

**REF** 1024 **IVD** **R<sub>x</sub>** only

## INTENDED USE

The Silaris™ Influenza A&B Control Kit is intended for in vitro diagnostic use in quality control testing with the Silaris™ Influenza A&B Test.

## SUMMARY

The Silaris Influenza A&B Control Kit provides swabs coated with dried, inactivated influenza A or influenza B virus. The level of influenza A or influenza B virus applied to the swab is sufficient to provide a positive result when used with the Silaris Influenza A&B Test. The influenza A control swab acts as a negative control for influenza B; the influenza B control swab serves as a negative control for influenza A. When used for quality control in the Silaris Influenza A&B Test, these controls are useful as an aid in verifying test and operator performance.

## MATERIALS PROVIDED:

- 5 - Influenza A Positive Control Swab (Yellow Shaft) contains inactivated influenza A virus dried onto a swab.
- 5 - Influenza B Positive Control Swab (Blue Shaft) contains inactivated influenza B virus dried onto a swab.
- Instructions For Use

## MATERIALS REQUIRED BUT NOT PROVIDED

- Silaris Influenza A&B Test (Catalog #1027)
- Silaris Dock (Catalog #1026)

## WARNINGS AND PRECAUTIONS

- For in vitro diagnostic use.
- Federal Law restricts sale of this product to or on the order of a licensed practitioner.
- To be used in conjunction with the Silaris™ Influenza A&B Test and the Silaris Dock.
- DO NOT use the Controls past their expiration date.
- Inactivated and dried viruses are used to make the control swabs. However, control swabs and used cassettes should be handled as though they could transmit disease. Observe established precautions against microbial hazards during use and disposal.
- Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when handling samples.
- Do not use any damaged kit contents.
- Do not touch the heads of the Control swabs. Cross contamination may occur due to the high sensitivity of the test.
- Follow proper infection control guidelines for handling all specimens and related items. Properly dispose of all contaminated waste according to federal, state, and local requirements.
- Not for patient use
- Swabs stored in foil pouch at 15°- 30°C (59°-86°F) are stable until the expiration date printed on the pouch.

## STORAGE

- The Silaris Influenza A&B Control Kit must be stored at 15°-30°C (59° - 86°F).
- The swabs should be kept in the pouch until testing.

## INSTRUCTIONS FOR USE

- Process the Silaris™ Influenza A&B Control swabs as you would a patient sample in accordance with the procedure for the Silaris™ Influenza A&B Test (Catalog #1027). Read the instructions for use prior to utilizing the Silaris™ Influenza Control Kit.

## EXPECTED RESULTS

- The Positive A Control should yield a positive A result and a negative result for B.
- The Positive B Control should yield a positive B result and a negative result for A.

## DISPOSING OF MATERIAL

- Discard of hazardous or biologically contaminated materials according to your institutions practices. Discard all materials in a safe and acceptable manner that is in compliance with all country, state, and local requirements.








## REORDER NUMBER

Catalog No. 1024 Silaris™ Influenza A&B Control Kit  
 Catalog No. 1027 Silaris™ Influenza A&B Test  
 Catalog No. 1026 Silaris™ Dock

## TECHNICAL ASSISTANCE

If External QC testing fails, repeat the test using a new Control swab, reagents and test cassettes or contact Sekisui Diagnostics Technical Support for assistance, Monday through Friday from 8:30 a.m. to 5:00 p.m. Eastern Standard Time at 800-332-1042 (US Only) or 781-652-7800 (outside the US), before continuing with further samples.

## KEY TO COMPONENT LABELING

	Instructions For Use	<b>CONT</b>	Contents		Use by YYYY-MM-DD
<b>IVD</b>	In Vitro Diagnostics	<b>CONTROL</b> 	Positive Control		Manufacturer
<b>R<sub>x</sub></b> only	Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.	<b>CONTROL</b> 	Negative Control		Single-use only. Do Not Reuse.
	Temperature	<b>REF</b>	Product Catalog Number		
<b>MF</b>	Manufactured For	<b>LOT</b>	Product Batch Number		



*Because every result matters™*



**Sekisui Diagnostics, LLC**  
6659 Top Gun Street  
San Diego, CA 92121 USA  
Tel: 781-652-7800  
[www.sekisuidiagnostics.com](http://www.sekisuidiagnostics.com)



**Mesa Biotech, Inc.**  
6190 Cornerstone Court East  
Suite 200  
San Diego, CA 92121 USA  
[www.mesabiotech.com](http://www.mesabiotech.com)