**INTENDED USE**

The SARS-CoV-2 Rapid Antigen Test is a lateral flow rapid immunochromatographic immunoassay for qualitative detection of nucleocapsid protein (N) antigen of SARS-CoV-2 present in human nasal swab samples. This test is INTEGRATED for use in an ASPIRE-ColiAg device to detect asymptomatic COVID-19 cases with clinical symptoms within 5 days. Results are for the identification of SARS-CoV-2 nucleocapsid antigen. Antigen is generally detectable in human nasal swab samples during the acute phase of infection. Positive results indicate the presence of viral antigen, but false positive results with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The antigen detected may not be different of disease. Negative results should be treated as unprocessed, and do not rule out SARS-CoV-2 infection and should be repeated for the same case if treatment for a management decision is necessary. Include infection controls decisions. Negative results should be considered in the context of a patient’s recent history. A positive result does not exclude the possibility of clinical signs and symptoms consistent with COVID-19, and should be considered with a molecular assay, if necessary, for patient management. The SARS-CoV-2 Rapid Antigen Test is intended for use in laboratories or POC settings by healthcare professionals, or self-collection under the supervision of a healthcare worker.

**INTRODUCTION**

Coronaviruses can cause a variety of acute and chronic diseases. Common signs of a person infected with a coronavirus include respiratory symptoms, fever, cough, shortness of breath, and diarrhea. In more severe cases, infection can cause pneumonia, severe acute respiratory syndrome (SARS), and even death. In late 2019 a new coronavirus, later named SARS-CoV-2, was found to be a cause of pneumonia cases, and the World Health Organization described the global SARS-CoV-2 epidemic as a pandemic on March 11, 2020. The disease associated with SARS-CoV-2 infection was named as COVID-19 (Coronavirus Disease 2019).

**PRINCIPLE OF THE TEST**

The SARS-CoV-2 Rapid Antigen Test has two pre-coated lines: a "T" Control line and a "T" Test line on the surface of the test strip. Both the test line and the control line in the test card window will not be visible before applying any samples. Monoclonal anti-SARS-CoV-2 antibody conjugated with dyes is immobilized on the test strip. Positive and negative controls should be included in each kit. The test device contains anti-SARS-CoV-2 antibody, conjugated with a color particle. The sample is applied to the test device. If the test is positive, the test line will appear. The result can be read within 15 minutes. If the test is negative, no line appears. The test should be discarded after use. Even if the test line is very faint or not uniform the test result should be interpreted as a positive result. If SARS-CoV-2 antigens are not present in the sample, no color appears in the test line. The control line is used for procedural control, and always appears in the test window. If the test control is not visible, the test should be considered as invalid.

**ACTIVE COMPONENTS**

- monoclonal anti-SARS-CoV-2 antibody
- conjugate (gold)
- monoclonal anti-SARS-CoV-2 antibody-gold conjugate
- Purified Chicken IgY-gold conjugate
- Recombinant COVID-19 nucleocapsid protein (positive controls)

**KIT CONTENTS**

- Test device
- Extraction buffer tube
- Nozzle cap
- Sterile swab
- Instructions for use
- Positive and negative controls
- Buff er tube
- Sterile swab
- Instructions for use
- Positive and negative controls

**TEST STORAGE**

- Store the kit at 2-30°C / 36-86°F out of direct sunlight.
- Foil pouch with desiccant and biohazard waste.
- Laboratory chemical wastes must be handled and discarded in accordance with all local, state, and national regulations.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after handling kit reagents.
- The device contains benzyl alcohol and even benzaldehyde and is flammable.
- Follow up: If buff er is spilled, do not use the tube.

**WARIANS AND PRECAUTIONS**

1. Equilibrate the kit contents and specimens to operating temperature before testing.
2. Do not use the test if the pouch is damaged or the swab is broken.
3. Do not use the extraction buffer tube of another lot.
4. Do not use the extraction buffer tube of another lot.
5. Do not use the extraction buffer tube of another lot.
6. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after the tests are done.
7. Use clean spines thoroughly using an appropriate disinfectant.
8. Avoid exposure to dust or other small particles.
9. Do not use the extraction buffer tube of another lot.
10. Do not use the extraction buffer tube of another lot.

**Rapid Ag Test Kit**

**PREPARATION**

1. Open the foil pouch and remove the test device and the desiccant package. Use the test immediately after opening the pouch.
2. Place the test device on a flat surface and apply 3 drops of extracted sample to the specimen well of the test device.
3. Remake the swab while squeezing the sides of the tube to extract the liquid from the swab once. If necessary, discard the device after use.
4. Place the swab device on a flat surface.
5. Dispense the specimen at a 90-degree angle to allow for free falling drops and avoid pipetting the specimen.
6. Do not read test results after 30 minutes. It may give false results.

**INTERNAL QUALITY CONTROL**

A control line and a control line are used to check the test result. A control line should appear if the control line is present. If the control line is not visible, the test should be considered as invalid.

**EXTERNAL QUALITY CONTROL**

1. Place the test device in a flat surface and apply 3 drops of extracted sample at a 90-degree angle to the specimen well of the test device.
2. Check the test device in a flat surface and apply 3 drops of extracted sample at a 90-degree angle to the specimen well of the test device.
3. Place the test device in a flat surface and apply 3 drops of extracted sample at a 90-degree angle to the specimen well of the test device.
4. Place the test device in a flat surface and apply 3 drops of extracted sample at a 90-degree angle to the specimen well of the test device.
5. Place the test device in a flat surface and apply 3 drops of extracted sample at a 90-degree angle to the specimen well of the test device.
6. Place the test device in a flat surface and apply 3 drops of extracted sample at a 90-degree angle to the specimen well of the test device.
7. Place the test device in a flat surface and apply 3 drops of extracted sample at a 90-degree angle to the specimen well of the test device.
8. Place the test device in a flat surface and apply 3 drops of extracted sample at a 90-degree angle to the specimen well of the test device.
9. Place the test device in a flat surface and apply 3 drops of extracted sample at a 90-degree angle to the specimen well of the test device.
10. Place the test device in a flat surface and apply 3 drops of extracted sample at a 90-degree angle to the specimen well of the test device.

**INTERPRETATION OF TEST RESULTS**

<table>
<thead>
<tr>
<th>Test result</th>
<th>Example</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negative*</td>
<td>A colored band will appear in the top section of the result window to show that the test is working properly.</td>
<td>A colored band will appear in the top section of the result window to show that the test is working properly.</td>
</tr>
<tr>
<td>Positive*</td>
<td>A colored band will appear in the lower section of the result window. This band is test line of SARS-CoV-2 antigen.</td>
<td>A colored band will appear in the lower section of the result window. This band is test line of SARS-CoV-2 antigen.</td>
</tr>
</tbody>
</table>

**LIMITATIONS**

The test procedure, precursors, and interpretation of results for this test must be followed strictly when testing.

1. This test is intended for use during the acute phase of infection.
2. This test is intended for use during the acute phase of infection.
3. This test is intended for use during the acute phase of infection.

**SPECIFIC PERFORMANCE DATA**

**Clinical evaluation**

Clinical performance of the SARS-CoV-2 Rapid Antigen Test was evaluated using nasal swab samples from 696 subjects presenting with symptoms consistent with a clinical case in Germany. The study cohort included adults at high risk for SARS-CoV-2 infection according to clinical suspicion. 312 subjects underwent nasal sampling performed by healthcare professionals and 394 subjects followed instructions to obtain a nasal swab sample by themselves. Self-collection was performed under the supervision of healthcare workers without interference or assistance. Test procedure and test results were analyzed by healthcare professionals. Kit performance was compared with SARS-CoV-2 RNA testing (PCR tests, BioMérieux myACucure SARS-CoV-2 gene assay) using clinical samples and the comparator methods. Nasal swab samples were used in all tested pharyngeal SARS-CoV-2 RNA tests. The relative sensitivity and relative specificity were 0.12 (95% CI: 0.02 - 2.54) and 0.57 (95% CI: 0.51 - 0.63) in self-collected nasal samples.

**Sample information and performance:**

**SARS-CoV-2 Rapid Antigen Test Nasal**

The relative sensitivity and relative specificity were 0.12 (95% CI: 0.02 - 2.54) and 0.57 (95% CI: 0.51 - 0.63) in self-collected nasal samples.

**Sample information and performance:**

**SARS-CoV-2 Rapid Antigen Test Nasal**

The relative sensitivity and relative specificity were 0.12 (95% CI: 0.02 - 2.54) and 0.57 (95% CI: 0.51 - 0.63) in self-collected nasal samples.

**Sample information and performance:**

**SARS-CoV-2 Rapid Antigen Test Nasal**

The relative sensitivity and relative specificity were 0.12 (95% CI: 0.02 - 2.54) and 0.57 (95% CI: 0.51 - 0.63) in self-collected nasal samples.

**Sample information and performance:**

**SARS-CoV-2 Rapid Antigen Test Nasal**

The relative sensitivity and relative specificity were 0.12 (95% CI: 0.02 - 2.54) and 0.57 (95% CI: 0.51 - 0.63) in self-collected nasal samples.

**Sample information and performance:**

**SARS-CoV-2 Rapid Antigen Test Nasal**

The relative sensitivity and relative specificity were 0.12 (95% CI: 0.02 - 2.54) and 0.57 (95% CI: 0.51 - 0.63) in self-collected nasal samples.

**Sample information and performance:**

**SARS-CoV-2 Rapid Antigen Test Nasal**

The relative sensitivity and relative specificity were 0.12 (95% CI: 0.02 - 2.54) and 0.57 (95% CI: 0.51 - 0.63) in self-collected nasal samples.
In vitro


Temperature limit


SARS-CoV-2 positive and negative samples were tested. There was no interference on the test result from potentially interfering substances listed below.

Endogenous / exogenous interference substances studies

For microorganisms that did not cross-react, additional microbial testing was performed and no microbial interference was found.

Microbial interference

For microorganisms that did not cross-react, additional microbial testing was performed and no microbial interference was found.

Endogenous / exogenous interference substances studies

There was no interference on the test result from potentially interfering substances listed below. SARS-CoV-2 positive and negative samples were tested.

<table>
<thead>
<tr>
<th>Potential interfering substance</th>
<th>Concentration</th>
<th>Viral strain level</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Microorganisms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mucin</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Chloramphenicol (Mellor's Bacteriocin)</td>
<td>1.5 mg/mL</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus (ATCC 10033)</td>
<td>5% v/v</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>SARS-CoV-2 cultured virus</td>
<td></td>
<td>POS</td>
<td></td>
</tr>
<tr>
<td><strong>Chemicals and Drugs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzocaine (Phenol)</td>
<td>5% v/v</td>
<td>POS</td>
<td></td>
</tr>
<tr>
<td>Chlorhexidine (Phenol)</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Nonivirax</td>
<td>0.01%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td><strong>Homeopathic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alkalol</td>
<td>1:10 dilution</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Zicam</td>
<td>1:100 dilution</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>CVS Health Nasal Spray (Ginseng)</td>
<td>1:100 dilution</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td><strong>Interfering Substances</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human coronavirus HKU1</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Mycobacterium tuberculosis</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Pneumocystis jirovecii</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
</tbody>
</table>

b) Results from interference testing with SARS-CoV-2 positive samples:

<table>
<thead>
<tr>
<th>Potential interfering substance</th>
<th>Concentration</th>
<th>Viral strain level</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Microorganisms</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mucin</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Chloramphenicol (Mellor's Bacteriocin)</td>
<td>1.5 mg/mL</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Staphylococcus aureus (ATCC 10033)</td>
<td>5% v/v</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>SARS-CoV-2 cultured virus</td>
<td></td>
<td>POS</td>
<td></td>
</tr>
<tr>
<td><strong>Chemicals and Drugs</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Benzocaine (Phenol)</td>
<td>5% v/v</td>
<td>POS</td>
<td></td>
</tr>
<tr>
<td>Chlorhexidine (Phenol)</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Paracetamol</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Nonivirax</td>
<td>0.01%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td><strong>Homeopathic</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Alkalol</td>
<td>1:10 dilution</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Zicam</td>
<td>1:100 dilution</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>CVS Health Nasal Spray (Ginseng)</td>
<td>1:100 dilution</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td><strong>Interfering Substances</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Human coronavirus HKU1</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Mycobacterium tuberculosis</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
<tr>
<td>Pneumocystis jirovecii</td>
<td>0.1%</td>
<td>NEG</td>
<td></td>
</tr>
</tbody>
</table>

REFERENCES


For all questions about the SARS-CoV-2 Rapid Antigen Test Nasal that are not answered in this package insert, there is a FAQ document available on the Roche Canada website (www.roche.com). Please log in to the documentation section via the search engine on the website. Please contact Roche Care Center for technical questions at 1-877-274-5433.

The SARS-CoV-2 Rapid Antigen Test is distributed in Canada by: Roche Diagnostics

201 1st Avenue NE Calgary, Alberta, Canada T2Y 4H2

CAN FV3
Issue date: 2021-12

SD Biosensor, Inc.

Head office: C-44648, 16, Deoggo-dong, Daegu, 42565, Republic of Korea

Manufacturing site: 14, Cheongwang-dong, Buyeo-gun, Chungcheongnam-do, 33570, REPUBLIC OF KOREA

www.sdbiosensor.com

Roche order number: 093502017601