HEALGEN®

QUICK REFERENCE GUIDE (QRG)

Healgen® COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab)

For Emergency Use Authorization (EUA) only
For *In Vitro* Diagnostic Use.
For Prescription Use Only.

INTENDED USE

The Healgen COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is a lateral flow immunochromatographic assay intended for in vitro rapid, simultaneous qualitative detection and differentiation of influenza A and influenza B nucleoprotein antigens and SARS-CoV-2 nucleocapsid antigen directly from anterior nasal swab specimens of individuals with signs and symptoms of respiratory infection consistent with COVID-19 within the first five (5) days of symptom onset when tested at least twice over three days with at least 48 hours between tests. Clinical signs and symptoms of respiratory viral infection due to SARS-CoV-2 and influenza can be similar. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CUA), 42 U.S.C. § 263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.
Please see the Instructions for Use for the full intended use.

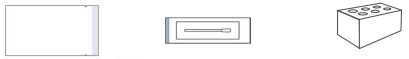
IMPORTANT WARNINGS

Read the instructions fully and carefully before performing the procedure. Failure to follow the instructions may result in inaccurate results.

- In the USA, this product has not been FDA cleared or approved; but has been authorized by FDA under an Emergency Use Authorization. This product has been authorized only for the detection of proteins from SARS-CoV-2, Influenza A, and Influenza B, 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 SARS-CoV-2 negative results at least twice over three days (with 48 hours between tests) for symptomatic individuals. You may need to purchase additional tests to perform this serial (repeat) testing.
- Do not read test results before 15 minutes or after 20 minutes. Results read before 15 minutes or after 20 minutes may result in false positive, false negative or invalid results.
- Exposure to hand sanitizer may cause false negative results with this test.
- Individuals who recently received nasally administered influenza A or influenza B vaccine may have false positive test results after vaccination.

MATERIALS PROVIDED

Sealed Test Casette | Sterile Nasal Swab | Tube Holder



Prefilled Extraction Buffer Tube | Extraction Tube Tip

Required but not provided:
- Timer or clock.
- External Controls
  (Catalog no.: GCFC-PN2, GCFC-PN20 -Sold separately)

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.

1. **Check the test's expiration date printed on the outer test packaging.**

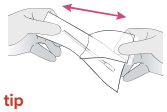
Pouch | Box

2. Wash your hands with soap and water for 20 seconds and dry them thoroughly, or use hand sanitizer.
3. Insert the extraction buffer tube into the tube holder.
   Ensure that the tube is stable and upright.

4. Tear off the sealing film on the extraction tube gently to avoid spilling the liquid.
5. Remove the test cassette from sealed pouch and lay it on a flat surface.

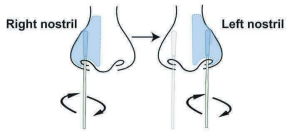
SAMPLE COLLECTION

1 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.

2 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.

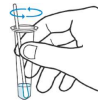


5x for 15 seconds, each nostril

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 ½ to ¾ of an inch, and you may require another adult to hold the child's head while swabbing.

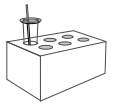
RUNNING THE TEST

3 Immerse the swab into the prefilled extraction buffer tube and swirl the swab in the buffer. Ensure the sample is mixed thoroughly by **making at least 6 circles.**



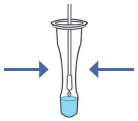
Sample must be mixed in the extraction buffer within 2 hours of sample collection.

4 Leave the swab in the extraction tube for **1 minute**. A timer is recommended for this step.

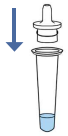


5 After 1 minute, pinch the tip of the swab from the outside of the tube to remove any excess sample in the swab.

Remove and discard the swab.

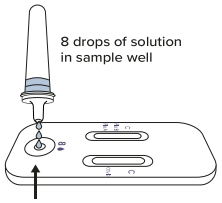


6 Hold the tube upright and insert the extraction tube tip into the tube opening. Ensure a tight fit to prevent leaking.



7 Invert the extraction buffer 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.

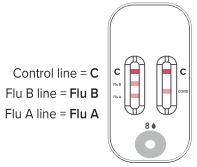


8 Start timer. Read results at 15 minutes.

Do not interpret results after 20 mins.


15 minutes

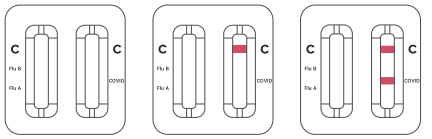
INTERPRETING THE RESULTS



- 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.

INVALID TEST RESULT

Missing 'C' line on ONE or BOTH strips

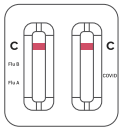


Check to see if a line is visible at the control line 'C' on both strips.

STOP The test could not tell whether or not the patient has COVID-19, influenza A (Flu A), or influenza B (Flu B). The test needs to be repeated with a new kit and sample.

Note: The 3 images displayed are examples only; for additional invalid results, scan the QR code in the Instructions for Use.

NEGATIVE TEST RESULT



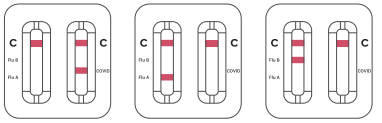
Both 'C' lines only

The virus from COVID-19, Flu A, and/or Flu B were not detected in the sample. A negative result does not mean it is certain that the patient does not have COVID-19, Flu A and/or Flu B infection. There is a higher chance of false negative results with antigen tests compared to laboratory-based molecular tests. If the patient tested negative and continues to experience COVID-19, Flu A and/or Flu B-like symptoms, the patient should seek follow-up care with the healthcare provider.

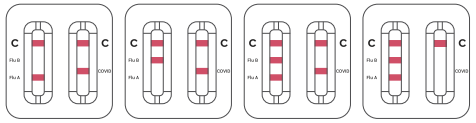
POSITIVE TEST RESULT

Both 'C' lines must be PRESENT

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 & Flu B Positive



The COVID-19, Flu A, and/or Flu B virus(es) were detected in the patient sample. It is very likely that the patient has the respective infection(s) and are contagious. Please contact the healthcare provider or local health authorities and follow local guidelines for self-isolation. There is a small chance that this test can give a positive result that is incorrect (a false positive).

SERIAL TESTING

Repeat testing is needed for all samples that are negative for SARS-CoV-2 on the first day of testing, even if they are positive for influenza A and/or B. Repeat testing is needed to improve test accuracy for SARS- CoV-2. Please follow the table below when interpreting test results. Serial (repeat) testing does not need to be performed if patients have a positive SARS-CoV-2 result on the first day of testing.

Status on First Day of Testing	Day 0 (First Test)	Serial Testing?	Day 2 (Second Test)	Final Interpretation
With Symptoms	SARS-CoV-2 (+) Influenza A and B (-)	NO	Not needed	Positive for COVID-19 Presumptive negative for Influenza
	SARS-CoV-2 (+) Influenza A and/or B (+)	NO	Not needed	Positive for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/or B (-)	Positive for COVID-19 Presumptive Negative for Influenza
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (-) Influenza A and/or B (-)	Presumptive Negative for COVID-19 Presumptive Negative for Influenza
	SARS-CoV-2 (-) Influenza A and/or B (-)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/or B (-)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (-) Influenza A and/or B (+)	Presumptive Negative for COVID-19 Positive for Influenza A and/or B
	SARS-CoV-2 (-) Influenza A and/or B (+)	YES	SARS-CoV-2 (+) Influenza A and/or B (+)	Positive for COVID-19 Positive for Influenza A and/or B

QUALITY CONTROL

Internal Quality Control: A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient sample volume, test functionality and correct procedural technique.

External Quality Control: Positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify test performance. Quality control testing should be performed according to local, state and/or federal regulations as well as your laboratories' quality control procedures.

Control materials are not supplied with this kit but can be purchased separately. Healgen® offers External Control- COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) (Catalog Number: GCFC-PN2, GCFC-PN20). It is recommended to run external controls once-
- every 30 days (to check storage)
- each new shipment
- each new kit lot
- each new operator
- as required by site quality control procedures and in accordance with local, state, and federal regulations or any accreditation requirements.

TECHNICAL SUPPORT

Healgen Scientific Limited Liability Company
Address: 3818 Fuqua Street, Houston, TX 77047, USA.
Tel: +1713-733-8088 Fax: + 1713-733-8848
Website: www.healgen.com

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