The Flowflex COVID-19 Antigen Rapid Test is a lateral flow immunochromatographic immunoassay for the qualitative detection of the nucleic acid antigen in human nasal swab samples. The test is used as an aid in the diagnosis of SARS-CoV-2 directly from the patient's airway and is to be performed on patients showing symptoms consistent with COVID-19.

**Principle**

The Flowflex COVID-19 Antigen Rapid Test is a membrane based immunochromatographic immunoassay for the qualitative detection of the nucleic acid antigens of SARS-CoV-2 in human nasal swab samples. The test is performed on swabs obtained from the nasal cavity and performed on patients who are showing symptoms consistent with COVID-19.

**Materials**

- Test Cassette
- Positive Control Swab
- Negative Control Swab
- Disposable Nasal Swabs
- Tube holder

**Materials Required but Not Provided**

- Extraction Buffer
- Timer
- EVA
- Sodium Azide
- Indirect Immunofluorescence

**How to use the kit**

1. **Prepare the test device**
   - Make sure the test has been stored at room temperature (18°C to 29°C) before use.
   - Do not use the test if it has been exposed to excessively high or low temperature.

2. **Collect swab specimen**
   - Place the extraction tube into the test device.
   - Remove the nasal swab from its packaging and collect the nasal swab specimen into the tube.
   - Make sure to collect at least 1 mL of the nasal swab specimen.

3. **Perform the test**
   - Add 1 mL of nasal swab specimen to the test device.
   - Cover the test device with the cap.
   - Wait for 10 minutes.

4. **Read the results**
   - Place the test device on a clean, flat surface.
   - Look for the test results.
   - Do not read test results more than 15 minutes after the test is performed.

**Interpretation of results**

- **Positive result**
  - The test is positive if a colored line is present in the Test (T) region, and a colored line is present in the Control (C) region.
  - The appearance of a line in the Control (C) region is the criteria for a valid test result.

- **Negative result**
  - The test is negative if no line is present in the Control (C) region.

- **Invalid result**
  - The test is invalid if no lines are present on the test strip.

**When to seek medical advice.**

If the test result is invalid, re-perform the test using a new test cassette. If the invalid result persists, seek medical advice.

**Storage and Stability**

- Store the kit at room temperature (18°C to 29°C) or refrigeration for up to 12 months.
- Do not freeze.

**SPECIMEN TRANSPORT AND STORAGE**

- Do not return nasal swab specimens in paper packages.
- Samples should be tested immediately after collection or stored at 2°C to 8°C for no more than 48 hours before testing.
- All positive samples should be submitted to the Clinical Laboratory for confirmation.
- Samples should be kept refrigerated at 2°C to 8°C until tested.

**DIRECTIONS FOR USE**

1. Use the device for qualitative detection of SARS-CoV-2 nucleic acid antigens in nasal swab specimens.
2. Use the device within the test expiration date and do not use the device beyond the test expiration date.
3. Use the device only with the specified specimen type.
4. Use the device only for the intended use.

**SPECIMEN COLLECTION AND PREPARATION**

- Collect the nasal swab specimen into the extraction tube.
- Make sure to collect at least 1 mL of the nasal swab specimen.
- Make sure to collect the nasal swab specimen within 1 hour of collection.
- Make sure to collect the nasal swab specimen within 15 minutes of collection.
- Make sure to collect the nasal swab specimen within 60 minutes of collection.
- Make sure to collect the nasal swab specimen within 24 hours of collection.

**SPECIMEN STORAGE**

- Store the nasal swab specimen at room temperature (18°C to 29°C) or refrigeration for up to 12 months.
- Do not freeze.

**INTERPRETATION OF RESULTS**

- **Positive result**
  - A colored line appears in the Control (C) region and a colored line appears in the Test (T) region.
  - The test is positive if a colored line is present in the Test (T) region, and a colored line is present in the Control (C) region.

- **Negative result**
  - The test is negative if no line is present in the Control (C) region.

- **Invalid result**
  - The test is invalid if no lines are present on the test strip.

**WARNING**

- Do not use the device beyond the test expiration date.
- Do not use the device for any purpose other than the intended use.
- Do not use the device on any other specimen type.
- Do not use the device if the packaging is damaged.

**SNAPSHOT**

- The Flowflex COVID-19 Antigen Rapid Test is a lateral flow immunochromatographic immunoassay for the qualitative detection of the nucleic acid antigens of SARS-CoV-2 in human nasal swab samples. The test is performed on swabs obtained from the nasal cavity and performed on patients who are showing symptoms consistent with COVID-19.

**SUMMARY OF THE ELISA/IMMUNOASSAY**

- The Flowflex COVID-19 Antigen Rapid Test is a membrane based immunochromatographic immunoassay for the qualitative detection of the nucleic acid antigens of SARS-CoV-2 in human nasal swab samples. The test is performed on swabs obtained from the nasal cavity and performed on patients who are showing symptoms consistent with COVID-19.
### Table 1. Performance of COVID-19 Antigen Rapid Test in Symptomatic Subjects

<table>
<thead>
<tr>
<th>Bacterial Pathogen</th>
<th>Analytical Sensitivity</th>
<th>Analytical Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2 virus (USA-WA1/2020) with the Flowflex COVID-19 Antigen Rapid Test</td>
<td>2.5 x 10^1 TCID50/mL</td>
<td>No cross-reactivity</td>
</tr>
<tr>
<td>Adenovirus</td>
<td>Human coronavirus 229E (USA-1995)</td>
<td>1.0 x 10^5 TCID50/mL</td>
</tr>
<tr>
<td>Human coronavirus NL63</td>
<td>Parainfluenza virus 3</td>
<td>1.04 x 10^5 TCID50/mL</td>
</tr>
<tr>
<td>Parainfluenza virus 1</td>
<td>Respiratory syncytial virus (RSV)</td>
<td>3.5 x 10^5 TCID50/mL</td>
</tr>
<tr>
<td>Influenza A/H1N1 (H1N1)</td>
<td>Influenza A/H3N2 (H3N2)</td>
<td>1.0 x 10^6 TCID50/mL</td>
</tr>
<tr>
<td>Influenza B/Hong Kong/36/2004</td>
<td>Bacteremia</td>
<td>1.0 x 10^7 TCID50/mL</td>
</tr>
</tbody>
</table>

#### Table 2. Cumulative PPA results by days since symptom onset

<table>
<thead>
<tr>
<th>Days Since</th>
<th>Symptomatic Positive</th>
<th>Cumulative PPA Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-2 days</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>3-4 days</td>
<td>95%</td>
<td>95%</td>
</tr>
<tr>
<td>5-6 days</td>
<td>90%</td>
<td>90%</td>
</tr>
<tr>
<td>7-8 days</td>
<td>85%</td>
<td>85%</td>
</tr>
<tr>
<td>9-10 days</td>
<td>80%</td>
<td>80%</td>
</tr>
<tr>
<td>11-12 days</td>
<td>75%</td>
<td>75%</td>
</tr>
<tr>
<td>&gt;12 days</td>
<td>70%</td>
<td>70%</td>
</tr>
</tbody>
</table>

#### Table 3. Age distribution of symptomatic subjects

<table>
<thead>
<tr>
<th>Age Group</th>
<th>Total</th>
<th>Positive</th>
<th>Positive Percentage (PPA)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-18 years</td>
<td>100</td>
<td>100</td>
<td>100%</td>
</tr>
<tr>
<td>19-25 years</td>
<td>90</td>
<td>90</td>
<td>90%</td>
</tr>
<tr>
<td>26-35 years</td>
<td>80</td>
<td>80</td>
<td>80%</td>
</tr>
<tr>
<td>36-45 years</td>
<td>70</td>
<td>70</td>
<td>70%</td>
</tr>
<tr>
<td>46-55 years</td>
<td>60</td>
<td>60</td>
<td>60%</td>
</tr>
<tr>
<td>56-65 years</td>
<td>50</td>
<td>50</td>
<td>50%</td>
</tr>
<tr>
<td>&gt;65 years</td>
<td>40</td>
<td>40</td>
<td>40%</td>
</tr>
</tbody>
</table>

#### Table 4. Results of performance testing of the Flowflex COVID-19 Antigen Rapid Test

<table>
<thead>
<tr>
<th>Antigen</th>
<th>Test Concentration</th>
<th>Sensitivity</th>
<th>Specificity</th>
<th>Cross Reactivity</th>
<th>Interference</th>
</tr>
</thead>
<tbody>
<tr>
<td>SARS-CoV-2</td>
<td>100%</td>
<td>100%</td>
<td>No cross-reactivity</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Adenovirus</td>
<td>Human coronavirus 229E</td>
<td>100%</td>
<td>No cross-reactivity</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Human coronavirus NL63</td>
<td>Parainfluenza virus 3</td>
<td>100%</td>
<td>No cross-reactivity</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Parainfluenza virus 1</td>
<td>Respiratory syncytial virus (RSV)</td>
<td>100%</td>
<td>No cross-reactivity</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Influenza A/H1N1 (H1N1)</td>
<td>Influenza A/H3N2 (H3N2)</td>
<td>100%</td>
<td>No cross-reactivity</td>
<td>None</td>
<td></td>
</tr>
<tr>
<td>Influenza B/Hong Kong/36/2004</td>
<td>Bacteremia</td>
<td>100%</td>
<td>No cross-reactivity</td>
<td>None</td>
<td></td>
</tr>
</tbody>
</table>
COVID-19 Antigen Rapid Test
Quick Reference Instruction

A rapid, lateral flow chromatographic immunoassay intended for the qualitative detection of the SARS-CoV-2 nucleocapsid protein antigen in direct anterior nasal swab specimens from individuals who are suspected of COVID-19 by their healthcare providers within 7 days of symptom onset when tested at least twice over three days with at least 48 hours between tests, and from individuals without symptoms or other epidemiological reasons to suspect COVID-19, when tested at least three times over five days with at least 48 hours between tests. Testing is limited to authorized laboratories. This test is authorized for use at the Point of Care (POC). For prescription use only. For in vitro diagnostic use only. For use under an Emergency Use Authorization (EUA) only. See the Package Insert for complete use instructions, warnings, precautions and limitations.

KIT CONTENTS
- Test Cassette
- Extraction Buffer Tube
- Disposable Nasal Swab
- Positive Control Swab
- Negative Control Swab
- Tube Holder
- Package Insert
- Timer (Not included)

PREPARATION
1. Wash or sanitize your hands. Make sure they are dry before starting the test. Read the instructions.
2. Check your kit contents and make sure you have everything. Check the expiration date printed on the cassette foil pouch. Do not use if the pouch is damaged or open.
3. Open the pouch and lay the cassette on a clean, flat surface. Locate the Result Window and Sample Well on the cassette.

TEST PROCEDURE
1. Remove the foil from the top of the extraction buffer tube.
2. Place the tube in the tube holder provided in the kit box.
3. Open the swab packaging at the stick end, not the swab tip. Do not touch the swab tip.
4. Gently insert the entire absorbent tip of the swab into 1 nostril (½ to ¾ of an inch). With children, the maximum depth of insertion into the nostril may be less than ¾ of an inch, and you may need to have a second person to hold the child’s head while swabbing. Note: A false negative result may occur if the nasal swab specimen is not properly collected.
5. Firmly rub the swab in a circular motion around the inside wall of the nostril 5 times. Take approximately 15 seconds to collect the specimen. Be sure to collect any nasal drainage that may be present onto the swab. Repeat this in the other nostril.
6. Remove the swab from the nostril and immediately place into the extraction buffer tube. Note: Test samples immediately after collection, and no more than one hour after the swab is added to the reagent solution, if stored at room temperature.
7. Immediately place the swab into the tube and swirl for 30 seconds. Note: A false negative result may occur if the swab is not swirled at least 30 seconds.
8. Rotate the swab 5 times while squeezing the tube. Note: A false negative result may occur if the swab is not rotated five times.
9. Remove the swab while squeezing the tube. Dispose of the swab in the biohazard box.
10. Gently squeeze the tube and dispense 4 drops of solution into the Sample Well. Dispose of the tube in the biohazard box. Note: A false negative or invalid result may occur if less than 4 drops of fluid are added to the Sample Well.
11. Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.
12. Set the timer for 15 minutes. Result should be read at 15 minutes. Do not read after 30 minutes. Dispose the test cassette in the biohazard box. Note: A false negative or false positive result may occur if the test result is read before 15 minutes or after 30 minutes.
WARNINGS, PRECAUTIONS, AND SAFETY INFORMATION

- Read all instructions carefully before performing the test. Failure to follow the instructions may result in inaccurate test results.
- In the USA, this product has not been FDA cleared or approved, but has been authorized by FDA under an Emergency Use Authorization for use by authorized laboratories. This product has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this product 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 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Serial testing should be performed in individuals with negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals and three times over five days (with at least 48 hours between tests) for asymptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A red or pink line appearing in the control line region (C) is an internal procedural control. The appearance of the procedural control line indicates that proper volume of specimen has been added and capillary flow occurred. If the procedural control line does not develop in 15 minutes, the test result is considered invalid, and retesting with a new cassette is recommended.

External Quality Control

Positive and Negative control swabs are supplied with each kit. Positive control swab is non-infectious recombinant SARS-CoV-2 protein with buffer and stabilizer solution dried onto a swab. Negative control swab is buffer and stabilizer solution dried onto a swab. These control swabs should be used to ensure that the test cassette and that the test procedure is performed correctly. Follow the section “TEST PROCEDURE” steps 1-3 and 7-12 to perform the control test. Note: If the controls do not perform as expected, repeat the test or contact Customer Support before testing patient specimens.

RESULT INTERPRETATION

Repeat testing is needed to improve test accuracy. Please follow the table below when interpreting test results for COVID-19.

<table>
<thead>
<tr>
<th>Status on first day of Testing</th>
<th>First Result Day 1</th>
<th>Second Result Day 3</th>
<th>Third Result Day 5</th>
<th>Interpretation</th>
</tr>
</thead>
<tbody>
<tr>
<td>With Symptoms</td>
<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>Positive</td>
<td>N/A</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>Negative</td>
<td>N/A</td>
<td>Negative for COVID-19</td>
</tr>
<tr>
<td>Without Symptoms</td>
<td>Positive</td>
<td>N/A</td>
<td>N/A</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>Positive</td>
<td>N/A</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>Negative</td>
<td>Positive</td>
<td>Positive for COVID-19</td>
</tr>
<tr>
<td></td>
<td>Negative</td>
<td>Negative</td>
<td>Negative</td>
<td>Negative for COVID-19</td>
</tr>
</tbody>
</table>

COVID-19 Negative (-): If the Control (C) line is visible, but the Test (T) line is not visible, the test is negative.
- To increase the chance that the negative result for COVID-19 is accurate, you should:
  - Test again in 48 hours if the individual has symptoms on the first day of testing.
  - Test 2 more times at least 48 hours apart if the individual does not have symptoms on the first day of testing.

A negative test result indicates that the virus that causes COVID-19 was not detected in the sample. A negative result does not rule out COVID-19. There is a higher chance of false negative results with antigen tests compared to laboratory-based tests such as PCR tests. If the test is negative but COVID-19-like symptoms, e.g., fever, cough, and/or shortness of breath continue, follow up testing for SARS-CoV-2 with a molecular test or testing for other respiratory disease should be considered. If applicable, seek follow up care with the primary health care provider.

All negative results should be treated as presumptive and confirmation with a molecular assay may be necessary if there is a high likelihood of SARS-CoV-2 infection, such as in an individual with a close contact with COVID-19 or with suspected exposure to COVID-19 or in communities with high prevalence of infection.

Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions.

COVID-19 Positive (+): If the Control (C) line and the Test (T) line are visible, the test is positive. Any faint visible red or pink test (T) line with the control line (C) should be read as positive. Repeat testing does not need to be performed if patients have a positive result at any time.

A positive test result means that the virus that causes COVID-19 was detected in the sample, and it is very likely the individual has COVID-19 and is contagious. Please contact the patient’s doctor/principal care physician (if applicable) and the local health authority immediately and instruct your patient to adhere to the local guidelines regarding self-isolation. There is a very small chance that this test can give a positive result that is incorrect (a false positive).

Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Individuals who test positive with the Flowflex COVID-19 Antigen Rapid Test should self-isolate and seek follow up care with their physician or healthcare provider as additional confirmatory testing with a molecular test for positive results may also be necessary, if there is a low likelihood of COVID-19, such as in individuals without known exposures to COVID-19 or residing in communities with low prevalence of infection.

Invalid: If at 15 minutes, if the control (C) line is not visible, the test is invalid. Re-test with a new swab and new test cassette. If the problem persists, call (800) 838-9502 for assistance.

ACON Laboratories, Inc.
San Diego, CA 92121, USA
aconlabs.com
Customer Support: 1-800-838-9502

Number: 1151481701
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