WHO Emergency Use Assessment Coronavirus disease (COVID-19) IVDs
PUBLIC REPORT

Product: Wantai SARS-CoV-2 RT-PCR Kit
EUL Number: EUL-0500-005-00
Outcome: Accepted

The EUL process is intended to expedite the availability of in vitro diagnostics needed in public health emergency situations and to assist interested UN procurement agencies and Member States in determining the acceptability of using specific products in the context of a Public Health Emergency of International Concern (PHEIC), based on an essential set of available quality, safety and performance data. The EUL procedure includes the following:


Wantai SARS-CoV-2 RT-PCR Kit code WS-1248, CE-mark regulatory version, manufactured by Beijing Wantai Biological Pharmacy, No.31 Kexueyuan Road, Changping District Beijing 102206, China was listed on 14 August 2020.

Intended use:

According to the claim of intended use from Beijing Wantai Biological Pharmacy, “this kit is intended for qualitative detection of the Severe Acute Respiratory Syndrome Coronavirus 2 (SARSCoV-2) RNA extracted from oropharyngeal swab, nasopharyngeal swab, sputum, endotracheal aspirate and bronchoalveolar lavage fluid specimens of patients suspected for infection with COVID-19. Target genes detected by the assay are the N and ORF1ab genes of SARS-CoV-2. Testing may be conducted manually or automatically. Results are for the identification of SARS-CoV-2 RNA, which is generally detected in respiratory specimens during the acute phase of infection. Positive results are indicative of the presence of SARS-CoV-2; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or coinfection with other viruses. The agent detected may not be the definite cause of disease. This kit is only for in vitro diagnostic use (IVD) to aid the diagnosis of COVID-19. It is intended to be used by laboratory professionals or qualified staff in laboratories that are biosafety level 2 or above.

Infection with SARS-CoV-2 can cause the respiratory disease COVID-19. Its symptoms include fever, weakness and dry cough, and breathing problems that appear gradually. In severe cases,
acute respiratory distress syndrome (ARDS), septic shock, metabolic acidosis that is hard to correct, coagulation disorders and death may occur.”

Specimen type that was validated:

Oropharyngeal swab, Nasopharyngeal swab, sputum, endotracheal aspirate and bronchoalveolar lavage fluid specimens.

Test kit contents:

<table>
<thead>
<tr>
<th>Component</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>RT-PCR master mix</td>
<td>1.25mL×1 vial</td>
</tr>
<tr>
<td>Mn(OAc)$_2$</td>
<td>125μL×1 vial</td>
</tr>
<tr>
<td>Primer and probe</td>
<td>125μL×1 vial</td>
</tr>
<tr>
<td>Positive control</td>
<td>1 mL×1 vial</td>
</tr>
<tr>
<td>Negative control</td>
<td>1 mL×1 vial</td>
</tr>
</tbody>
</table>

Items required but not provided:

Specimen collection, storage and transportation materials:

Specimen collection kits:

- Validated commercial VTM kits: “Wantai SARS-CoV-2 VTM” (catalog No. ZCT1261) manufactured by Beijing Wantai Biological Pharmacy Enterprise Co. Ltd.

- VTM&UTM (catalog No. MT0301) manufactured by Yocon biotechnology Co., Ltd.

Extraction/Purification:

Extraction kits:

- Wantai Nucleic Acid Extraction Kit (catalog No. ZCT1246).
- GenMagBio (catalog No. NA007-1).
- QIAGEN (catalog No. 57704).

Extraction equipment:

- Kingfisher Flex 96 (manufactured by Thermo Fisher).
- SLA-32 (Manufactured by Taiwan Advanced Nanotech Inc. (TANBead))
Real-Time PCR equipment:
- BIO-RAD CFX96 (software version Bio-Rad CFX Manager 3.1)
- ABI 7500 (software version 7500 version 2.3).

General laboratory equipment and consumables
- PCR tubes and caps
  - When using the BIO-RAD CFX96 amplificator, it is necessary to include the Low-Profile PCR Tubes (Catalog No. TLS0851) and Optical Flat 8-Cap Strips for 0.2ml tube strips/plates (Catalog No. TCS0803) of BIO-RAD.
  - When using the ABI7500 amplificator, it is necessary to include the PCR STRIP TUBES (PCR-0208-C) and PCR STRIP CAPS (PCR-2CP-RT-C) of Axygen or PCR consumables of ABI accessories.
- Class II (or higher) biological safety cabinet (BSC).
- Benchtop centrifuge
- Vortex mixer
- Adjustable calibrated pipettes
- Aerosol barrier pipette tips
- Powder free disposable gloves

Storage:
Store Wantai SARS-CoV-2 RT-PCR Kit below -15 °C. Avoid exposing the kit to direct sunlight.

Shelf-life upon manufacture:
12 months.

Warnings/limitations:
Refer to the instructions for use (IFU)

Product dossier assessment
Beijing Wantai Biological Pharmacy submitted a product dossier for the Wantai SARS-CoV-2 RT-PCR Kit for detecting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) as per the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_0347 version 4)”. The information (data and documentation) submitted in the product dossier was reviewed by WHO staff and external technical experts (assessors) appointed by WHO.
Post listing Commitment for EUL:

As commitments to listing, the manufacturer is required to review the limit of detection with the WHO international standard when available.

Risk benefit assessment conclusion: acceptable.

Quality Management Systems Review

To establish the eligibility for WHO procurement, Beijing Wantai Biological Pharmacy was asked to provide up-to-date information about the status of their quality management system.

Based on the review of the submitted quality management system documentation by WHO staff, it was established that sufficient information was provided by Beijing Wantai Biological Pharmacy to fulfil the requirements described in the “Instructions for Submission Requirements: In vitro diagnostics (IVDs) Detecting SARS-CoV-2 Nucleic Acid (PQDx_347)”.

Quality management documentation assessment conclusion: acceptable.

Plan for Post-Market Surveillance

Post-market surveillance, including monitoring all customer feedback, detecting and acting on adverse events, product problems, non-conforming goods and processes is a critical component of minimizing potential harm of an IVD listed for emergency use.

The following post-EUL activities are required to maintain the EUL listing status:

1. Notification to WHO of any planned changes to a EUL product, in accordance with “WHO procedure for changes to a WHO prequalified in vitro diagnostic” (document number PQDx_121); and

Beijing Wantai Biological Pharmacy is also required to submit an annual report that details sales data and all categories of complaints in a summarized form. There are certain categories of complaints and changes to the product that must be notified immediately to WHO, as per the above-mentioned documents.

The manufacturer has committed to ensure that post-emergency use listing safety, quality and performance monitoring activities are in place which are in accordance with WHO guidance “WHO guidance on post-market surveillance of in vitro diagnostics”.

1 Available on the web page https://www.who.int/diagnostics_laboratory/postmarket/en/
Scope and duration of procurement eligibility

Wantai SARS-CoV-2 RT-PCR Kit, product code WS-1248 manufactured by Beijing Wantai Biological Pharmacy is considered to be eligible for WHO procurement for 12 months from the day of listing. The assay may be used for the detection of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) RNA. This listing does not infer that the product meets WHO prequalification requirements and does not mean that the product is listed as WHO prequalified.

As part of the on-going requirements for listing as eligible for WHO procurement, Beijing Wantai Biological Pharmacy must engage in post-market surveillance activities to ensure that the product continues to meet safety, quality and performance requirements. Beijing Wantai Biological Pharmacy is required to notify WHO of any complaints, including adverse events related to the use of the product within 7 days and any changes to the product.

WHO reserves the right to rescind eligibility for WHO procurement, if additional information on the safety, quality, performance during post-market surveillance activities, and if new data becomes available to WHO that changes the risk benefit balance.
Labelling

1.0 Labels

2.0 Instructions for Use (IFU)
1.0 Product labels
Wantai SARS-CoV-2 RT-PCR Kit

Nucleic Acid Detection Kit for Detection of Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2)
(PCR-Fluorescence Probing)

<table>
<thead>
<tr>
<th>Components</th>
<th>Code</th>
<th>Format</th>
</tr>
</thead>
<tbody>
<tr>
<td>RT-PCR master mix</td>
<td>1</td>
<td>1 x 1.25ml</td>
</tr>
<tr>
<td>NEGATIVE CONTROL</td>
<td>5</td>
<td>1 x 1ml</td>
</tr>
<tr>
<td>POSITIVE CONTROL</td>
<td>4</td>
<td>1 x 1ml</td>
</tr>
<tr>
<td>Mn(OAc)2</td>
<td>2</td>
<td>1 x 125μL</td>
</tr>
<tr>
<td>Primer and probe</td>
<td>3</td>
<td>1 x 125μL</td>
</tr>
</tbody>
</table>
Reagents labels:

<table>
<thead>
<tr>
<th>Code</th>
<th>SARS-CoV-2 RT-PCR</th>
<th>1.25ml</th>
<th>PCR Master Mix</th>
<th>IVD</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
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</tr>
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<td>IVD</td>
</tr>
<tr>
<td>4</td>
<td>SARS-CoV-2 RT-PCR</td>
<td>1ml</td>
<td>Positive Control</td>
<td>IVD</td>
</tr>
<tr>
<td>5</td>
<td>SARS-CoV-2 RT-PCR</td>
<td>1ml</td>
<td>Negative Control</td>
<td>IVD</td>
</tr>
</tbody>
</table>

Revision History:

<table>
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<tr>
<th>Version</th>
<th>Reason of Revision</th>
<th>Revised Content</th>
<th>Revision Date</th>
<th>Revised by</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0</td>
<td>International version</td>
<td>Major revision, adding of new pictograms and hazard markings</td>
<td>February 26, 2020</td>
<td>Delemir Delev</td>
<td>Zhao Lingzhi</td>
</tr>
</tbody>
</table>
2.0 Instructions for use

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2 English version of the IFU was the one that was assessed by WHO. It is the responsibility of the manufacturer to ensure correct translation into other languages.
Infection with SARS-CoV-2 can cause the respiratory disease COVID-19. Its symptoms include fever, weakness and fatigue, dry cough, sore throat, and others. In severe cases, infection often becomes complicated and even life-threatening, with symptoms such as ARDS, septic shock, metabolic acidosis that is hard to correct, coagulation disorders and death may occur.

WanTai SARS-CoV-2 RT-PCR Kit is designed for in vitro diagnostic use (IVD) only. This kit is for semi-automatic detection and analysis of the SARS-CoV-2 pathogen in human nasopharyngeal swab, oropharynx swab, or bronchial aspirate specimen to aid the diagnosis of COVID-19, which should be consumed by laboratory professionals in biosafety level 2 or above laboratories.

**Usage and precautions**
- For institutional use only.
- The WanTai SARS-CoV-2 RT-PCR Kit has been authorized only for the detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab, oropharyngeal swab, or bronchial aspirate specimen.
- This kit is not applicable for the diagnosis of patients suspected for infection with COVID-19 during the latent period of infection.
- Keep the kit stored at room temperature (15°C - 25°C) and humidity less than 75% RH.

**Components**

**Amplification and control**
- RT-PCR master mix: 1x
- Primer and probe: 125 μL x 2
- Negative control: 1 mL
- Positive control: 1 mL

**Materials required but not provided**
- Specimen: a sterile swab for extracting the test sample
- Transport medium: V&K transport media (SLA-32 Taiwan Advanced Nanotech Inc. (TANBead))
- Pipette tips, Powder free disposable gloves, Thermostatic equipment (water bath, thermostatic incubator)
- PCR consumables of ABI accessories (catalog No. MT0301) manufactured by Axygen or PCR STRIP CAPS (PCR-2CP-RT-C) of Axygen or PCR consumables of Northern Bioscience (Catal No. 57704) . Validated initial specimen volumes of 200 μL and elution volumes of 50 μL
- Powder free sterile gloves

**Storage and shelf-life**
- Store the kit in a dry place away from direct sunlight.
- After opening, the kit can be stored at -15°C. Avoid exposing the kit to direct sunlight. Do not press the package.

**RT-PCR Instruments**
- Used by laboratory professionals.
- When using BIORAD CFX96 (Bio-Rad CFX Manager 3.1) or ABI 7500 (7500 software v2.3) whereas extraction may occur in different laboratories. Cross-use of equipment from different laboratories and analysis area.) Each phase of the test uses special-purpose amplification and analysis instruments. Cross-use of equipment from different laboratories and analysis area.)
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**Specimen preparation**
- After collecting the specimen, insert the microbial swab into the sterilized VTM (1 mL) for transport. After centrifugation (12000rpm/min for 5 minutes) with proper dilution of no more than 2x, extract the filtrate and store in -70°C. Avoid exposing the kit to direct sunlight. Do not press the package.
- Use a microbial swab to wipe the posterior pharyngeal wall and tonsil on both sides with liquid. After airflow suction and bronchoalveolar lavage (10 mL), and airways of the patients are aspirated and bronchoalveolar lavage (BAL) fluid is collected. The bronchoalveolar lavage fluid is then stored at -70°C. Avoid exposing the kit to direct sunlight. Do not press the package.

**Guidelines and application**
- Use personal protective equipment (PPE) consistent with current guidelines for the handling of potentially infectious specimens.
- If biohazard/biological leakage fluid is not clear, the following approaches with the specimens:
  - After centrifugation (12000rpm/min for 5 minutes) extract the clarified filtrate
  - After centrifugation (12000rpm/min for 5 minutes) with proper disinfection of no more than 2x, extract the filtrate

**Materials**
- Single-use disposable plastic sterile swabs
- V&K transport media (SLA-32 Taiwan Advanced Nanotech Inc. (TANBead))
- Microbiological pipette 600 μL
- Powder free sterile gloves

**Storage and shelf-life**
- Store at room temperature for up to 9 months.
- After opening, the kit can be stored at -15°C. Avoid exposing the kit to direct sunlight. Do not press the package.

**Components**
- PCR amplification reagents and probes: 50 μL x 2
- PCR STRIP CAPS (PCR-2CP-RT-C)
- PCR consumables of Axygen or PCR STRIP CAPS (PCR-2CP-RT-C) of Axygen or PCR consumables of Northern Bioscience (Catal No. 57704) . Validated initial specimen volumes of 200 μL and elution volumes of 50 μL

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Establishing of the analytical sensitivity of the kit has been evaluated on 3 kit lots.

### Performance Validation of the Kit

The performance validations of the kit have been conducted with the Applied Biosystem® 7500 Real-Time PCR system and Bio-Rad CFX 96 instruments. For specimen extraction, Wantai Nucleic Acid Extraction Kit with 100% recovery rate has been used.

#### Analytical Sensitivity

- **Specimen Type**: Oropharyngeal swab
- **Specimen**: Used for testing the sensitivity of the kit in different concentrations (positive 1000 copies/ml, low positive 150 copies/ml and negative 0 copies/ml) for 5 days.
- **Test Systems**: Applied Biosystem® 7500 Real-Time PCR system, Lot-1,2,3 using Wantai nucleic acid extraction reagent
- **Test Equipment**: technician-1, CFX-96

### Results

<table>
<thead>
<tr>
<th>Lot</th>
<th>Specimen Type</th>
<th>Mean Cq</th>
<th>Cq Standard</th>
<th>% Replicate</th>
<th>Mean Cq</th>
<th>Cq Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lot-1</td>
<td>Oropharyngeal swab</td>
<td>35.9</td>
<td>0.5</td>
<td>100%</td>
<td>35.9</td>
<td>0.5</td>
</tr>
<tr>
<td>Lot-2</td>
<td>Oropharyngeal swab</td>
<td>35.9</td>
<td>0.5</td>
<td>100%</td>
<td>35.9</td>
<td>0.5</td>
</tr>
<tr>
<td>Lot-3</td>
<td>Oropharyngeal swab</td>
<td>35.9</td>
<td>0.5</td>
<td>100%</td>
<td>35.9</td>
<td>0.5</td>
</tr>
</tbody>
</table>

### Conclusion

The kit has demonstrated very good specificity and sensitivity. The results indicate that the kit can be used for the detection of COVID-19.

### Acknowledgments

Chunfang Qian, Qiangzhong Sun, Qingli Hu, Honglan Liu, Sikuan Ye, Xiaomei Xiang, Yi Zhou, Wei Zhang, Jiayi Yang, Manqing Liu, Yang Zhao, Xiaoying Zhang, Tao Zhu, Tao Peng, Jie Xie, Yunhua Gao, Di Wang, Yun Lianhua Dong, Junbo Zhou, Chunyan Niu, Quanyi Wang, Yang Pan, Sitong Sheng, Xia Wang, Yongzhuo Zhang, Jianhui Zhou, Qiang Xiao, Hong Shan.

### References

4. Householder Secondary Attack Rate of COVID-19 and Associated Determinants

### [CT Markings]

#### In Vivo Diagnostic Device
- Use by
- Current Sufficiency For In Test
- CE Marking – ISO 9001
- EU Authorized Representative
- Catalog Number
- Manufacturer
- Beijing Wantai Biological Pharmacy Enterprise Co., Ltd., No.31 Kexueyuan Road, Changping District, Beijing 102206, China
- Website: www.wbph.com, Email: velpe@wbph.com

#### In Vitro Diagnostic Medical Device
- Use by
- Current Sufficiency For In Test
- CE Marking – ISO 13485
- EU Authorized Representative
- Catalog Number
- Manufacturer
- Chunfang K. B. Co., Ltd, Beijing, Email: care@cfk.com