Instruction manual
SARS-CoV-2 Antigen Rapid Test

Read the instructions for use completely before performing the test.
For in vitro diagnostic and for self-testing use.

Product
SARS-CoV-2 Antigen Rapid Test

Purpose
HIGHTOP Antigen Rapid Test for self-application is used for the detection of SARS-CoV-2 antigens in samples from the human anterior nasal cavity area. It is used to detect SARS-CoV-2 nucleoprotein antigens within 7 days of the onset of symptoms suspected of coronavirus infection. Positive test results can be used for early isolation and rapid treatment of suspected cases, but they cannot serve as a basis for a definitive diagnosis of coronavirus infection.

Important for self-application:
In case of a positive test result, please isolate yourself and contact your doctor or call the Corona hotline. A positive test result must be confirmed by a PCR test. Note that even if the result is negative, infection is not guaranteed to be excluded, as a low virus load or a possible sampling error can result in a wrong result.

Delivery
Test cassette & desiccant
Extraction tubes with buffer, cap and drip cap
Swab

Safety
1. The test kits should be stored at temperatures of 4-30°C and should not be exposed to direct sunlight or moisture. Before use, tests stored at low temperature should be brought to room temperature.
2. Do not use expired and damaged products. The expiry date is printed on the outer packaging.
3. Suitable for people aged 16 and over. Keep the test kits away from young children to reduce the risk of accidentally drinking the buffer liquid or swallowing small parts.
4. The test cassette should be used as soon as possible after removal from the foil bag to avoid prolonged exposure to moisture, as these could affect the test result.
5. Under room temperature (15-30°C) and humidity of less than 60%, the test kits must be used within half an hour after opening the packaging. If the humidity exceeds 60%, use immediately after opening the packaging.
6. Do not freeze the test kits.
7. The test set should be disposed after use in a lockable garbage bag in the household waste.
8. Incorrect operation may affect the accuracy of the results, such as e. g. too little effective time in the buffer solution, too little or too much buffer in the solution, insufficient sample addition, inaccurate detection time, etc.
9. False-negative results can occur when the swab is placed in a bag between sampling and evaluation.
10. Do not suck the sample with your mouth.
11. During the test, do not smoke, eat, drink alcohol, apply make-up or put in contact lenses, or take them out.
12. Disinfect spilled samples or reagents with disinfectant.
13. If the extraction reagent come into contact with the skin or eyes, wash / rinse the affected area with plenty of water. If irritation is found, contact your doctor.
14. After the test, stow all components in a sealable plastic bag and dispose of them in household or residual waste.
15. Wash hands thoroughly after test completion.

Test flow
Bring all components of the test kit 30 minutes before use to room temperature (15-30°C) and wash your hands.

1. Preparation:
   • Have a watch ready or use a timer.
   • Open the extraction tube with buffer by unscrewing the cap. Do not spill the liquid.
   • Open the foil bag with the test cassette at the marked location and discard the desiccant.
   • Remove the test cassette and place it on a flat and clean surface. The test cassette becomes unusable half an hour after opening. Therefore, perform the test immediately.
   • Unpack the swab on the stem.

2. Sample in the anterior nose:
   • Insert the swab about 2-2.5cm into the first nostril. The swab tip should be completely immersed in the nasal cavity. If you feel resistance, no longer penetrate deeper into the anterior nose.
   • Rub 5 times in circular movements on the inner nasal wall (approx. 15 sec.).
   • Then insert the same swab into the second nostril and repeat the above operation.

3. Preparation of the sample
   • After sampling, immerse the swab in the solution of the extraction tube and rotate the swab 10 times. Let it work for 1 minute.
   • Squeeze out the swab using the extraction tube. Collect the liquid in the tube.
   • Remove the swab and put it in the garbage bag.
   • Close the extraction tube with the sample with the cap. Unscrew the drip cap at the top. The sample is ready for testing.

4. Evaluation of the sample
   • Add 2, max. 3 drops of mixed liquid from the extraction tube to the sample well (S) to the test cassette.
   • Read the result after 15 minutes. Results after 20 minutes have no
Interpretation of the test result

<table>
<thead>
<tr>
<th>POSITIVE</th>
<th>NEGATIVE</th>
<th>INVALID</th>
</tr>
</thead>
<tbody>
<tr>
<td>A red line appears on both the control line (C) and the test line (T)</td>
<td>The red line appears only on the control line (C), no red line on the test line (T).</td>
<td>No line appears on the control line (C), indicating insufficient sample volume, incorrect operation, or expired tests.</td>
</tr>
<tr>
<td>The lines shown can vary in intensity!</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Restrictions of the test procedure

1. The results of this product should not be considered a definitive diagnosis and are for clinical reference only. The judgment should be based on the RT-PCR results, clinical symptoms, prevalence of infectious diseases, and other clinical data.
2. If the virus antigen content in the sample is below the detection limit, the test result may be negative.
3. As the disease lasts, the number of antigens in the sample may decrease and the results may be negative 7 days after symptoms appeared compared to the RT-PCR test.
4. Due to the limitations of testing procedures, negative results cannot rule out the possibility of infection. A positive result should not be viewed as a definitive diagnosis, but should be assessed in the context of clinical symptoms and other diagnostic methods.

Performance specification of the rapid test

1. Limit of Detection
   The LOD of SARS-CoV-2 Antigen Rapid Test is 8 TCID_{50}/mL.
2. Clinical performance
   The performance of the SARS-CoV-2 antigen rapid test was evaluated in Germany with European subjects. A total of 402 frozen swab samples including 102 positive samples and 300 negative samples from the anterior nose were tested. All the swab specimens were confirmed as positive or negative and validated with Ct value by the RT-PCR (throat swab) as a comparator method.

<table>
<thead>
<tr>
<th>SARS-CoV-2 Antigen Rapid Test</th>
<th>RT-PCR</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>Negative</td>
<td>2</td>
<td>302</td>
</tr>
<tr>
<td>Total</td>
<td>102</td>
<td>402</td>
</tr>
</tbody>
</table>

Sensitivity (Ct<36): 98.04% (95%CI: 93.13%-99.44%)
Specificity: 100% (95%CI: 98.74%-100%)
Reliability: 99.5% (95%CI: 98.20%-99.86%)

Explanation of terms:
Sensitivity: right positive / all positives *100
Specificity: right negative / all negatives * 100
Reliability: (right positive + right negative) / total * 100

3. Analytical specificity
1) Interfering substances
   The test showed no interference with following substances:

<table>
<thead>
<tr>
<th>Name</th>
<th>Concentration</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mucin</td>
<td>0.50%</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Blood (human) 5%
Guaiacol glycerin ether 1ug/mL Negative
Arbidol hydrochloride hydrate 1mg/mL Negative
Zanamivir 2mg/mL Negative
Meropenem 1mg/mL Negative
Oseltamivir 3mg/mL Negative
Ritonavir 1mg/mL Negative
Peramivir trihydrate 3mg/mL Negative
Ribavirin 1mg/mL Negative
Histamine hydrochloride 2mg/mL Negative
Levofoxacin 1mg/mL Negative
Oxymetazoline hydrochloride 1mg/mL Negative
Ceftriaxone sodium 1mg/mL Negative
Cefradine 100mg/mL Negative
Cefalexin 100mg/mL Negative
Benzocaine 5mg/mL Negative
Tobramycin 2mg/mL Negative
Lopinavir 1mg/mL Negative
Azithromycin 3mg/mL Negative
Watermelon frost buccal tablets 100mg/mL Negative
Dexamethasone 0.5mg/mL Negative
Flunisolide 2mg/mL Negative
Bicloheximide 10mg/mL Negative
Sodium chloride 0.90% Negative
Alpha interferon 1mg/mL Negative
Phenylephrine hydrochloride 5mg/mL Negative
Acetaminophen 10mg/mL Negative
Ibuprofen 1mg/mL Negative
Aspirin 5mg/mL Negative
Acetylsalicylic acid 5mg/mL Negative
Hydrocortisone 1mg/mL Negative
Albuterol 1mg/mL Negative
Chlorpheniramine 5mg/mL Negative
Diphenhydramine 5mg/mL Negative
Budesonide 10mg/mL Negative
Mometasone 1mg/mL Negative
Fluticasone 1mg/mL Negative
NeiImed 5mg/mL Negative
Menthol 0.15mg/mL Negative
Quinine (malaria) 150uM Negative
Lamivudine (retroviral drug) 1mg/mL Negative
Biotin 100ug/mL Negative
HAMA 600ng/mL Negative
2) Cross-reactivity
By testing 26 viruses and 14 other microorganisms, except for the Human SARS-coronavirus Nucleoprotein, other viruses and microorganisms have no effect on the test results.

<table>
<thead>
<tr>
<th>Virus</th>
<th>Concentration</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCoV-NL63</td>
<td>1 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>HCoV-OC43</td>
<td>8 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>HCoV-229E</td>
<td>1 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>HCoV-HKU1</td>
<td>10⁻⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>MERS</td>
<td>4 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Human SARS-coronavirus Nucleoprotein</td>
<td>25 ng/ml</td>
<td>Positive</td>
</tr>
<tr>
<td>Adenovirus Type3</td>
<td>1.0 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Adenovirus Type7</td>
<td>1.0 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Adenovirus Type1</td>
<td>2.0 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Adenovirus Type5</td>
<td>3.0 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Adenovirus Type8</td>
<td>2.5 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Adenovirus Type11</td>
<td>3.0 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Adenovirus Type21</td>
<td>3.0 x 10^3 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Adenovirus Type55</td>
<td>3.0 x 10^3 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Echovirus</td>
<td>4.0 x 10^2 PFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Influenza virus A (H1N1)</td>
<td>2.5 x 10^2 PFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Influenza virus A(H3N2)</td>
<td>8.0 x 10^2 PFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Influenza virus B Strain</td>
<td>3 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Parainfluenza Type 1</td>
<td>1 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Parainfluenza Type 2</td>
<td>1 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Parainfluenza Type 3</td>
<td>1 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Parainfluenza Type 4</td>
<td>1 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Respiratory syncytial virus (RSV) type A</td>
<td>4 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Respiratory syncytial virus (RSV) type B</td>
<td>4 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Rhinovirus A16</td>
<td>1 x 10^4 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Human Metapneumovirus (hMPV) 16 Type A1</td>
<td>1 x 10^3 TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Candida albicans</td>
<td>1.8 x 10⁵ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Legionella pneumophila</td>
<td>1 x 10⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Streptococcus pneumoniae</td>
<td>1.0 x 10⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Pseudomonas aeruginosa</td>
<td>1 x 10⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Staphylococcus epidermidis</td>
<td>1 x 10⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Staphylococcus salivarius</td>
<td>1 x 10⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Mycoplasm Pneumoniae</td>
<td>1 x 10⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Chlamydia Pneumoniae</td>
<td>1 x 10⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Streptococcus pyogenes</td>
<td>1 x 10⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Mycobacterium tuberculosis</td>
<td>1 x 10⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Hemophilus influenzae</td>
<td>1 x 10⁶ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Bordetella pertussis</td>
<td>5 x 10⁵ CFU/mL</td>
<td>Negative</td>
</tr>
</tbody>
</table>

Pooled human nasal wash 1 x 10⁴ CFU/mL Negative

3) Microbial Interference Studies
By testing 10 other microorganisms, it was found that other microorganisms have no effect on the test results.

<table>
<thead>
<tr>
<th>Other microorganism</th>
<th>Concentration</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococcus aureus</td>
<td>1 x 10⁴ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Escherichia coli</td>
<td>1 x 10⁴ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Streptococcus salivarius</td>
<td>1 x 10⁴ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Proteus mirabilis</td>
<td>1 x 10⁴ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Klebsiella pneumoniae</td>
<td>1 x 10⁴ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Staphylococcus haemolyticus</td>
<td>1 x 10⁴ CFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Mumps Virus Ag</td>
<td>2 x 10⁴ TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Avian Influenza Virus (H7N9)</td>
<td>8.0 x 10⁴ PFU/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Measles virus</td>
<td>2 x 10⁴ TCID₅₀/mL</td>
<td>Negative</td>
</tr>
<tr>
<td>Norovirus</td>
<td>1 x 10⁴ TCID₅₀/mL</td>
<td>Negative</td>
</tr>
</tbody>
</table>

4. Hook Effect
No high dose hook effect was observed up to 1.6 x 10⁴ TCID₅₀/mL of SARS-CoV-2 with SARS-CoV-2 Antigen Rapid Test.

What your results mean and what to do with your results

Positive result
A positive result means it is very likely you have SARS-CoV-2 infection. Please isolate yourself, stay at home, avoid contact with your roommates as much as possible and don’t receive visitors. Contact your doctor or call the Corona hotline. A positive test result must be confirmed by a PCR test.

Negative result
This means you probably don’t have SARS-CoV-2 infection. Pay attention! A negative result of a self-test is not 100% reliable. So stay careful. You still need to take precautions. Keep your distance, wear a mouth mask and wash your hands often.

Invalid result
An invalid result means this test was unable to determine whether you have SARS-CoV-2 or not. A new test is needed to get a valid result.

Explanation of the symbols

Consult instructions for use
Temperature limit
Keep dry
Do not re-use
Batch code
In vitro diagnostics medical device
Manufacturer
Date of Manufacture
Use-by date
Contains sufficient for <n> tests
Keep away from sunlight

Information of swabs
The information about swab manufacturer, CE number and European representative are placed on swab package and outer packing box.

Manufacturer information

MANUFACTURER / POST-SALE SERVICE UNIT
Qingdao Hightop Biotech Co., Ltd.
Add.: No.369 Hedong Road, Hi-tech Industrial Development Zone,
Qingdao,Shandong,266112, China
Tel: +86-532-58710705
Fax: +86-532-58710706
Web: www.hightopbio.com
E-mail: sales@hightopbio.com

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