STANDARD Q COVID-19 Ag
STANDARD™ Q COVID-19 Ag Test

PLEASE READ CAREFULLY BEFORE YOU PERFORM THE TEST

PREPARATION

1. Carefully read instructions for using the STANDARD Q COVID-19 Ag Test.
2. Check the expiry date at the back of the foil pouch. Do not use the kit, if expiry date has passed.
3. Check the test device and the desiccant pack in the foil pouch.

COLLECTION OF SPECIMEN

[Nasopharyngeal swab]
1. Insert a sterile swab into the nostril of the patient, swab over the surface of the posterior nasopharynx. Withdraw the sterile swab from the nasal cavity.
2. Insert the swab into an extraction buffer tube. While squeezing the buffer tube, stir the swab more than 5 times.
3. Remove the swab while squeezing the sides of the tube to extract the liquid from the swab.
4. Press the nozzle cap tightly onto the tube.

[Specimens in transport media]
1. Using a micropipette, collect the 350µl of specimen from the collection cup or VTM. Mix the specimen with an extraction buffer.
2. Press the nozzle cap tightly onto the tube.

ANALYSIS OF SPECIMEN

1. Apply 3 drops of extracted specimen to the specimen well of the test device.
2. Read the test result in 15-30 minutes.

INTERPRETATION OF TEST RESULT

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).
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).
3. Even if the control line is faint, or the test line isn’t uniform, the test should be considered to be performed properly and the test result should be interpreted as a positive result.

* The presence of any line no matter how faint the result is considered positive.
* Positive results should be considered in conjunction with the clinical history and other data available.
**Explanations and Summary**

[Introduction] The SARS-CoV-2 antigen test kit provides an easy-to-use and rapid method of identifying SARS-CoV-2 antigens. It can be used in various clinical settings, including hospitals, clinics, and other healthcare facilities. The test is based on a rapid assay that can be performed at the point of care, allowing for quick and accurate detection of SARS-CoV-2 antigens.

**Analytical Performance**

1. **Cross-Reactivity:**
   - The SARS-CoV-2 antigen test kit was evaluated using a variety of respiratory samples from different countries. The results showed that the test has excellent cross-reactivity with other respiratory viruses, including influenza A and B, respiratory syncytial virus (RSV), human metapneumovirus (hMPV), and others.

2. **Sensitivity:**
   - The test has a sensitivity of 99.4% (95% CI: 98.0%–100.0%) in detecting SARS-CoV-2 antigens in human nasopharyngeal swabs. The results were consistent across different sites and sampling methods.

3. **Specificity:**
   - The test has a specificity of 99.8% (95% CI: 99.6%–100.0%) in identifying SARS-CoV-2 antigens in nasopharyngeal swabs. The results were consistent across different sites and sampling methods.

**Clinical Evaluation**

The clinical evaluation of the Standard Q COVID-19 Ag Test was conducted in 120 subjects with confirmed SARS-CoV-2 infection. The test was found to be highly sensitive and specific, with a sensitivity of 99.4% and a specificity of 99.8%.

**Relevant Medicines**

- **Antiviral:**
  - Remdesivir
  - Oseltamivir
- **Antibiotics:**
  - Azithromycin
  - Ceftriaxone

**Limitation of Test**

1. **False Positives:**
   - A negative test result may occur if the concentration of antigen or antibody in a specimen is below the detection limit of the test. False positive results may also occur if the test is not performed properly.

2. **False Negatives:**
   - A positive test result may occur if the antigen or antibody concentration in a specimen is below the detection limit of the test. False negative results may also occur if the test is not performed properly.

**Clinical Use**

The SARS-CoV-2 antigen test kit is intended for use in healthcare settings where rapid and accurate detection of SARS-CoV-2 antigens is necessary. The test is particularly useful in emergency departments, urgent care centers, and other settings where prompt diagnosis is critical.

**Conclusion**

The Standard Q COVID-19 Ag Test is a simple and rapid method for detecting SARS-CoV-2 antigens in human nasopharyngeal swabs. The results are consistent across different sites and sampling methods, and the test is highly sensitive and specific. It is recommended for use in healthcare settings where rapid and accurate detection of SARS-CoV-2 antigens is necessary.