**FREQUENTLY ASKED QUESTIONS**

- **When can I test myself?**
  
  You can always test yourself whether you have symptoms or not. Please note that the test result is a snapshot that is valid for this point in time. Tests should therefore be repeated according to the regulations of the responsible authorities.

- **What should I pay attention to in order to obtain the most exact test result possible?**

  Always follow the instructions for use exactly. Perform the test immediately after collecting the sample. Dispense the drops from the test tube only into the designated well of the test cassette. Dispense three drops from the sample tube. Too many or too few drops can lead to an incorrect or invalid test result.

  - The test strip is very discolored. What is the reason or what am I doing wrong?
    
    The reason for a clearly visible discoloration of the test strip is that too large a quantity of drops has been dispensed from the sample tube into the test cassette well. The indicator strip can only hold a limited amount of liquid. If the control line does not appear or the test strip is very discolored, please repeat the test with a new test kit according to the instructions for use.

- **What should I do if I took the test but didn’t see a control line?**

  In this case, the test result is to be considered invalid. Please repeat the test with a new test kit according to the instructions for use.

- **I am unsure of the interpretation of the results. What should I do?**

  If you cannot clearly determine the result of the test, contact the nearest medical facility applying the regulations of your local authority.

- **My result is positive. What should I do?**

  If a horizontal colored line is visible in the control area (C) as well as in the test area (T), your result is positive and you should immediately contact the health service providing the requirements of your local authorities. Your test result may be checked and the next steps will be explained to you.

- **My result is negative. What should I do?**

  If only a horizontal colored line is visible in the control area (C), this may mean that you are negative or that the viral load is too low to be recognized by the test.

- **If you experience symptoms such as headaches, migraines, fever, loss of sense of smell and taste, contact the nearest medical facility applying the regulations of your local authority.**

In addition, you can repeat the test with a new test kit.

- **Can this test cassette be reused or used by multiple people?**

  This test cassette is for one-time use and cannot be reused or used by multiple people.

**TRADE NAME**

SARS-CoV-2 Antigen Test (Colloidal Gold)

**MODEL NUMBER**

Model E

**SPECIFICATIONS**

1T/kit, 5T/kit, 20T/kit, 25T/kit, 40T/kit, 50T/kit

**INTENDED USE**

This kit is used for in vitro qualitative determination of SARS-CoV-2 antigens in human anterior nasal swab samples. It can be used for rapid investigation of suspected COVID-19 cases, and can also be used as a reconfirmation method for nucleic acid detection in discharged cases.

A positive test result indicates that the sample contains SARS-CoV-2 antigen. A negative test result does not rule out the possibility of infection. This kit is for home use by laymen in a non-laboratory setting (such as person's home or certain non-traditional sites such as offices, sporting events, airports, schools etc.). The test results of this kit are for clinical reference only. It is recommended to conduct a comprehensive analysis of the condition based on the patient's clinical manifestations and other laboratory tests.

**COMPONENTS**

1. SARS-CoV-2 Antigen Test Cassette
2. Sample extraction buffer
3. Disposable virus sampling swab
4. Biohazard specimen bag

**SPECIMEN REQUIREMENTS**

1. Sample collection

- Gently insert the entire soft tip of the swab into one nostril for 1.5cm until you feel a bit of resistance.
- Using medium pressure, rub the swab slowly in a circular motion around the inside wall of your nostril 4 times for a total time of 15 seconds.
- Repeat the same process with the same swab in the other nostril.

2. Sample treatment

- The swab after sampling is soaked below the liquid level of the sample extraction buffer. Rotate and press 3 times. The swab soaking time is not less than 15 seconds.
- The swab head is pressed, then take out the swab and tighten the sampling tube.

3. Sample preservation: The treated sample should be tested within 1h.

**TEST PROCEDURE**

1. Place the test cassette, sample extraction buffer at room temperature for 15~30 minutes, and equilibrate to room temperature (10~30℃).

2. Open the aluminum foil pouch of the test cassette, place the test cassette on a flat surface.

3. Add 4 drops of the treated sample into the sample well of the test cassette. (In case of chromatographic abnormalities, add an extra of 1~2 drops of the treated sample accordingly). Incubate at 10~30℃ for 15 minutes.

4. Observe the results after incubating at 10~30℃ for 15 minutes. The result obtained after 30 minutes is invalid.

**INTERPRETATION OF RESULT**

Positive: Two color bands appear in the observation window, that is, a red or magenta line appears at the position of the quality control line (C line) and the detection line (T line) (as shown in result 1), indicating the test result of SARS-CoV-2 antigens in the sample is positive.

Negative: A red or magenta line appears at the position of the quality control line (C line) in the observation window, and no line appears at the position of the test line (T line) (as shown in the result 2), indicating the test result of the SARS-CoV-2 antigens in the sample is negative or the concentration is below the limit of detection of the kit.

Invalid: No line appears in the position of the quality control line (line C) in the observation window (as shown in result 3), indicating that the test is invalid, and the sample should be re-collected and re-tested.

**PRINCIPLE OF THE ASSAY**

This kit is based on the colloidal gold immunochromatographic technology, and uses the double antibody sandwich method to detect N protein of SARS-CoV-2 antigen in human anterior nasal swab samples. The detection line (T line) of the SARS-CoV-2 antigen test cassette was coated with SARS-CoV-2 antibody, and the quality control line (C line) was coated with sheep anti-mouse antibody. During the test, the sample is dropped into the test cassette and the liquid is chromatographed upward under the capillary effect. The SARS-CoV-2 antigen in the sample first binds to the colloidal gold-labelled SARS-CoV-2 antibody to form a solid phase SARS-CoV-2 antibody-SARS-CoV-2 antigen-labelled SARS-CoV-2 antibody colloidal gold complex at the T line position, and form a solid phase sheep anti-mouse-labelled SARS-CoV-2 antibody colloidal gold complex was
formed at the C line position. After the test is completed, observe the colloidal gold color reaction of T line and C line to determine results of SARS-CoV-2 antigen in human anterior nasal swab samples.

STORAGE AND SHELF LIFE
1. The kit should be stored at 4°-30°C, the shelf life is set for 18 months.
2. After the foil bag is opened, it should be used within 30 minutes (temperature 10°-30°C, humidity ≤70%).
3. The sample extraction buffer should be used within 18 months after opening (temperature 10°-30°C, humidity ≤70%).

See label for manufacture date and expiration date.

LIMITATIONS
1. The test result of this kit is not the only confirmation indicator of clinical indications. The infection should be confirmed by a specialist along with other laboratory results, clinical symptoms, epidemiology, and additional clinical data.
2. In the early stages of infection, low levels of antigen expression can result in negative results.
3. The sample test results are related to the quality of sample collection, processing, transportation and storage. Any errors may lead to inaccurate results. If cross-contamination is not controlled during sample processing, false positive results may occur.

PERFORMANCE CHARACTERISTICS
1. Limit of Detection (LoD)
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) has been confirmed can detect SARS-CoV-2 at 2.5 × 10^2 TCID₅₀/mL, which was collected from a confirmed COVID-19 patient in China.

4. Hook Effect:
There is no hook effect at 1.0 × 10^6 TCID₅₀/mL of SARS-CoV-2 isolated from a SARS-CoV-2 confirmed patient in China.

5. Clinical Performance:
Clinical performance of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) has been determined by testing 108 positive and 115 negative specimens for SARS-CoV-2 antigen (Ag). The sensitivity is 96.30% (95% CI: 90.79-98.98%), and the specificity is 99.13% (95% CI: 95.25-99.98%).

<table>
<thead>
<tr>
<th>PCR Test Results</th>
<th>Positive</th>
<th>Negative</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Novel Coronavirus: 2019-nCoV Antigen Test (Colloidal Gold) Results</td>
<td>108</td>
<td>115</td>
<td>223</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>96.30% (90.79-98.98%)</td>
<td>99.13% (95.25-99.98%)</td>
<td>97.76% (94.85-99.27%)</td>
</tr>
</tbody>
</table>

EXPLANATION FOR IDENTIFICATION

Beijing Hotgen Biotech Co., Ltd.
9th Building, No. 9 Tianfu Street, Biomedical Base, Daxing District, Beijing, 102600, P.R. China.

MedNet GmbH
Borkstrasse 10, 48163 Muenster, Germany

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