SARS-CoV-2 Antigen Rapid Test (Colloidal Gold)

**INTENDED USE**

SARS-CoV-2 Antigen Rapid Test (Colloidal Gold) is intended for the qualitative detection of SARS-CoV-2 Antigen in nasal swab specimens in vitro.

**FEATURES**

- Rapid testing for SARS-CoV-2 in 15 minutes
- High Sensitivity and Specificity
- Detect 2-3 days after contracted virus
- Easy sampling method: nasal swab

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www.wizbiotech.com
**SPECIMEN COLLECTION**

Nasal Swab:

1. Insert the disposable swab into one of the patient’s nostril, 2.5 cm (1 inch) away from the edge of the nostril.
2. Roll the swab tip for 5 times on the mucosa of the nostril to collect both mucus and cells.
3. Use the same swab to repeat this process for the other nostril to collect more samples. Withdraw the swab from the nasal cavity.

**TEST PROCEDURE**

1. Remove a vial of extraction solution from the kit, screw off or cut off the sealing head of the extraction solution, and squeeze all the extraction solution into the extraction tube.
2. Dip the swab head into the extraction solution rotate the swab close to the specimen extraction tube wall for about 10 seconds or 10 times.
3. Squeeze the tip of the swab along the inner wall of the specimen extraction tube. Remove and discard the swab. Then tighten tube cover and stand by.
4. Vertically invert the specimen extraction tube (the extraction tube with processed specimens), add 2 drops vertically into the sample well of the test device.
5. Read the result within 15 to 20 minutes, invalid if more than 30 minutes.

**LIMIT OF DETECTION**

1.7x10² TCID50/mL

**RESULT INTERPRETATION**

**Negative**: The red line in the "C" control line region appears. No line appears in the "T" test line regions.

**Positive**: The red line in the "C" control line region appears and a red line appears in the "T" test line region.

**Invalid**: The red line in the "C" control line region doesn't appear.

**CLINICAL PERFORMANCE**

<table>
<thead>
<tr>
<th>WIZ Results</th>
<th>Reference PCR Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>POS</td>
</tr>
<tr>
<td>POS</td>
<td>328</td>
</tr>
<tr>
<td>NEG</td>
<td>14</td>
</tr>
<tr>
<td>Total</td>
<td>342</td>
</tr>
</tbody>
</table>

PPA: 95.91% (C.I. 93.25%~97.55%)  
NPA: 100.00% (C.I. 99.26%~100.00%)  
OPA: 98.37% (C.I. 97.28%~99.03%)

**PACKAGE**

Per box: 20 tests/box

- Size: 210x140x70mm
- Accessories: Test device (20pcs), Extraction solution(20pcs), Extraction tube(20pcs), Disposable swabs(20pcs), Package insert(1pcs)

Per carton: 40 boxes/carton

- N.W.: 12kg
- G.W.: 15kg
- Volume: 0.097 cbm (730x435x305mm)