

OHC COVID-19/Flu Control Swab Kit

For *in vitro* diagnostic use.

For professional use only.

For use under Emergency Use Authorization only.

For prescription use.

Please follow the instructions carefully when performing the test.

INTENDED USE

The OHC COVID-19/Flu Control Swab Kit is an external qualitative quality control intended for ensuring that reagents and materials are working and that the test procedure is correctly performed.

Components	Qty	Description
COVID-19/Flu Positive Control Swab	10 ea	The COVID-19/Flu Positive Control Swab consists of non-infectious recombinant SARS-CoV-2 nucleocapsid antigen and inactivated Influenza A&B virus culture fluid spiked onto a sterile swab.
COVID-19/Flu Negative Control Swab	10 ea	The COVID-19/Flu Negative Control Swab consists of a sterile swab with <i>Streptococcus</i> group A or B antigens.
Instructions for use	1 ea	User manual

Materials required but not provided

1. Test kit (OHC COVID-19/Flu Antigen Test Pro, etc.)
2. Disposable glove
3. Timer

STORAGE

1. Store at 2-30 °C (35.6 - 86 °F).
2. Do not freeze the product or store it above 30 °C (86 °F).

TEST PROCEDURE

For full instructions for use on how to use these controls, please refer to OHC COVID-19/Flu Antigen Test Pro Healthcare Provider Instructions for Use (IFU).

We recommend controls be run once for:

- Each new kit lot,
- Each new operator,
- Each new shipment,
- As required by site quality control procedures and in accordance with local, state and federal regulations or accreditation requirements.













If either or both external control results are unexpected or invalid, repeat the external controls with a new swab, extraction buffer tube and test cassette and if results continue to be unexpected or invalid, contact customer service (ohc_cs@osanghc.com).

WARNING AND PRECAUTIONS

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.

1. For *in vitro* diagnostic use.
2. For professional use only.
3. Do not use control swabs for patient specimen collection; use only as a test quality control.
4. Do not re-use any contents in the product.
5. Do not use if any content package is damaged.
6. Use of Nitrile or Latex gloves is recommended when working with these controls.
7. Follow the instructions for use carefully. If they are not followed, the reliability of the test results cannot be guaranteed.
8. Do not use the product beyond the labeled expiry date.
9. Incompatibilities between this product and other manufacturers test kits may occur.
10. If stored at 2-8°C, keep it at 18-30°C for 30 minutes before opening the product before use.
11. The swab should remain in the sealed pouch until use.
12. After the inspection, clean your hands and disinfect them with disinfectant.
13. Controls contain inactivated materials but no test result guarantees products non-infectious. All the products should be handled as potentially hazardous and infectious.
14. Do not arbitrarily disassemble or alter the product.
15. Use such as disassembling or taking the product may cause serious harm, so never use it for anything other than its intended purpose.

SYMBOL

	<i>In vitro</i> Diagnostic medical device		Control
	Catalogue number		Negative Control
	Batch code		Positive Control
	Use-by date		Caution
	Manufacturer		Temperature limit
	Consult Instruction For Use		Do not re-use

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