

CONSULT® COVID-19/Flu A&B Antigen Test

For *in vitro* diagnostic use

McKesson's Consult® COVID-19/Flu A&B Antigen Test is a lateral flow immunochromatographic assay intended for the qualitative detection and differentiation of influenza A, and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly in anterior nasal swab samples from individuals with signs and symptoms of respiratory tract infection. Symptoms of respiratory infections due to SARS-CoV-2 and influenza can be similar. This test is for use by individuals aged 14 years or older testing themselves, or adults testing individuals aged 2 years or older.

All negative results are presumptive and should be confirmed with an FDA-cleared molecular assay when determined to be appropriate by a healthcare provider. Negative results do not rule out infection with influenza and SARS-CoV-2 or other pathogens. Individuals who test negative and experience continued or worsening respiratory symptoms, such as fever, cough, and/or shortness of breath, should therefore seek follow-up care from their healthcare provider.

Positive results do not rule out co-infection with other respiratory pathogens and therefore do not substitute for a visit to a healthcare provider or appropriate follow-up.

The clinical performance of this test was established based on the evaluation of a limited number of clinical specimens collected between February 2024 through April 2024. The clinical performance has not been established for all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. There is a risk of false negative results due to the presence of novel, emerging respiratory virus variants. Test accuracy may change as new virus variants of COVID-19 and influenza emerge.

Key Benefits

- Simultaneously detect 3 viruses (SARS-CoV-2, Flu A&B)
- No repeat testing necessary (compare to EUA kits)
- Two result windows for easy readability
- Shallow nasal swab sample collection
- Suitable for 2+ years old

* Swabbing should be performed by an adult for children aged 2 to 13. User must be aged 14 + to perform self-test..

Specifications

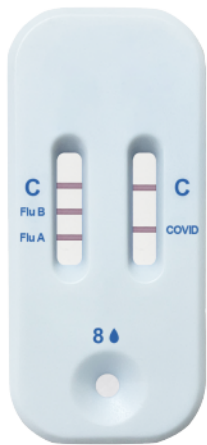
Specimen: Nasal Swab

Time to results: 15 minutes

Stability: 24 months

Storage: 36-86°F (2-30°C)

Interpreting Your Results



C = Control line
Flu B = Flu B line
Flu A = Flu A line
COVID = Covid-19 line

Look for lines next to "C" (Control) Flu B, Flu A and COVID.
Check to see if a line is visible at the Control Line labeled "C" on the device.
Look Closely! Any faint line is still a line.

POSITIVE TEST RESULT

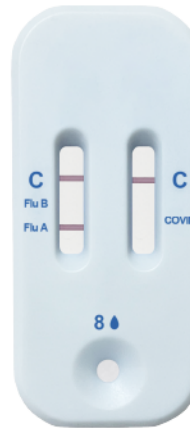
Both 'C' lines must be PRESENT

Consult your healthcare provider to discuss your positive test result.
Self-isolate at home per CDC recommendations to stop spreading virus to others.

COVID-19 Positive



Flu A Positive



Flu B Positive



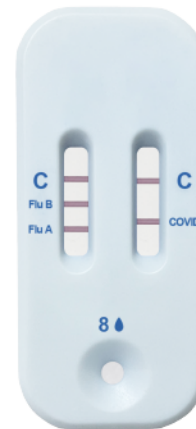
COVID-19 & Flu A Positive



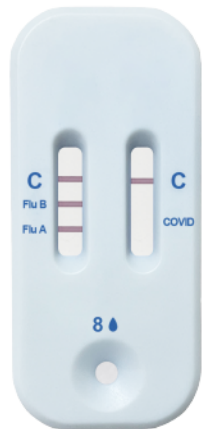
COVID-19 & Flu B Positive



COVID-19 & Flu A & Flu B Positive



FLU A & B Positive



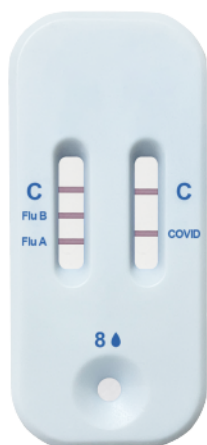
NEGATIVE TEST RESULT



Both 'C' lines only

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. If you still have COVID-19, Flu A or Flu B symptoms, you should seek follow up care with your healthcare provider.

Interpreting Your Results



C = Control line
Flu B = Flu B line
Flu A = Flu A line
COVID = Covid-19 line

Look for lines next to "C" (Control) Flu B, Flu A and COVID.

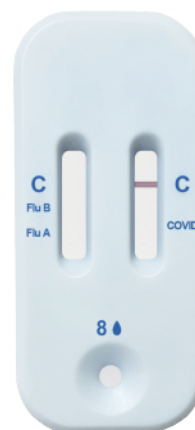
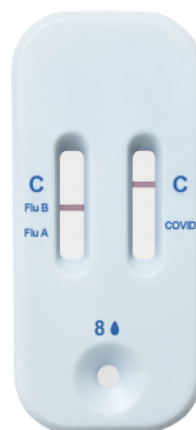
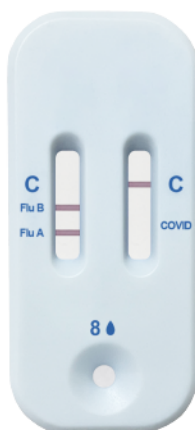
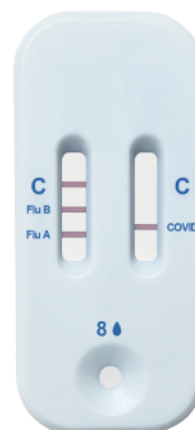
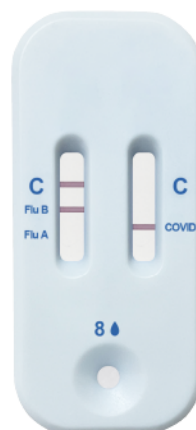
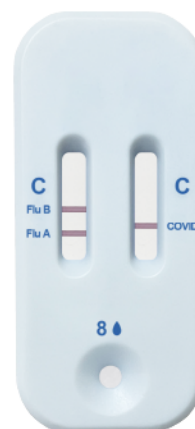
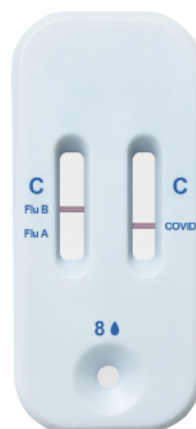
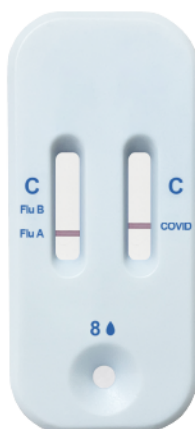
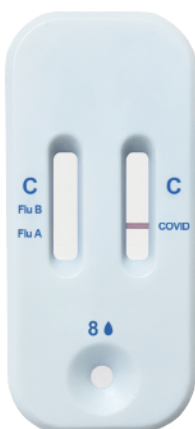
Check to see if a line is visible at the Control Line labeled "C" on the device.

Look Closely! Any faint line is still a line.

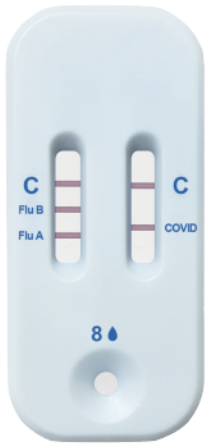
INVALID TEST RESULT

Missing 'C' line on ONE or BOTH strips

Check to see if a line is visible at the control line 'C' on both strips. If you do not see any C line, or only see one C line, DO NOT CONTINUE reading the results. It means your test is invalid. Repeat the test with a new sample and new test kit materials.



Interpreting Your Results



C = Control line
Flu B = Flu B line
Flu A = Flu A line
COVID = Covid-19 line

Look for lines next to "C" (Control) Flu B, Flu A and COVID.

Check to see if a line is visible at the Control Line labeled "C" on the device.

Look Closely! Any faint line is still a line.

INVALID TEST RESULT

Missing 'C' line on ONE or BOTH strips

Check to see if a line is visible at the control line 'C' on both strips. If you do not see any C line, or only see one C line, DO NOT CONTINUE reading the results. It means your test is invalid.

Repeat the test with a new sample and new test kit materials.

