Status[®] Flu A & B Control Set

For In vitro diagnostic use

Cat. No.: 36022CS

Intended Use

Status[®] Flu A & Control is to be used as an external control to ensure the performance of the following test kits. These controls are used to ensure proper performance of these tests:

- Status[®] Flu A & B (Cat. No.: 36025/36022/36005)
- BioSign[®] Flu A + B (Cat. No.: BSP-510-25/BSP-510-22)
- McKesson Influenza (Cat. No.: 181-36025)

Summary and Principle

The Status[®] Flu A & Positive Control Swab consists of recombinant nucleoproteins of influenza A and B viruses dried onto the swab. The Negative Control Swab consists of inactivated Group B Streptococcus dried onto the swab.

Materials Supplied

- Flu A & B Positive Control Swabs (5): Influenza A and B antigens (non-infective recombinant nucleoprotein)
- Flu A & B Negative Control Swabs (5): Inactivated Group B Streptococcus antigen (non-infective)
- Package Insert (1)

Precautions/Warnings

- For *In vitro* diagnostic use.
- Do not use after the expiration date.
- Controls contain recombinant protein and inactivated microorganisms. However, handle as if capable of transmitting Infectious disease.
- Wear disposable gloves while handling these controls.
- Dispose of used controls In accordance with Federal, State, and Local requirements.
- Follow proper hand washing hygiene after handling these controls.
- The Control Swabs are designed for use only with the tests listed above.

Stability and Storage

Status[®] Flu A & Control Set may be stored at 2-30°C (35-86°F) in the original sealed pouch, away from direct sunlight. The contents are stable until the expiration date printed on the pouch or box.

Test Procedure

Refer to the package insert for the test. The Status[®] Flu A & B Control Swabs must be used at room temperature (18-30°C)

Interpretation of Results

Refer to the package insert for the test.

Technical Assistance

For technical assistance and customer service, contact:

LifeSign, LLC 85 Orchard Road Skillman, NJ 08558 Phone: (800) 526-2125 Fax (732) 246-0570 www.lifesignmed.com