**COVID-19 Antigen Home Test Quick Reference Instructions**

**Fast result in 10 minutes | Nasal Test**

**Study the Instructions for Use and User Manual thoroughly before using Quick Reference Instructions. This is not a complete Instructions for Use.**

After viewing the video guide via the QR code and familiarizing yourself with how to use the rapid antigen test, follow the instructions below:

**STEP 1 PREPARATION**

1. **Wash your hands.**

   ! It is recommended to wear gloves when using the product.

2. **Check the kit contents before testing.**

   - Test cassette
   - Buffer tube
   - Extraction tube & absorbent cap
   - Sterile swab
   - Instructions for Use & Quick Reference Instructions

3. **Check the expiry date shown on the foil pouch packaging. Check that the test cassette inside is intact and that it contains one test strip framed within the result window.**

   - Foil pouch
   - Test cassette

**STEP 2 SAMPLE COLLECTION**

4. **Twist the top off the buffer tube to open and pour all the extraction buffer solution into the extraction tube.**

   ![Image of buffer tube and extraction tube]

5. **Place the extraction tube in the workstation.**

   ![Image of extraction tube in workstation]

6. **Open the sterile swab pouch and hold the swab.**

   ![Image of swab pouch and swab]

   - **Do not touch swab tip when handling swab sample.**

7. **Insert the sterile swab and rotate around all sides of both nostrils for about 10 times, for at least 10 seconds.**

   ![Image of swab insertion and rotation]

    - **The sterile swab should be inserted about 2-3 cm into the nostril, parallel to the palate until the resistance is met and turbulences.**

8. **Place the swab in the extraction tube. Rotate the swab for at least 10 seconds and stir for 10 times while pushing the swab tip against the sides of the tube to squeeze out the solution from the swab.**

   ![Image of swab rotation and extraction]

   - **10x times**

**STEP 3 TEST PROCEDURE**

8. **Place the swab in the extraction tube. Rotate the swab for at least 10 seconds and stir for 10 times while pushing the swab tip against the sides of the tube to squeeze out the solution from the swab.**

   ![Image of swab rotation and extraction]

   - **10x times**

9. **In case of contact with your skin or eyes, wash immediately with plenty of water.**

   ![Image of hand washing]

10. **Screw the cap onto the extraction tube and make sure it is firmly in place.**

    ![Image of cap sealing]

**STEP 4 INTERPRETATION OF TEST RESULT**

**Negative**

Negative result: A coloured band will appear in the control line (C) result window only.

Negative results should be treated as presumptive only and may not mean you are not infectious. If you are experiencing COVID symptoms, you must seek immediate further laboratory PCR testing and follow-up clinical care.

**Positive**

Positive result: Coloured bands will appear in both the control line (C) and test line (T) result windows.

**IMPORTANT:** Look very closely! The color intensity in the test region will vary. Any faint coloured line in the result window should be considered as positive.

A positive test result indicates that antigens from SARS-CoV-2 were detected, and you are likely to be infected and presumed to be contagious. You must immediately undergo a laboratory PCR test at a COVID-19 respiratory clinic; COVID-19 respiratory clinics are dedicated health centres located around the country, focusing on testing people who may have COVID.

**Invalid**

Re-test: If the control line (C) has not appeared in the result window, it is an invalid result.

Re-test using a new swab sample and test cassette.

An invalid test result indicates that your test has experienced an error and is unable to interpret the result of the test. Insufficient sample volume or incorrect handling are the most likely reasons for this. You will need to re-test with a new test or contact your State or Territory Coronavirus testing services to get a laboratory PCR test. If you still have symptoms, you should self-isolate at home and avoid contact with others prior to the re-test.

**CUSTOMER SUPPORT**

For assistance regarding the use of the product and interpretation of test results call 1800 773 463. This service is available between 9am and 7pm (AEST) or 9am and 8pm (ADT), 7 days a week.

Manufactured by:
HANGZHOU TESTSEAL BIOTECHNOLOGY CO., LTD.,
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PHARMA SOUL Pty Ltd
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**TestSealabs COVID-19 Antigen Test Cassette**

**Precautions**
- Do not use the expiration date.
- Do not eat, drink or smoke in the area where the specimen and kits are handled.
- Do not reuse any kit contents that are visibly damaged.
- Handle all specimen as if they contain infectious agents.
- Observe all workplace procedures and follow the standard procedures for all the standard procedures for all the following standard procedures.
- Wear protective clothing, if possible, when the specimen is collected, prepared, processed and prepared.
- Follow standard biosafety guidelines for handling and disposal of potential reactive materials.
- Humidity and temperature can adversely affect results.
- The test must be performed immediately after the sampling and tested. No more than the sampling at room temperature for more than 1 hour.

**Storage and Stability**
Store the package in a cool place at room temperature (4-30°C). The kit is stable up to the expiration date printed on the sealed package. The test must remain in the sealed package until use.

**Quality Control**
Internal Control

- Quality controls are included in the test kit. The control line will appear in the test zone (C) if an internal control procedure confirms that an adequate amount of the buffer solution sample has been applied and correct procedural steps have been followed.

**Warnings and Limitations**
- Each test can be used only once.
- Test results must be read at 10 minutes and no later than 15 minutes.
- Interpretation of any result after 20 minutes may yield inaccurate test results.
- If you receive a positive result, you must immediately leave the PCR laboratory and follow-up care.
- A positive result cannot determine whether you are infected.
- False-negative results are more likely to occur if the test is performed after 5 days of infection.
- False-negative results are more likely to occur in the later phase of infection and in asymptomatic individuals.
- A negative result does not rule out infection with another type of respiratory virus.
- Negative results should be treated as precautionary and may not mean you are not infected. If you are experiencing any COVID-19 symptoms you should seek immediate further laboratory testing and follow-up clinical care.

- Children aged 2 to 12 years old should have their samples collected and tested by an adult. Do not use the test for anyone under 2 years of age.

**Support Services**
Information regarding available support services can also be obtained by contacting your local state and territory health department at:
- ACT: 02 5124 9213 www.health.act.gov.au
- NT: 08 8922 8044 www.health.nt.gov.au
- QLD: 13 423 584 www.health.qld.gov.au
- TAS: 1300 139 513 www.dhhs.tas.gov.au
- WA: 08 9222 4222 www.health.wa.gov.au

**COVID-19 Information**
What is COVID-19?
COVID-19 is a new virus caused by the SARS-CoV-2 virus, which is a new virus causing a contagious respiratory illness. COVID-19 can present with a wide range of symptoms, although some people infected with COVID-19 may have no symptoms at all. Serious outcomes of COVID-19 can include hospitalization or death. Other symptoms and people of any age with underlying medical conditions had a higher risk of severe illness from COVID-19.


**VARIANTS DETECTABLE BY THIS TEST**
This test has been tested and proven to detect multiple variants of COVID-19, including Alpha, Beta, and others. Importantly, the Delta variant has been identified, which makes it essential that these variants can detect new variants that become available.

**Cross-Reactivity**
Test results will not be affected by other respiratory viruses and commonly encountered microbial pathogens and low pathogenic coronaviruses listed here, as long as they are not at significant co-infections: Candida Albicans, Staphylococcus Epidermidis, Corynebacterium, Streptococcus Pneumoniae, Listeria Monocytogenes, Staphylococcus Aureus, E.coli, Moraxella Catarrhalis, Salmonella enterica, Esherichia coli, Pneumococcus, Influenza A/H1N1, Influenza A/H3N2.

**INTERFERING SUBSTANCES**
The following compounds have been used to test the TestSealabs COVID-19 Antigen Test Cassette and no interference was observed.

**Performance Characteristics**
**Clinical Evaluation**
The clinical performance of the TestSealabs COVID-19 Antigen Test Cassette for patient self-testing was evaluated using a case series of 135 participants who underwent COVID-19 antigen tests using the TestSealabs COVID-19 Antigen Test Cassette. The study participants were evaluated with no complications. The study cohort included children aged 0-15 years, symptomatic adults aged 16-70 years, and asymptomatic adults aged 70 years who were suspected of having a SARSCoV-2 infection. The study participants were evaluated with no complications. The study was designed to evaluate the performance of the TestSealabs COVID-19 Antigen Test Cassette.

**Specificity and Sensitivity**
Sensitivity and specificity were evaluated using two different test kits: a positive control test kit and a negative control test kit. The positive control test kit is designed to test the specimen and the negative control test kit is designed to test the specimen. The test was found to have a sensitivity of 99.5% and a specificity of 99.5%.

**Limit of Detection**
The limit of detection for TestSealabs COVID-19 Antigen Test Cassette was determined to be 50 TCD50/s/ml using inactivated SARS-CoV-2 Virus.