FREQUENTLY ASKED QUESTIONS (FAQ)

1. How do I perform the test?

The Rapid SARS-CoV-2 Antigen Test Card is a one step lateral flow test for the detection of SARS-CoV-2 virus antigen in nasal swab specimens. The test is used only for the detection of SARS-CoV-2 viral antigen in nasal swab specimens. Children under 14 years of age should be assisted by an adult.

INTENDED USE
Rapid SARS-CoV-2 Antigen Test Card is a one step lateral flow test for the detection of SARS-CoV-2 virus antigen in nasal swab specimens. The following 27 microorganisms had no impact on the performance of the Rapid SARS-CoV-2 Antigen Test Card: Human SARS-coronavirus, Influenza A virus (H3N2), Influenza B virus (Yamagata), Influenza B virus (Victoria), Adenovirus, NERS-coronavirus, Chlorpyrifos, Streptococcus pneumoniae, Streptococcus pyogenes, Borrelia pertussis, Mycobacterium tuberculosis, Legionella pneumophila, Mycoplasma pneumoniae, Haemophilus influenzae, Candida albicans, Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli.

INTERFERENCE
None of the following substances at the tested concentration showed any interference with the test result: Whole Blood 1%, Phenylenediamine 1%, Menthol 0.15%, Fluosilicate Proparlene 5%, Citrium Phosphate 0.5%, (B)oric Acid 1200 ppm, Alkaloid 10%, Tobramycin 0.0004%, Cornstarch 15%, Magnesium (0.2%), sodium chloride 5%, Musite 2%, Deplycopine 15%, Benzocaine 0.15%. Zaxan Nasal Spray 5%, Human Anthrax Antibody (HAMA) 60 ng/mL.

ACCURACY
The accuracy of the rapid SARS-CoV-2 antigen test card was determined using 833 nasal swab specimens. Positive test results did not rule out co-infections with other disease-causing agents. Positive results may occur in cases of infection with SARS-CoV-2.
Rapid SARS-CoV-2 Antigen Test Card

Quick Reference Guide for Patients

This guide is a reference for using the Rapid SARS-CoV-2 Self Test for Nasal Swab Specimens.

**Materials Provided**

- Sterile swab
- Test Card (sealed foil pouch)
- Extraction tube
- Sample extraction buffer
- Tube stand
- Instructions for use

**Preparation**

- Wash your hands.
- Clear and dry a flat surface.
- Check the kit contents.
- Make sure that nothing is damaged or broken.
- Have a timer ready.
- Blow your nose several times before taking the sample.
- Wash your hands again.

**Procedure**

1. Place the extraction tube in the tube stand to avoid spilling the liquid.
2. Rotate the lid of sample extraction buffer bottle.
   - **CAUTION:** Open it away from your face and be careful not to spill any of the liquid.
3. Squeeze all the extraction buffer out of the bottle into the extraction tube.
   - **CAUTION:** Avoid touching the bottle against the tube.
4. Find the swab in the sealed wrapper. Identify the soft, fabric tip on the swab.
5. Peel open the wrapper of the swab and carefully pull out the swab.
   - **CAUTION:** Do not touch the soft, fabric tip of the swab with your fingers while removing the swab any deeper if you feel strong resistance or pain.
6. Carefully insert the swab into one nostril. The swab tip should be inserted at least 2.5 cm from the edge of the nostril. Roll the swab 3-4 times along the mucosa inside the nostril to ensure that both mucus and cells are collected.
7. Leave swab in the nostril for several seconds. Using the same swab, repeat this process for the other nostril.
   - **CAUTION:** This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.
8. Pinch the extraction tube together 3-5 times.
   - **CAUTION:** Do not add drops to the larger well. Do not add more than 3 drops. Do not agitate the tube. Avoid the formation of air bubbles.
9. Install the nozzle cap onto the sample extraction tube tightly. Replace the tube in the tube holder.
10. Open the foil pouch and remove the test card. Place the test card on a flat and level surface.
   - **CAUTION:** Once opened, the test card must be used immediately.
11. Insert the extraction tube and add 3 drops only of test specimen into the speciﬁm well (S), by gently squeezing the extraction tube.
   - **CAUTION:** Do not add drops to the larger well. Do not add more than 3 drops. Do not agitate the tube. Avoid the formation of air bubbles.
12. Read the results at 15-20 minutes.
   - **CAUTION:** Results after 20 minutes may not be accurate.

**Disposal Instructions**

Place all the used test components into a tear-resistant waste bag and dispose of them in the trash according to local waste regulations.

**Interpretation of Results**

**Negative**

If one coloured band appears in the Control Zone (C) and no colored band appears in the Test Zone (T) within 15-20 minutes, the test result is negative and valid. A negative result does not exclude a viral infection with SARS-CoV-2 and should be confirmed by laboratory RT-PCR if COVID-19 is suspected.

**Positive**

If two coloured bands appear, with one coloured band in the Control Zone (C) and another in the Test Zone (T) within 15-20 minutes, the test result is positive and valid. The result should be considered as positive no matter how faint the coloured band is in the Test Zone (T). A positive test must be confirmed by laboratory RT-PCR.

**Invalid**

If no coloured band appears in the control area (C) within 15-20 minutes, the test is invalid even if there is a coloured band in the Test Zone (T). Repeat the test with a new test card.

**Quality Control**

The control line is used to control the procedure. The control line appears when the test has been performed correctly and the reagents are reactive.