OSOM® ULTRA PLUS FLU A&B Control Kit

INSTRUCTIONS FOR USE

R_{X}ONLY REF 1034

INTENDED USE

The OSOM ULTRA PLUS FLU A&B Control Kit is intended for *in vitro* diagnostic use in quality control testing with the OSOM ULTRA PLUS FLU A&B Test.

SUMMARY

The OSOM ULTRA PLUS FLU A&B Control kit includes five Influenza A+ Control Swabs and five Influenza B+ Control Swabs, each of which contains recombinant antigen, for external quality control testing. The Influenza A+ Control Swabs act as negative controls for the influenza B antigen and conversely, the Influenza B+ Control Swabs act as negative controls for influenza A antigen.

Use the OSOM ULTRA PLUS FLU A&B Control Kit to help ensure that the OSOM ULTRA PLUS FLU A&B Test is functioning properly and to demonstrate proper performance by the test operator.

- When the Influenza A+ Control Swab is tested, the appearance of ANY shade of a very light or faint pink to purple line at the A Test Line along with a C Control Line indicates that the influenza antigen binding property of the Test Stick is functional.
- When the Influenza B+ Control Swab is tested, the appearance of ANY shade of a very light or faint pink to purple line at the B Test Line along with a C Control Line indicates that the influenza antigen binding property of the Test Stick is functional.

External controls are intended to monitor substantial reagent failure.

If External Quality Control testing fails, repeat the testing of the failed control or contact Sekisui Diagnostics Technical Services at (800) 332-1042 or SDADiagnosticsTSDL@sekisuidiagnostics.com before running patient samples.

External quality control requirements should be established in accordance with local, state, and federal regulations or accreditation requirements. Minimally, Sekisui Diagnostics recommends that positive and negative external controls be run with each new lot, shipment received, and with each new untrained operator.

KIT CONTENTS

5 - Influenza A+ Control Swabs (packaged with a desiccant tablet) coated with non-infectious recombinant influenza A containing 0.05% sodium azide
5 - Influenza B+ Control Swabs (packaged with a desiccant tablet) coated with non-infectious recombinant influenza B containing 0.05% sodium azide
1 - OSOM ULTRA PLUS FLU A&B Control Kit Instructions for Use

MATERIALS REQUIRED BUT NOT PROVIDED

- OSOM ULTRA PLUS FLU A&B Test Kit (Catalog Number 1032)
- Timer or watch

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostics use only.
2. Caution: Federal law restricts this device to sale by or on the order of a physician.
3. DO NOT use the OSOM ULTRA PLUS FLU A&B Control Kit past the expiration date.
4. Not for patient use.

KIT STORAGE AND STABILITY

- The OSOM Influenza A&B Control Kit must be stored at room temperature (15-30ºC/59-86ºF).
- Swabs stored in the closed tube at room temperature (15-30ºC/59-86ºF) are stable until the expiration date printed on the box label.

QC TESTING PROCEDURES

To perform a positive or negative control test, complete the steps in the Test Procedure section of the assay Instructions for Use treating the control swab in the same manner as a patient swab (refer to OSOM ULTRA PLUS FLU A&B Test Instructions for Use).

EXPECTED RESULTS

The Influenza A+ Control Swab should yield a positive A result and a negative result for B. The Influenza B+ Control Swab should yield a positive B result and a negative result for A. Refer to the OSOM ULTRA PLUS FLU A&B Test Instructions for Use for a complete description of the assay procedure and interpretation of results.

DISPOSING OF MATERIALS

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

REORDER

OSOM ULTRA PLUS FLU A&B Test Kit (Catalog Number 1032)
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DEFINITIONS OF SYMBOLS

LOT	Batch code
REF	Catalog number
	Consult instructions for use
	Contains sufficient for <n> tests
Contents	Contents listing
	Device for near-patient testing
	Device not for self-testing
	Do not re-use
Influenza A CONTROL +	Influenza A Positive Control Swab
Influenza B CONTROL +	Influenza B Positive Control Swab
Instructions for Use	Instructions for use
IVD	*in vitro* diagnostic medical device
	Manufacturer
℞ ONLY	Caution: Federal law restricts this device to sale by or on the order of a physician
	Uncontaminated recycled content-packaging, kit box, Instructions for Use is recyclable if it can be collected, separated, or otherwise recovered from the waste stream through an established recycling program.
	Temperature limit
	Use-by date
CE	CE Mark


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SEKISUI DIAGNOSTICS

Because every result matters™

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