

osom[®]

Ultra Flu A&B Control Kit

FOR IN VITRO DIAGNOSTIC USE ONLY

REF 1005

INTENDED USE

OSOM Ultra Flu A&B Control Kit is intended for in vitro diagnostic use in quality control testing with the OSOM Ultra Flu A&B Test.

SUMMARY

OSOM Ultra Flu A&B Positive and Negative Controls, are external control swabs that are used to ensure proper kit and operator performance with the OSOM Ultra Flu A&B Test.

MATERIALS PROVIDED

- 5- Positive Control Swab: Influenza A and B antigens (non-infective recombinant nucleoprotein)
- 5- Negative Control Swab: Inactivated Group B Streptococcus antigen (non-infective)

MATERIALS REQUIRED BUT NOT PROVIDED

- OSOM Ultra Flu A&B Kit (Catalog # 1006)
- Latex gloves
- Clock or Timer

WARNINGS AND PRECAUTIONS

- For *in vitro* diagnostic use only
- **DO NOT** use the Controls beyond the expiration date.
- Potential biohazard. Handle as if potentially infectious. Handle this product according to established good laboratory practices using appropriate precautions.
- Not for patient use.

STORAGE AND STABILITY

- The OSOM Ultra Flu A&B Control Kit must be stored at 2-30°C.
- The swabs should be kept in the pouch.
- Controls are stable until the expiration date on the label.

INSTRUCTIONS FOR USE

Use the OSOM Ultra Flu A&B Control Swabs as you would a patient swab sample in accordance with the procedure for the OSOM Ultra Flu A&B Test. Read the procedural instructions from the assay directional insert prior to testing.

- If refrigerated, allow the Control Swabs to reach room temperature prior to use.

EXPECTED RESULTS

- The Positive A&B Control should yield reddish purple lines at the C, A and B positions.
- The Negative A&B Control should yield reddish purple line at the C position only.
- If the controls do not perform as expected, do not report patient results.
- Refer to the assay directional insert for a full description in the Interpretation of Test Results section.

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.

RE-ORDER NUMBER

Catalog No. 1006 OSOM Ultra Flu A&B Test (25 tests)

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TECHNICAL ASSISTANCE

For assistance in the U.S., please contact Sekisui Diagnostics Technical Assistance at (800) 332-1042.

KEY TO COMPONENTS LABELING

Read Instructions



In vitro use only



Batch Code



Use by YYYY-MM-DD



Temperature Limitation



Catalog Number



Manufacturer



Do Not Reuse



Manufactured For

MF

SEKISUI
DIAGNOSTICS

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