PCR tests cannot be used for the test.
11. The used test should be discarded according to local regulations.
12. Humidity and temperature can affect the results.

**[MATERIALS]**
- Test cassettes
- Extraction buffer
- Procedure card
- Sterile swabs
- Extraction tubes and tips (Optional)
- Materials required but not provided

**[TIME]**
- 10-15 minutes

**[STORAGE AND STABILITY]**
- Store in refrigerator or at room temperature (2-30 °C).
- The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use beyond the expiration date.

**[SPECIMEN COLLECTION, TRANSPORT AND STORAGE]**
- Nasal Swab Specimen Collection
  1. Insert a sterilized swab less than one inch (about 2 cm) into a nostril (until resistance is met at the turbinate).
  2. Rotate the swab 5-10 times against the nasal wall. Using the same swab repeat the collection procedure with the second nostril.
  3. Withdraw the sterile swab; avoid excess volume and high-viscous nasal discharge.

- Nasopharyngeal Swab Specimen Collection
  1. Insert a sterilized swab into the nostril of the patient, reaching the surface of the posterior nasopharynx.
  2. Swab over the surface of the posterior nasopharynx 5-10 times.
  3. Withdraw the sterile swab from the nasal cavity and avoid excess volume and highly-viscous nasopharyngeal discharge.

- **Caution:** If the swab stick breaks during specimen collection, repeat specimen collection with a new swab.

**[PROCEDURE]**

1. Place the swab specimen in the Extraction tube with Extraction buffer. Rotate the swab for 10-15 seconds while pressing the head against the inside of the extraction tube as you remove it to expel as much liquid as possible from the swab. Discard the swab in accordance with your biohazard waste disposal protocol.

**NOTE:** The storage of the specimen after extraction is stable for 2 hours at room temperature and 24 hours at 2-8 °C.

**[DIRECTIONS FOR USE]**
- Allow the test, extracted specimen and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.
- 1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
- 2. Invert the specimen extraction tube and add 3 drops of extracted specimen (approx. 75-100µl) to the sample well(S) and then start the timer.
- 3. Wait for the coloured line(s) to appear. Read the result at 15 minutes. Do not interpret the result after 20 minutes.

**[INTERPRETATION OF RESULTS]**

- **POSITIVE:** Two coloured lines appear. One coloured line should be in the control region (C) and another coloured line should be in the Test region (T). Positive result in the Test region indicates presence of SARS-CoV-2 antigens in the sample.
  - **NOTE:** The intensity of the colour in the test line region (T) will vary based on the amount of SARS-CoV-2 antigen present in the sample. So any shade of colour in the test line region should be interpreted to be positive.
- **NEGATIVE:** One coloured line appears in the control region (C). No apparent coloured line appears in the test line region (T).
  - **INVALID:** Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Reverse the test procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

**[QUALITY CONTROL]**

- **External Quality Control**
  Positive/negative controls are not included in this kit. However, in compliance with Good Laboratory Practice (GLP), these controls are recommended.
  - **Internal Quality Control**
    Internal procedural controls are included in the test. A coloured line appearing in the control region (C) is an internal procedural control. It confirms sufficient specimen volume and correct procedural technique.

**[EXPECTED VALUES]**

The Pathflow COVID-19 Rapid Antigen Pro (Swab) has been compared with a leading commercial RT-PCR test. The correlation between these two systems is no less than 97%.

**[LIMITATIONS]**

1. The performance of the Pathflow COVID-19 Rapid Antigen Pro (Swab) was evaluated using the procedures provided in this product insert only. Modifications to these procedures may alter the performance of the test. Viral Transport Media (VTM) may affect the test result; extracted specimens for PCR tests cannot be used for the test.
2. The test Procedure and the Interpretation of test Result must be followed closely while testing for the presence of SARS-CoV-2 Nucleocapsid protein antigens in the human nasopharynx from suspected individuals. For optimal test performance, proper sample collection is critical. Failure to follow the procedure may give inaccurate results.
3. The Pathflow COVID-19 Rapid Antigen Pro (Swab) is for in vitro diagnostic use only. This test should be used for detection of SARS-CoV-2 Nucleocapsid protein Antigens in swab specimens as an aid in the diagnosis of patients with suspected SARS-CoV-2 infection in conjunction with clinical presentation and the results of other laboratory tests. Neither the quantitative value nor the rate of increase in the concentration of SARS-CoV-2 antigens can be determined by this qualitative test.
4. The Pathflow COVID-19 Rapid Antigen Pro (Swab) will only indicate the presence of SARS-CoV-2 Antigens in the specimen and should not be used as the sole basis for treatment or patient management decisions. Negative results should not be interpreted after 20 minutes.
The results obtained with the test should be considered within laboratory tests and evaluations. If the test result is negative or non-reactive and clinical symptoms persist, it is recommended to re-sample the patient and test again with a molecular diagnostic device to rule out infection in these individuals.

7. The test will show negative results under the following conditions:
   a) The concentration of the novel coronavirus antigens in the sample is lower than the minimum detection limit of the test.
   b) The optimal sampling time (peak virus concentration) after infection has not been verified, so collecting samples at different times for the same patient may avoid false negatives.
8. Negative results may not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.
9. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
10. Positive results of SARS-CoV-2 may be due to infection with non-SARS-CoV-2 coronavirus strains or other interference factors.

**PERFORMANCE CHARACTERISTICS**

**Sensitivity, Specificity and Accuracy**
The Pathflow COVID-19 Rapid Antigen Pro (Swab) has been evaluated with swab specimens obtained from the patients. RT-PCR (Nasopharyngeal Swab) is used as the reference method for the Pathflow COVID-19 Rapid Antigen Pro (Swab). Specimens were considered positive if RT-PCR (Nasopharyngeal Swab) indicated a positive result. Specimens were considered negative if RT-PCR (Nasopharyngeal Swab) indicated a negative result.

**Nasopharyngeal Swab Specimen**

<table>
<thead>
<tr>
<th>Pathflow COVID-19 Rapid Antigen Pro (Swab)</th>
<th>RT-PCR (Nasopharyngeal Swab)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>SARS-CoV-2</em> Positive</td>
<td>99</td>
<td>101</td>
</tr>
<tr>
<td><em>SARS-CoV-2</em> Negative</td>
<td>7</td>
<td>2016</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>106</td>
<td>2124</td>
</tr>
<tr>
<td>Relative Sensitivity</td>
<td>93.4% (95%CI: 86.8%-97.3%)</td>
<td></td>
</tr>
<tr>
<td>Relative Specificity</td>
<td>99.9% (95%CI: 99.6%-99.9%)</td>
<td></td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>99.6% (95%CI: 99.2%-99.8%)</td>
<td></td>
</tr>
</tbody>
</table>

**Confidence Intervals**

**Nasal Swab Specimen**

<table>
<thead>
<tr>
<th>Pathflow COVID-19 Rapid Antigen Pro (Swab)</th>
<th>RT-PCR (Nasopharyngeal Swab)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>SARS-CoV-2</em> Positive</td>
<td>115</td>
<td>117</td>
</tr>
<tr>
<td><em>SARS-CoV-2</em> Negative</td>
<td>8</td>
<td>306</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>123</td>
<td>423</td>
</tr>
<tr>
<td>Relative Sensitivity</td>
<td>93.5% (95%CI: 87.6%-97.2%)</td>
<td></td>
</tr>
<tr>
<td>Relative Specificity</td>
<td>99.3% (95%CI: 97.6%-99.9%)</td>
<td></td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>97.6% (95%CI: 95.7%-98.3%)</td>
<td></td>
</tr>
</tbody>
</table>

**Confidence Intervals**

**Limitation of Detection**
The Pathflow COVID-19 Rapid Antigen Pro (Swab) can detect SARS-CoV-2 heat-inactivated virus strain at 91.6% 10^3 TCID_50/ml.

**Specificity Testing with Various Viral Strains**
The Pathflow COVID-19 Rapid Antigen Pro (Swab) was tested with the following viral strains. No discernible line at either of the test-line regions was observed at these concentrations:

<table>
<thead>
<tr>
<th>Description</th>
<th>Test Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Human coronavirus 229E</td>
<td>5x 10^3 TCID_50/ml</td>
</tr>
<tr>
<td>Human coronavirus NL63</td>
<td>1x 10^3 TCID_50/ml</td>
</tr>
<tr>
<td>Human coronavirus OC43</td>
<td>1x 10^3 TCID_50/ml</td>
</tr>
<tr>
<td>ME RS coronavirus Florida</td>
<td>1.1x10^3 TCID_50/ml</td>
</tr>
<tr>
<td>Human coronavirus HKU1</td>
<td>1x 10^3 TCID_50/ml</td>
</tr>
<tr>
<td>Influenza A H1N1</td>
<td>3.16 x 10^3 TCID_50/ml</td>
</tr>
<tr>
<td>Influenza A H3N2</td>
<td>1 x 10^3 TCID_50/ml</td>
</tr>
<tr>
<td>Influenza B</td>
<td>3.16 x 10^3 TCID_50/ml</td>
</tr>
<tr>
<td>Parainfluenza virus 2</td>
<td>1.58 x 10^3 TCID_50/ml</td>
</tr>
<tr>
<td>Parainfluenza virus 3</td>
<td>1.58 x 10^3 TCID_50/ml</td>
</tr>
<tr>
<td>Respiratory syncytial virus</td>
<td>8.89 x 10^3 TCID_50/ml</td>
</tr>
</tbody>
</table>

**TCID_50** - Tissue Culture Infectious Dose is the dilution of virus that under the conditions of the assay can be expected to infect 50% of the culture vessels inoculated.

**Specificity Testing with Various Organisms**
The following organisms were tested at 1x10^3 org/ml and all found to be negative when tested with the Pathflow COVID-19 Rapid Antigen Pro (Swab):

- *Adenovirus type 1, 2, 4, 7*
- *Human Rhinovirus 2, 14*
- *Human Rhinovirus 16*
- *Measles*
- *Mumps*
- *Parainfluenza virus 2, 3*
- *Respiratory syncytial virus*

**Interfering Substances**
The interfering substances below were spiked with negative, SARS-CoV-2 Antigen weak positive. No substances showed any interference with the Pathflow COVID-19 Rapid Antigen Pro (Swab).

- **Substance**
  - Whole Blood: 20μg/ml
  - Mucin: 20μg/ml
  - Bludesode Nasal Spray: 200μg/ml
  - Dexamethasone: 0.6mg/ml
  - Fluoride: 6.6mg/ml
  - Mupirocin: 12mg/ml
  - Oxymetazoline: 0.6mg/ml
  - Phenylephrine: 12mg/ml
  - Nebulizer: 5μg/ml
  - Relenza: 328mg/ml
  - Tamiflu: 1μg/ml
  - Tobramycin: 2.43mg/ml

**Precision**

- **Intra-Assay & Inter-Assay**
  - Within-run and Between-run precision has been determined by using three specimens of SARS-CoV-2 standard control. Three different lots of Pathflow COVID-19 Rapid Antigen Pro (Swab) have been tested using negative, P1 and P5 specimens. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified 99%-99.9% of the time.

**BIBLIOGRAPHY**


**Index of Symbols**

- **For in vitro diagnostic use only**
- **Store between 2-30°C**
- **Do not use if package is damaged**
- **Consult instructions for use**
- **Authorized Representative**
- **Do not reuse**
- **Catalog #**
- **Single use only**