

RAPID SARS-COV-2 ANTIGEN TEST CARD

INSTRUCTION GUIDE FOR ANTERIOR NASAL SWAB SPECIMENS

For private use/home use/self-testing

Temporarily approved for self-testing according to §11 MPG in Germany (BfArM GZ: 5640-S-007/21) without completed conformity assessment procedure.

REF 1N40C5-2 For 1 Test/Box

REF 1N40C5-4 For 5 Tests/Box

REF 1N40C5 For 20 Tests/Box

Please follow the instruction leaflet carefully.

INTENDED USE

Rapid SARS-CoV-2 Antigen Test Card is an immunochromatography based one step in vitro test. It is designed for the rapid qualitative determination of SARS-CoV-2 virus antigen in anterior nasal swabs from individuals suspected of COVID-19 within the first seven days of symptom onset. Rapid SARS-CoV-2 Antigen Test Card shall not be used as sole basis to diagnose or exclude SARS-CoV-2 infection.

SUMMARY

The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection, asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

MATERIALS PROVIDED

Components	For 1 Test/Box	For 5 Tests/Box	For 20 Tests/Box
Rapid SARS-CoV-2 Antigen Test Card (sealed foil pouch)	1	5	20
Sterilized swab	1	5	20
Extraction tube	1	5	20
Sample extraction buffer	1	5	20
Instructions for use (this leaflet)	1	1	1
Tube stand	1 (packaging)	1	1

IMPORTANT INFORMATION BEFORE THE EXECUTION

1. Read this instruction guide carefully.
2. Do not use the product beyond the expiration date.
3. Do not use the product if the pouch is damaged or the seal is broken.
4. Store the test device at 4 to 30°C in the original sealed pouch. Do Not Freeze.
5. The product should be used at room temperature (15°C to 30°C). If the product has been stored in a cool area (less than 15°C), leave it at normal room temperature for 30 minutes before using.
6. Handle all specimens as potentially infectious.
7. Inadequate or inappropriate specimen collection, storage, and transport may yield inaccurate test results.
8. Use the swabs included in the test kit to ensure optimal performance of the test.
9. Correct specimen collection is the most important step in the procedure. Make sure to collect enough specimen material (nasal secretion) with the swab, especially for anterior nasal sampling.
10. Blow the nose several times before collecting specimen.
11. The specimens should be tested as soon as possible after collection.
12. Apply the drops of test specimen only to the specimen well (S).
13. Too many or too few drops of extraction solution can lead to an invalid or incorrect test result.
14. Children under 14 years of age should be assisted by an adult.

LIMITATIONS

1. The test is to be used exclusively for the qualitative detection of SARS-CoV-2 viral antigen in anterior nasal swab specimens. The exact concentration of SARS-CoV-2 viral antigen cannot be determined as part of this test.
2. Proper specimen collection is critical. Failure to follow the procedure may result in inaccurate test results. Improper collection, storage, or even freezing and thawing of the specimen can lead to inaccurate test results.
3. If the viral load of the specimen is below the detection limit of the test, the test may produce a negative result.
4. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the result of a single test, but should be made by the physician after evaluation of all clinical and laboratory results.
5. A negative result does not exclude viral infection except for SARS-CoV-2 and should be confirmed by molecular diagnostic methods if COVID-19 is suspected.
6. A positive result does not exclude coinfection with other pathogens.
7. The SARS-CoV-2 rapid antigen test can detect both viable and non-viable SARS-CoV-2 material. The performance of the SARS-CoV-2 rapid test is dependent on viral load and may not correlate with other diagnostic methods performed on the same specimen.
8. Users should test specimens as soon as possible after specimen collection and within two hours of specimen collection.
9. Sensitivity for nasal or oropharyngeal swabs may be lower than nasopharyngeal swabs. It is recommended to use the nasopharyngeal swab specimens by healthcare professionals.
10. Monoclonal antibodies may fail to detect, or detect with less sensitivity, SARS-CoV-2 viruses that have undergone minor amino acid changes in the target epitope region.
11. The amount of antigen in a sample may decrease as the duration of illness increases. Specimens collected after day 5-7 of illness are more likely to be tested negative compared to a RT-PCR assay.
12. The kit was validated with the assorted swabs. Use of alternative swabs may result in false negative results.
13. The validity of Rapid SARS-CoV-2 Antigen Test Card has not been proven for identification/confirmation of tissue culture isolates and should not be used in this capacity.

PREPARATION

- Clear, clean and dry a flat surface.
- Check the test kit contents. Make sure that nothing is damaged or broken.
- Timer at hand.
- Blow your nose several times before collecting specimen.
- Wash hands.

DISPOSAL

The test kit may be disposed of with normal household waste in accordance with the applicable local regulations.

PROCEDURE

This test is suitable for people of all ages. The recommended operators are aging from 14 to 90. Children under 14 years of age should be tested by an adult. Do not continue the test if the child feels any pain.

1



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.

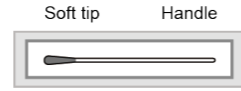
2



Squeeze all extraction buffer out of the bottle into the extraction tube.

Caution: Avoid touching the bottle against the tube.

3



Find the swab in the sealed wrapper in front of you. Identify the soft, fabric tip of the swab.

4



Peel open the swab packaging and gently take out the swab.

Caution: Never touch the soft, fabric tip of the swab with your hands.

5



Carefully insert swab into one nostril. The swab tip should be inserted no less than 2.5 cm (1 inch) from the edge of the nostril. Roll swab 3-4 times along the mucosa inside the nostril. Leave swab in the nostril for several seconds. Using the same swab, repeat this process for the other nostril. Withdraw swab from the nasal cavity.

Caution: This may feel uncomfortable. Do not insert the swab any deeper if you feel strong resistance or pain.

6



Place swab into extraction tube. Roll swab three to five (3-5) times. **Leave swab in extraction buffer for 1 minute.**

7



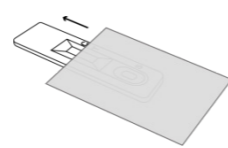
Pinch extraction tube with fingers and remove the solution from swab as much as possible.

8



Install the nozzle cap onto the sample extraction tube tightly.

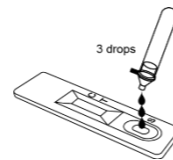
9



Bring the kit components to room temperature before testing. Open the pouch and remove the card. Place the card on a flat and level surface.

Caution: Once opened, the test card must be used immediately.

10



Invert the extraction tube and add **3 drops** of test specimen into the specimen well (S) by gently squeezing the extraction tube.

Caution: The formation of air bubbles in the specimen well (S) must be avoided.

11

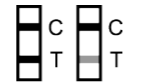


Read the results at **15-20 minutes**.

Caution: Results after 20 minutes may not be accurate.

The used device may be disposed of with normal household waste in accordance with the applicable local regulations.

INTERPRETATION OF RESULTS



Positive

Positive:

If two colored bands appear with one colored band in the Control Zone (C) and another in the Test Zone (T) within 15-20 minutes, the test result is positive.

Caution: No matter how faint the colored band is in the Test Zone (T), the result should be considered as positive.



Negative



Invalid

Negative:

If one colored 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.

Invalid:

If no color line appears in the control area (C) within 15-20 minutes, the test is invalid. Repeat the test with a new test card.

QUALITY CONTROL

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

ACCURACY

The accuracy of Rapid SARS-CoV-2 Antigen Test Card was established with 230 nasal specimens collected from individual symptomatic patients (within 7 days of onset) who were suspected of COVID-19. The following table summarizes the accuracy of the Rapid SARS-CoV-2 Antigen Test Card compared to RT-PCR.

Rapid SARS-CoV-2 Antigen Test Card		RT-PCR		
		Positive	Negative	Total
	Positive	101	1	102
	Negative	4	124	128
	Total	105	125	230

The sensitivity was 96.19% (95%CI: 92.53%~99.85%). The specificity was 99.20% (95%CI: 97.64%~99.99%). The accuracy was 97.83% (95%CI: 95.94%~99.71%).

FREQUENTLY ASKED QUESTIONS (FAQ)

- 1. How does the detection work?**

The N protein of the SARS-CoV-2 virus reacts with the stripe-like coating of the test line and, if present, results in a color change, i.e. a red line appears. Therefore, if the sample does not contain any viral proteins or antigens, there will be no red test line (T).
- 2. When should/can I test myself?**

You can test yourself whether you have symptoms or not. Studies show that earlier testing within the first 4 days of illness typically means a higher viral load, which is easier to detect. Since the test result is a snapshot valid for that point in time, testing should be repeated as recommended by local authorities.
- 3. What can affect my test result? What should I pay attention to?**

Be sure to blow your nose multiple times before collecting the specimen. Be sure to visibly collect sample material (nasal secretions). Perform the test immediately after taking the sample. Follow the instructions for use carefully. Apply the drops of extraction solution only to the sample well (S). Too many or too few drops of extraction solution can lead to an invalid or incorrect test result.
- 4. The test strip is clearly discolored or smudged? What is the reason for this?**

Please note that the test card should not be used with more than 3 drops of sample, as the liquid absorption of the test strip is naturally limited. If the control line does not appear or the test strip is badly smudged or discolored, making it unreadable, please repeat the test according to the instructions.
- 5. I have taken the test, but I don't see a control line (C). What should I do?**

Your test result is invalid. Observe the answer to question 4 and repeat the test according to the instructions for use.
- 6. I am unsure about reading the result. What should I do?**

For the result to be positive, 2 straight horizontal lines must be clearly visible with the full width of the cassette. If you are still unsure about the results, contact the nearest health facility according to the recommendations of your local authorities.
- 7. My result is positive. What should I do?**

If your result is positive and the test kit thus clearly indicates the control line as well as the test line, you should contact the nearest medical facility as recommended by your local authorities. Your test result may be double-checked and the authority or facility will explain the appropriate next steps.
- 8. My result is negative. What should I do?**

If the test kit only clearly shows the control line, this may mean that you are negative or that the viral load is too low to be detected. If you experience symptoms (headache, fever, migraine, loss of sense of smell or taste, etc.), please consult your primary care physician, or the nearest health care facility as recommended by your local authorities. If you are not sure, you can repeat the test.
- 9. How can I dispose of the product?**

The test kit may be disposed of with normal household waste in accordance with the applicable local regulations.

EXPLANATION FOR SYMBOLS

IVD	In Vitro Diagnostics Use	See Instruction for Use	Expiry Date
Σ	Tests per Kit	Keep Dry	LOT
EC REP	Authorized Representative	Keep away from Sunlight	Manufacturer
2	Do not reuse	Do not use if package is damaged	Store between 4 ~ 30°C
		REF	Catalogue Number
			Warning, please refer to the instruction

Manufacturer: Xiamen Boson Biotech Co., Ltd.
90-94 Tianfeng Road, Jimei North Industrial Park, Xiamen, Fujian, 361021, P.R.China.

Authorized Representative: Lotus NL B.V.
Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

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