SARS-CoV-2 Rapid Antigen Test

**Purpose**

To detect the presence of SARS-CoV-2 viral antigens in nasopharyngeal secretions using a rapid antigen test. The test is intended to detect antigen from SARS-CoV-2 in respiratory tract secretions or other body fluids (e.g., blood) within the first 2 to 3 days of SARS-CoV-2 infection.

**Summary**

Carefully read and understand the steps and procedures described in the test kit. It is recommended to perform the test as soon as possible after symptom onset.

**Test principle**

The test is based on the capture of SARS-CoV-2 viral antigens in the patient's respiratory tract secretions. The test uses a monoclonal antibody directed against a specific viral protein to capture the antigen on a nitrocellulose membrane. The captured antigens then react with conjugated antibody, which is detected by a color change on the test strip.

**Test components**

- Test device
- Sample collection device
- Specimen buffer
- Saline
- Swab
- User manual
- Wipes

**Test procedure**

1. In the absence of symptoms, patients should be tested for SARS-CoV-2 at least once per week. In the presence of symptoms, patients should be tested at least twice per week.
2. Before testing, ensure that the test area is clean and dry. Do not use the test if the expiry date has passed.
3. Open the test kit and remove the test device and the swab package. Use the test immediately after opening the pack.
4. Ensure that the test device is unopened and that the device status indicator shows valid (black).
5. Fill the test tube with a sample using the provided material. The sample should be collected from the nasopharynx using a sterile swab.
6. Remove the swab from the collection tube and place it in the provided collection tube. Allow the sample to react for 1 minute.
7. Place the swab cap tightly onto the tube. The sample should be tested as soon as possible after collection.
8. Store the sample at refrigerator temperature for up to 4 hours at -2 to +4 °C.
9. If the test result is invalid, repeat the test using a new test device and a new sample.

**Data from the two duplicate controls and analysis**

All clinical evaluations under different settings performed by independent investigators can be found online in the study site. The data presented in the study site were analyzed by a central laboratory using a validated assay. The test was performed using the provided test kit, and the results were interpreted according to the manufacturer's instructions. The test results were compared with those obtained by gold standard methods, such as PCR and immunostaining.

**References**