



**INSTRUCTIONS FOR USE**

**Healgen® Rapid Check™ COVID-19/Flu A&B Antigen Test**

For Self-Testing  
For In vitro diagnostic use only  
Please scan the QR code or use the URL below to access a digital version of the instructions, an online instructional video and information about accessing support services.  
<https://healgen.ai/human-health/infectious-disease-respiratory/covid-19-flu-ab-self-testing/>

Carefully read the instructions before performing the test.

**Materials Provided**

Required but not provided: Timer or clock.

**Preparing for The Test**

- NOTE:**
- Do not open the test contents until ready for use. If the test cassette is open for an hour or longer, invalid test results may occur.
  - Allow the test device and reagents to come to room temperature [15-30 C(59-86 F)] prior to testing.
- Check the test's expiration date printed on the outer test packaging.
  - Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.
  - Turn over the test kit box to locate the perforated hole.
  - Insert the extraction tube into the tube holder. Ensure that the tube is stable and upright.
  - Tear off the sealing film on the extraction tube gently to avoid spilling the liquid.

**Sample Collection**

- Remove the swab from the pouch. Carefully insert the sterile swab no more than 3/4 inch (1.5 cm) into the nostril. **Be careful not to touch the swab tip (soft end) with hand.**
  - Slowly rotate the swab at least 5 times against the nostril wall for at least 15 seconds. Remove the swab and repeat in the other nostril using the same swab.
    - Right nostril
    - Left nostril
- 5x for 15 seconds, each nostril

**Note:** If you are swabbing others, please wear a face mask. With children, the maximum depth of insertion into the nostril may be less than 1/2 to 3/4 of an inch, and you may require another adult to hold the child's head while swabbing.

**Running The Test**

- Immerse the swab into the pre-filled extraction tube and swirl the swab in the buffer. Ensure the sample is mixed thoroughly by making at least 6 circles. **Sample must be mixed in the extraction buffer within 1 hour of sample collection.**
- Leave the swab in the extraction tube for 1 minute. A timer is recommended for this step.
- After 1 minute, pinch the tip of the swab from the outside of the tube to remove any excess sample in the swab. Remove and discard the swab.
- Hold the tube upright and insert the extraction tube tip into tube opening. Ensure a tight fit to prevent leaking. **Note:** Return the Tube to the tube holder before proceeding to the next step.
- Remove test cassette from sealed pouch and lay it on a flat surface.
- Invert the extraction tube and squeeze 8 drops of test sample into the sample well. Then discard the tube. **Sample must be applied to the test cassette within one hour of completing step 3.**
- Start timer. Read results at 15 minutes. **Do not interpret results before 15 minutes or after 20 minutes, as this may result in false or invalid results.**

**Interpreting Your Results**

Control line = C  
Flu B line = Flu B  
Flu A line = Flu A

- Look for lines next to 'C' (Control), 'Flu B', 'Flu A' and 'COVID'.
- Look closely! Any faint line is still a line.
- Make sure there is a visible line next to 'C' in both result windows. If one or both 'C' lines are missing, the result is INVALID. Repeat with a new test and sample.

**Positive Test Result**

**POSITIVE**

If you see a line at any one, or multiple, of the 'COVID', 'Flu A' or 'Flu B' areas, it means that your test result is positive and the virus annotated next to the positive line was detected in your sample. Consult your healthcare provider to discuss your positive test result.

**NOTE:** Any pink or purple line in the correct, indicated locations, no matter how faint, should be considered an indication of a positive result.

- What you need to do:**
- If you tested positive for COVID-19 and/or Influenza A/B, please consult a medical practitioner for follow-up clinical care.
  - If you have a POSITIVE result, staying at home protects the people in your community.
  - If you have a POSITIVE result, do not visit high-risk settings like hospitals and aged & disability care settings for at least 7 days or until symptoms have gone, unless seeking immediate medical care.
  - To help protect those around you, we recommend to avoid contact with people, who are at higher risk of severe disease, wearing a mask outside the home, working from home where possible, avoiding going to school, public areas, or travel on public transport, in taxis, or ride-share services, practicing good hygiene, and leaving home.
  - If you feel unwell or need COVID-19 and/or Influenza advice for someone in your care, talk with your health provider, or speak to a nurse by calling the health direct helpline on 1800 022 222.
  - If you have symptoms such as severe shortness of breath or chest pain, call triple zero (000) immediately. Tell the call handler and the paramedics on arrival if you have COVID-19.
  - If you have only mild symptoms, or no symptoms at all (asymptomatic), you can manage these symptoms with over-the-counter medication.
  - Follow the guidance from your local state or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
  - If you are worried about your child's symptoms, contact your GP as soon as possible. A GP or nurse will treat your child based on their age, symptoms, and past medical history. If they are showing severe symptoms, call triple zero (000) immediately.

**Negative Test Result**

**NEGATIVE**

If you do not see a line at 'COVID', 'Flu A' or 'Flu B' it means you may not have COVID-19, Flu A or Flu B Virus.

**What you need to do:**

- Negative results do not completely rule out SARS-CoV-2, Influenza A or Influenza B infection. Please continue to comply with all applicable rules regarding contact with others and protective measures.
- If symptoms are developed the individual must have a laboratory PCR test performed even with a negative test result.
- Follow the guidance from your local State or Territory Health Department for guidance on confirmation testing if necessary, and if unwell seek medical assistance.
- If it is suspected, repeat the test after 1 - 3 days, as the coronavirus/Influenza virus cannot be precisely detected in all phases of an infection.

**Invalid Test Result**

**INVALID**

If a control line is not visible at "C" after 15 minutes, even if any other line is visible in the results window, **THE TEST HAS FAILED** and is considered invalid.

**What you need to do:**

An invalid test result means that the test is unable to determine if you are infected with influenza or SARS-CoV-2 (COVID-19) or not. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. If an invalid result is produced, please review the procedure and repeat with a new test. If the test results remain invalid, contact the sponsor hotline for further guidance.

**After Testing**

- After the test is complete, place all the components in a plastic bag and tightly sealed, then dispose in household waste or rubbish bin.
- Wash and dry your hands thoroughly again.

**Index of Symbols**

Consult instructions for use	Transported	Keep away from sunlight
For in vitro diagnostic use only	Use only with designated reagents	Do not reuse
Store at 30-40 °F (0-4 °C)	LOT	Batch code
Unique device identifier	Keep dry	Manufacturer
Do not use if packaging is damaged		

**HEALGEN®**  
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**For Customer Support Helpline:** Call 0415 860 461 9am-7pm (AEST), 7 days per week for information on the correct use of this test and for interpretation of the test results.

