External Controls

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

Instructions for Use

REF	CONTENTS	
GCFC-PN2	1 Positive swab	1 Negative swab
GCFC-PN20	10 Positive swabs	10 Negative swabs

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

Instructions for use must be carefully followed. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions.

INTENDED USE

The External Controls - Healgen® COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) is a ready-to-use external control kit for use with the Healgen® COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab). This kit is designed to verify proper test procedure and performance of the COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab).

CONTENTS

- The **positive control swabs** are composed of a SARS-CoV-2 recombinant antigen, Influenza A recombinant antigen and Influenza B recombinant antigen extract dried onto a swab, with a red shaft, containing 0.05% Proclin 300 as a preservative.
- The **negative control swabs** are composed of negative control buffer dried onto a swab, with a blue shaft, containing 0.05% Proclin 300 as a preservative.
- External Controls Instructions for Use.

WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use.
- 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 and influenza A/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.
- Do not use after expiration date.
- COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab). Incompatibilities between this product and other manufacturer's test kits may occur.
- The swab should remain in the sealed pouch until use.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30ºC/36-86ºF). The swab is stable through the expiration date printed on the sealed pouch. The swab must remain in the sealed pouch until use. Do not freeze (below 0ºC/32ºF).

MATERIALS

MATERIALS PROVIDED

- Negative control swab(s) (blue)
- Positive control swab(s) (red)
- Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- Disposable gloves
- Timer
- Prefilled Extraction Tube
- Extraction Tube Tip
- COVID-19/Flu A&B Ag Rapid Test Cassette kit
- Tube holder

CONTROL KIT TEST PROCEDURE

For the complete Test Procedure, refer to these sections in the Instructions For Use of the Healgen® COVID-19/Flu A&B Ag Combo Rapid Test Cassette (Swab) kit.

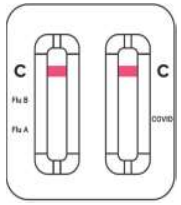
- Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink, or smoke in the area.
- All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The control swab and test device should be discarded in a proper biohazard container after testing.
- The swab must be used within 2 hours of opening the sealed pouch.

INTERPRETATION OF RESULTS

INVALID

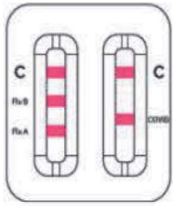
If a control band (**C**) is **not visible in both result windows** (i.e. only **one** window displays the (**C**) line) after performing the test, **DO NOT CONTINUE** reading the results. The result is considered invalid.
Some causes of invalid results are because of not following the directions correctly or the test may have deteriorated beyond the expiration date. It is recommended that the specimen be re-tested using a new test.

NEGATIVE



The presence of **Two** control lines (**C**), one in each result window, indicates a negative result. *This is the expected result for the negative control swab.*

POSITIVE



COVID-19/Flu A&B Positive: *This is the expected result for the positive control swab.*

The appearance of **five lines:**
Two control lines (**C**), one in each result window
One test line (**Flu B**) **One** test line (**Flu A**) **One** test line (**COVID**)

SYMBOLS

	Consult instructions for use		Manufacturer	Σ_n	Contains sufficient for <n> tests
IVD	For *in vitro* diagnostic use only		Use by	REF	Catalogue Code
	Temperature limitation	LOT	Lot Number	CONTROL+	Positive Control
CONTROL-	Negative Control				

TECHNICAL SUPPORT

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