

OSOM[®] Influenza A&B Control Kit

INTENDED USE

The OSOM[®] Influenza A&B Control Kit is intended for *in vitro* diagnostic use in quality control testing with the OSOM[®] Influenza A&B Test.

SUMMARY

The OSOM[®] Influenza A&B Control Kit provides swabs coated with a dried mixture containing influenza A or B antigens. The level of influenza A or B antigen applied to the swab is sufficient to provide a positive result when used with the OSOM[®] Influenza A&B Test. The influenza A control swab acts as a negative control for the influenza B antigen and conversely, the influenza B control swab serves as a negative control for influenza A antigen. When used for quality control in the OSOM[®] Influenza A&B Test, these controls are useful as an aid in verifying test and operator performance.

MATERIALS PROVIDED

5 Influenza A Positive Control Swabs (red shaft foam swab packaged with a desiccant tablet)

- Formalin inactivated influenza A/Kitakyushu/159/93 containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture.
- Result is representative of a mid-level positive

5 Influenza B Positive Control Swabs (blue shaft foam swab packaged with a desiccant tablet)

- Formalin inactivated influenza B/Lee/40 containing 0.05% sodium azide. Inactivity confirmed by inability of virus to infect cell culture.
- Result is representative of a mid-level positive

MATERIALS REQUIRED BUT NOT PROVIDED

- OSOM[®] Influenza A&B Test
- Clock or Timer

WARNINGS AND PRECAUTIONS

1. DO NOT use the Controls beyond the expiration date.
2. Potential biohazard. Handle as if potentially infectious. Handle this product according to established good laboratory practices using appropriate precautions.
3. Not for patient use.

STORAGE

- The OSOM[®] Influenza A&B Control Kit must be stored at room temperature (15°- 30°C; 59°- 86°F).

Stability

Swabs stored in the closed tube at 15°- 30°C (59°- 86°F) are stable until the expiration date printed on the tube and box label.

INSTRUCTIONS FOR USE

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

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. 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.

REFERENCES

Refer to the OSOM[®] Influenza A&B Test directional insert for additional information on this assay.

ASSISTANCE

For assistance, contact Genzyme Diagnostics Technical Assistance at (800)332-1042.

RE-ORDER

No. 190-OSOM[®] Influenza A&B Test (25 tests)
No. 191- OSOM[®] Influenza A&B Control Kit

OSOM[®] is a registered trademark of Genzyme Diagnostics.

Manufactured by:

Genzyme Diagnostics 6659 Top Gun Street, San Diego, CA 92121 USA



A division of Genzyme Corporation

Framingham, MA 01701-9322
TEL: 800-332-1042 (US only)
www.genzymediagnosics.com

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