The specificity of the WANTAI SARS-CoV-2 Ab Rapid Test early after infection is unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

False positive results for the WANTAI SARS-CoV-2 Ab Rapid Test may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using a second, different serology assay.

The WANTAI SARS-CoV-2 Ab Rapid Test is only for use under the Food and Drug Administration’s Emergency Use Authorization.

### INTENDED USE

The WANTAI SARS-CoV-2 Ab Rapid Test is a lateral flow assay for the qualitative detection of total antibodies (including IgG and IgM) to SARS-CoV-2 in human serum, plasma (dipotassium EDT A, lithium heparin, and sodium citrate), and venous whole blood. The WANTAI SARS-CoV-2 Ab Rapid Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2 indicating recent or prior infection. At this time, it is unknown for how long antibodies are present post-infection. In severe cases, infection can cause pneumonia, acute respiratory distress syndrome (ARDS), kidney failure, and death. Coronavirus disease 2019 (COVID-19) is a respiratory disease caused by infection with the SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In severe cases, infection can cause pneumonia, acute respiratory distress syndrome (ARDS), kidney failure, and death. Coronavirus (CoV) are a large family of viruses that cause a range of diseases from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The 2019 novel coronavirus, formerly known as 2019-nCoV and now known as SARS-CoV-2, is a new strain of coronavirus that was first identified during the recent COVID-19 pandemic.

### SUMMARY

Coronavirus disease 2019 (COVID-19) is a respiratory disease caused by infection with the SARS-CoV-2 virus. Common signs of infection include respiratory symptoms, fever, cough, shortness of breath and breathing difficulties. In severe cases, infection can cause pneumonia, acute respiratory distress syndrome (ARDS), kidney failure, and death. Coronavirus (CoV) are a large family of viruses that cause a range of diseases from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV) and Severe Acute Respiratory Syndrome (SARS-CoV). The 2019 novel coronavirus, formerly known as 2019-nCoV and now known as SARS-CoV-2, is a new strain of coronavirus that was first identified during the recent COVID-19 pandemic.

### PRINCIPLE OF THE ASSAY

The WANTAI SARS-CoV-2 Ab Rapid Test employs chromatographic lateral flow device in a cassette format. Colloidal gold conjugated recombinant antigens corresponding to SARS-CoV-2 are dry-immobilized at the end of nitrocellulose membrane strip. SARS-CoV-2 antigens are bound at the Test Zone (T) and antibodies are bound at the Control Zone (C). The antigen used in the assay is the receptor-binding domain of SARS-CoV-2 spike protein. When the specimen is added, it migrates by capillary diffusion and a red line appears. If present in the sample, SARS-CoV-2 antibody will bind with the gold conjugated antigens forming particles. These particles will continue to migrate along the strip until the Test Zone (T) where they are captured by the SARS-CoV-2 antigen generating a visible red line. If there is no SARS-CoV-2 antibody in specimen, no red line is formed in the Test Zone (T). The gold conjugate will continue to migrate alone until it is captured in the Control Zone (C) by the antibodies aggregating in a red line, which indicates the validity of the test.

### SPECIMEN COLLECTION

1. Human serum, plasma or venous whole blood specimens are used for this test. Plasma or whole blood specimens containing K2EDTA, sodium citrate or lithium heparin can be used for this test.
2. Specimens containing suspended fibrin or aggregates and severe hemolysis (hemoglobin content greater than 400mg/dL) cannot be used, but jaundice (bilirubin content less than 1.71mmol/L) and hyperlipemia (triglyceride content less than 170mmol/L) can be used.
3. Serum and plasma specimens can be refrigerated at 2-8°C for one week; in case of long-term storage, it shall be frozen below -15°C for no more than three weeks, and repeated freezing and thawing shall not exceed 3 times. Specimens should be brought to room temperature, mix the specimen before testing.
4. It is recommended to test the whole blood specimen immediately after blood collection. Do not use the specimen after long-term storage.

### STORAGEN AND STABILITY

The WANTAI SARS-CoV-2 Ab Rapid Test can be stored at room temperature (2-30°C, do not freeze) for 9 months from the date of manufacture.

### PRECAUTIONS AND SAFETY

1. This test has not been FDA cleared or approved but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories.
2. This test has been authorized only for detecting total antibodies to SARS-CoV-2, not for any other viruses or pathogens.
3. The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 584(b)(1) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb(b)(1), unless the declaration is terminated or authorization is revoked sooner.
4. This reagent is only for in vitro testing, and the operation should be carried out in strict accordance with the instructions. Make sure that the test is not expired (EXP Date indicated on the kit box). The test cassette cannot be reused.
5. Specimens should be used within the storage times noted above to avoid non-specific reactions.
6. Use of this test kit with sample types other than those specifically approved for use with this device may result in inaccurate test results.
7. Bring all reagents to room temperature (15-30°C) before use.
8. This test is not one of the components of any other type of test kit as a substitute for the components in this kit.
9. Due to the different antibody levels of the positive samples, the test line (T) may show the different color intensity. During the indicated reading time,
regardless of color intensity, even very weak color, should be judged as positive.

10. All the waste and specimens should be treated as contaminated and must be properly disinfected (autoclaving is preferred) before disposal. The desiccant in aluminum foil pouch cannot be taken internally.

11. Use routine laboratory precautions. Do not eat, drink or smoke in the area where samples and kit reagents are handled. Avoid any contact between hands, eyes or mouth during sample collection and testing.

12. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when handling patient samples. Wash hands thoroughly after handling specimens and kit reagents.

13. At room temperature, the test cassette should be used within 30 minutes after it is taken out of the package to avoid prolonged exposure to humid air (humidity > 60%), which may affect the test result. If the kit is stored at 2-8°C, the reagent should be brought to room temperature (30 minutes) before the experiment, then open the aluminum foil pouch for use.

14. During the test, the test cassette should be laid flat on the table, so as not to cause the lateral flow speed of specimen to be faster (or slower) and affect the test result.

15. Always interpret the results under good lighting conditions to avoid misreading of the test results. The result read after 20 minutes is invalid.

**ASAY PROCEDURE**

Place the cassette on flat surface. Before opening, allow the test cassette to reach room temperature. Use it immediately (within 30 minutes) after opening.

1. For venous whole blood / serum / plasma specimens:
   - Add 10μl of specimen into the specimen window (S).
   - Immediately add two drops of diluent buffer into the specimen window.
2. Read the results at 15 minutes after specimen and buffer loading, but no later than 20 minutes.

**CONDITIONS OF AUTHORIZATION FOR THE LABORATORY**


Authorized laboratories using the WANTAI SARS-CoV-2 Ab Rapid Test ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as listed below:

1. Authorized laboratories* using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories must use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product must notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product must have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories must collect information on the performance of your product and report to DMD/OHTT-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Beijing Wantai Biological Pharmacy Enterprise Co., Ltd. (wtxexport@ystwt.com) any suspected occurrence of false positive or false negative results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., authorized distributors, and authorized laboratories using your product must ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

"The letter of authorization refers to "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests" as "authorized laboratories."

**PERFORMANCE DATA**

1. Clinical validation study of the WANTAI SARS-CoV-2 Ab Rapid Test was conducted at three sites in China in 2020. Serum and plasma specimens were evaluated from 403 subjects. Out of the 403 samples, 132 subjects were COVID-19 cases confirmed positive by an RT-PCR assay while 271 subjects were confirmed PCR negative. All patients who were confirmed positive exhibited clinical signs or symptoms of COVID-19.

The WANTAI SARS-CoV-2 Ab Rapid Test evaluation centers

<table>
<thead>
<tr>
<th>Clinical institution</th>
<th>PCR Positive (Cases)</th>
<th>PCR Negative (Cases)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site 1</td>
<td>12</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>Site 2</td>
<td>39</td>
<td>195</td>
<td>234</td>
</tr>
<tr>
<td>Site 3</td>
<td>81</td>
<td>76</td>
<td>157</td>
</tr>
<tr>
<td>Total</td>
<td>132</td>
<td>271</td>
<td>403</td>
</tr>
</tbody>
</table>

Of the 132 positive samples, 125 were positive on the WANTAI SARS-CoV-2 Ab Rapid Test, and of the 271 negative samples, 268 were negative. The kit demonstrated the overall Positive Percent Agreement (PPA) of 94.70% (125/132) and the Negative Percent Agreement (NPA) of 98.89% (268/271), as indicated in the table below.

**Summary of clinical evaluation results**

<table>
<thead>
<tr>
<th>Cases</th>
<th>PCR Comparator</th>
<th>WANTAI SARS-CoV-2 Ab Rapid Test results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Positive</td>
<td>Negative</td>
</tr>
<tr>
<td>WANTAI SARS-CoV-2 Ab</td>
<td>125</td>
<td>3</td>
</tr>
<tr>
<td>Rapid Test cases</td>
<td>128</td>
<td>Total</td>
</tr>
<tr>
<td>Positive</td>
<td>7</td>
<td>268</td>
</tr>
<tr>
<td>Negative</td>
<td>275</td>
<td>Total</td>
</tr>
<tr>
<td>Total</td>
<td>132</td>
<td>271</td>
</tr>
</tbody>
</table>

**Summary of clinical performance**

<table>
<thead>
<tr>
<th>Performance</th>
<th>Results</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>PPA</td>
<td>94.70%</td>
<td>89.89%-97.41%</td>
</tr>
<tr>
<td>NPA</td>
<td>98.89%</td>
<td>95.83%-99.62%</td>
</tr>
</tbody>
</table>

It was observed that the detection rate of the kit was closely related to the time of disease onset, the kit showed higher positive detection rate in specimens from patients who had symptoms for longer periods of time. Therefore, the interpretation of the test results should consider the specimen’s collection time. The WANTAI SARS-CoV-2 Ab Rapid Test was evaluated with 415 samples collected over the course of time from 132 PCR-positive subjects. For performance calculation, only the results of the first bleed from each patient are considered, the performance of the test is as follows:

<table>
<thead>
<tr>
<th>Days from onset of symptoms</th>
<th>Total PCR positive specimens</th>
<th>Number Wantai positive result</th>
<th>PPA</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-7</td>
<td>62</td>
<td>38</td>
<td>61.29%</td>
<td>46.65%-72.42%</td>
</tr>
<tr>
<td>8-14</td>
<td>58</td>
<td>45</td>
<td>77.59%</td>
<td>65.34%-88.41%</td>
</tr>
<tr>
<td>15-21</td>
<td>13</td>
<td>11</td>
<td>84.62%</td>
<td>64.55%-94.57%</td>
</tr>
<tr>
<td>Total</td>
<td>132</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
1. Use of the WANTAI SARS-CoV-2 Ab Rapid Test is limited to laboratory personnel who have been trained. Not for home use.
2. The test is limited to the qualitative detection of antibodies specific for the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen. This test cannot be used as a quantitative test.
3. SARS-CoV-2 antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 15 days.
4. The positive result obtained with the WANTAI SARS-CoV-2 Ab Rapid Test should not be used to diagnose or exclude acute SARS-CoV-2 infection. Any positive result must be interpreted in conjunction with the patient clinical history and another laboratory testing results. Follow-up and supplementary testing of all positive specimens with other tests is required to confirm any positive result.
5. Do not use the WANTAI SARS-CoV-2 Ab Rapid Test with fingertip blood samples.
6. Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status. An assay that directly detects the virus should be used to evaluate symptomatic individuals for acute COVID-19.
7. It is not known at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection.
8. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for a second but different serology test to confirm an adaptive immune response.
9. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. The sensitivity of the WANTAI SARS-CoV-2 Ab Rapid Test early after infection is unknown. False positive results may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Samples with positive results should be confirmed with alternative testing method(s) and clinical findings before a diagnostic determination is made. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
10. This test is only used for the detection of human serum, plasma or venous whole blood specimens.

This test should not be used for screening of donated blood.

11. This test has not been validated for cross-reactivity with anti-Haemophilus influenzae positive specimens.
12. The kit should be used within 30 minutes after the aluminum foil bag is opened.
13. Testing should not be performed when ambient temperature is higher than 30°C or the relative humidity is higher than 70%.
14. The performance of this test has not been established in individuals that have received a COVID-19 vaccine. The clinical significance of a positive or negative antibody result following COVID-19 vaccination has not been established, and the result from this test should not be interpreted as an indication or degree of protection from infection after vaccination.
15. The performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 2020 and March 2020 in Beijing, China; Yunnan Province, China; and Zhejiang Province, China. The clinical performance of this test has not been established in all circulating variants, but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time.

REFERENCES
3. Bin Lou, et al. Serology characteristics of SARS-CoV-2 infection since the exposure and post symptom onset. doi: https://doi.org/10.1101/2020.03.23.20047365
5. Ying Liu, et al. Diagnostic Indexes of a Rapid IgG/IgM Combined Antibody Test for SARS-CoV-2. doi: https://doi.org/10.1101/2020.03.26.20044883