniae type5 (KCCM 41570)[a] | N/A | NEG |
| Streptococcus pyogenes (ATCC 12344)[a] | N/A | NEG |
| Candida albicans (ATCC 10231)[a] | N/A | NEG |
| Bordetella pertussis (NCCP 13671)[a] | N/A | NEG |
| Mycoplasma pneumoniae (ATCC 15531)[d] | N/A | NEG |
| Chlamydia pneumoniae (ATCC VR-2282)[d] | N/A | NEG |
| Legionella pneumophila (ATCC 33155)[a] | N/A | NEG |
| Staphylococcus aureus (NCCP 14647)[a] | N/A | NEG |
| Staphylococcus epidermidis (KCCM 35494)[a] | N/A | NEG |

a) Bionote
b) Zeptometrix
c) BEI
d) ATCC

Human coronavirus HKU1, Mycobacterium tuberculosis, and Pneumocystis jirovecii (PJP) have not been tested. A low probability of cross-reactivity was determined for in-silico analysis.

### Microbial interference

For microorganism that did not cross-react, additional microbial testing was performed and no microbial interference was found.

### Endogenous / exogenous interference substances studies

There was no interference on the test result from potentially interfering substances listed below. SARS-CoV-2 positive and negative samples were tested.

a) Results from interference testing from SARS-CoV-2 negative samples:

| Potential interfering substance | Concentration | Results |
|---|---|---|
| Whole blood (EDTA) | 4% | NEG |
| Mucin | 0.5% | NEG |
| Chloraseptic (Menthol/Benzocaine) | 1.5 mg/mL | NEG |
| Naso GEL (NeilMed) | 5% v/v | NEG |
| CVS Health Nasal Drops (Phenylephrine) | 15% v/v | NEG |
| Afrin (Oxymetazoline) | 15% v/v | NEG |
| CVS Health Oxymetazoline | 15% v/v | NEG |
| CVS Health Nasal Spray (Cromolyn) | 15% v/v | NEG |
| Zicam | 5% v/v | NEG |
| Homeopathic (Alkalol) | 1:10 dilution | NEG |
| Sore Throat Phenol Spray | 15% v/v | NEG |
| Tobramycin | 4 µg/mL | NEG |
| Mupirocin | 10 mg/mL | NEG |
| CVS Health Fluticasone Propionate | 5% v/v | NEG |
| Tamiflu (Oseltamivir Phosphate) | 5 mg/mL | NEG |

b) Results from interference testing with SARS-CoV-2 positive samples:

| Potential interfering substance | Concentration | Viral strain level[e] | Results[f] |
|---|---|---|---|
| Whole blood (EDTA) | 4% | SARS-CoV-2 cultured virus media[g] | POS |
| Mucin | 0.5% | SARS-CoV-2 cultured virus media[g] | POS |
| Chloraseptic (Menthol/Benzocaine) | 1.5 mg/mL | SARS-CoV-2 cultured virus media[g] | POS |
| Naso GEL (NeilMed) | 5% v/v | SARS-CoV-2 cultured virus media[g] | POS |
| CVS Health Nasal Drops (Phenylephrine) | 15% v/v | SARS-CoV-2 cultured virus media[g] | POS |
| Afrin (Oxymetazoline) | 15% v/v | SARS-CoV-2 cultured virus media[g] | POS |
| CVS Health Oxymetazoline | 15% v/v | SARS-CoV-2 cultured virus media[g] | POS |
| CVS Health Nasal Spray (Cromolyn) | 15% v/v | SARS-CoV-2 cultured virus media[g] | POS |
| Zicam | 5% v/v | SARS-CoV-2 cultured virus media[g] | POS |
| Homeopathic (Alkalol) | 1:10 dilution | SARS-CoV-2 cultured virus media[g] | POS |
| Sore Throat Phenol Spray | 15% v/v | SARS-CoV-2 cultured virus media[g] | POS |
| Tobramycin | 4 µg/mL | SARS-CoV-2 cultured virus media[g] | POS |
| Mupirocin | 10 mg/mL | SARS-CoV-2 cultured virus media[g] | POS |
| CVS Health Fluticasone Propionate | 5% v/v | SARS-CoV-2 cultured virus media[g] | POS |
| Tamiflu (Oseltamivir Phosphate) | 5 mg/mL | SARS-CoV-2 cultured virus media[g] | POS |

e) In multiples of LoD
f) Detected X/3
g) Dilution 2.78 X $10^{2.2}$ $TCID_{50}$/mL

### High-dose hook effect

SARS-CoV-2 cultured virus was spiked into negative clinical matrix. SARS-CoV-2 cultured virus did not show hook-effect up to 1 x $10^{6.2}$ $TCID_{50}$/mL.

## REFERENCES


1. Gorbalenya et al. Nat Microbiol. 2020;5:536-44.
2. WHO. https://www.who.int/director-general/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-March-2020. Accessed 6 Jan 2021.
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For all questions about the SARS-CoV-2 Rapid Antigen 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 Rapid Antigen Test is distributed in Canada by:

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REF Reference number
IVD *In vitro* Diagnostics
Consult Instructions for Use
GTIN Global Trade Item Number
UDI Unique Device Identifier
CODE Manufacturer's batch code
Contains Sufficient for <n> Tests
Caution
Note
Do not re-use.
Temperature limit
Use-by date
LOT Batch code
Manufacturer
Keep product dry
Keep away from sunlight
Do not use if package is damaged