Three Genes + Endogenous Quality Control
NO Missed Detection

SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method)

**Intended use**
Qualitative detection of SARS-CoV-2 virus RNA

**Package**
50 Tests/Kit; 200 Tests/Kit

**Packing Size&Weight**
6.5*4*5 cm & 20g/35g

**Specimen Type**
Sputum, throat swabs and other respiratory specimens

**Applicable Instruments**
Applied Biosystems® 7500/7500Fast real-time PCR systems.

**Limit of Detection**
1000 Copies/mL

**Cut-off Value**
40(Ct)

**Test Time**
2 Hours

**Detection targets**

<table>
<thead>
<tr>
<th>Gene detected</th>
<th>Fluorescence channel</th>
</tr>
</thead>
<tbody>
<tr>
<td>ORF1ab gene</td>
<td>FAM</td>
</tr>
<tr>
<td>S gene</td>
<td>ROX</td>
</tr>
<tr>
<td>N gene</td>
<td>CY5</td>
</tr>
<tr>
<td>Internal reference (human RNA)</td>
<td>VIC</td>
</tr>
</tbody>
</table>

**Features**

1. Multi-target detection of ORF1ab, N, S genes to avoid missed detection due to rapid mutation of SARS-CoV-2;
2. Anti-pollution system to avoid false positives caused by PCR aerosol pollution caused by increasing detection number;
3. Endogenous quality control of human RNA to avoid false negative RNA degradation caused by improper sample collection, transfer or storage

**Kit Components**

<table>
<thead>
<tr>
<th>Components</th>
<th>Main Ingredients</th>
<th>50 Tests/Kit</th>
<th>200 Tests/Kit</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 Master Mix</td>
<td>RT-PCR primer/probe sets, dNTP, Mg++, dUTP, Buffer</td>
<td>770 μL×1</td>
<td>1540 μL×2</td>
</tr>
<tr>
<td>SARS-CoV-2 Enzyme Solution</td>
<td>Reverse transcriptase, Uracil-DNA glycosylase, HotStart DNA Polymerase, Glycerol</td>
<td>60 μL×1</td>
<td>240 μL×1</td>
</tr>
<tr>
<td>SARS-CoV-2 Positive Control</td>
<td>Recombinant plasmids including the targets and human RNA fragments</td>
<td>50 μL×1</td>
<td>200 μL×1</td>
</tr>
<tr>
<td>SARS-CoV-2 Negative Control</td>
<td>Nuclease-free H2O</td>
<td>1000 μL×1</td>
<td>1000 μL×4</td>
</tr>
</tbody>
</table>

**Clinical significance**

1. Positive, early identification of SARS-CoV-2, helps prognosis and management
2. Negative two times one day apart, eliminates SARS-CoV-2 infection, reduces prevention and control pressure, and reduces social panic
**Specimen Handling** *(Reagents and devices are not provided in this kit)*

**Specimen sampling**
1) upper respiratory specimens: nasopharyngeal and/or oropharyngeal swabs using flocked swabs and VTM (Recommend Copan, PN 365C/366C/368C)
2) and/or lower respiratory specimens: sputum (if produced) and/or endotracheal aspirate or bronchoalveolar lavage

**Specimen shipment and storage**
Kits should be cold-chain shipped with gel pack or dry ice. During transportation, it can be kept up to 14 days at a temperature of -80 ~ 2°C and up to 7 days at a temperature of 2 ~ 8°C.

**Nucleic acid extraction**
1) RNeasy Mini Kit (Qiagen, PN 74104)
2) QIAsymphony RNA Kit (Qiagen, PN 931636)
3) or automated TANBead® extract system (Taiwan Advanced Nanotech, PN SLA-32/ Maelstrom 9600) with a TANBead Viral Auto Plate kit (Taiwan Advanced Nanotech, PN 665A46)
4) Other extraction methods can be used after validated by laboratory quality control system

Extracted nucleic acid should be used as template in this kit immediately.

### Example results

![Graphs showing positive and negative sample results](image)

<table>
<thead>
<tr>
<th>Product</th>
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<th>P/N</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method)</td>
<td>50 tests/kit</td>
<td>XC25073</td>
</tr>
<tr>
<td>SARS-CoV-2 Virus Detection Diagnostic Kit (RT-qPCR Method)</td>
<td>200 tests/kit</td>
<td>XC25087</td>
</tr>
</tbody>
</table>

**Ordering Information**

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Health Gene Technologies Co. Ltd. (HGT) is committed to developing and manufacturing simple, rapid and effective nucleic acid (DNA) testing solutions for molecular diagnostics, clinical research and forensic analysis.

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HEALTH Gene Technologies

Safer Society · Healthier Life

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