Influenza Rapid Test Control Pack
Part Number: KZMC033

These reagents are not a substitute for the mandatory positive and negative control reagents provided with licensed test kits.
For Research Use Only. Not for use in diagnostic procedures.

NAME AND INTENDED USE:
The Influenza Rapid Test Control Pack is intended for use with *in vitro* rapid tests for the determination of the presence or absence of Influenza A and B. This control pack is for **Research Use Only** and should not be used in diagnostic procedures.

SUMMARY:
The Influenza Rapid Test Control Pack is composed of three members representing Influenza A and B samples. Each panel member contains 1.5mL of artificial nasal matrix and inactivated influenza virus. This control pack can be used for training, lot-to-lot comparison of reagent test kits and to evaluate and compare intra and inter laboratory performance of influenza rapid test systems.

PRINCIPLES OF THE PROCEDURE:
The Influenza Rapid Test Control Pack has been designed for use with *in vitro* rapid tests for monitoring assay performance. The Influenza Rapid Test Control Pack is prepared from human and non-human components. Influenza virus has been inactivated to reduce infectious risk. The Influenza Rapid Test Control Pack members should be evaluated as unknown specimens per the instructions supplied by the manufacturer of the test kit being used.

REAGENTS:
1. One vial Influenza A (New Caledonia/20/99) Positive (1.5mL).
2. One vial Influenza B (Panama/45/90) Positive (1.5mL).
3. One vial Influenza A/B Negative (1.5mL)

WARNINGS AND PRECAUTIONS:
1. **FOR RESEARCH USE ONLY. NOT FOR USE IN DIAGNOSTIC PROCEDURES.**
2. **USE UNIVERSAL PRECAUTIONS: HANDLE AS IF CAPABLE OF TRANSMITTING INFECTIOUS AGENTS.**

Influenza Rapid Test Control Pack reagents are prepared from inactivated influenza virus. All materials used in the preparation of the Influenza Rapid Test Control Pack reagents are known to be non-reactive for HIV1/2 Ab, HBsAg and HCV Ab. However, no known test method can assure that products derived from human sources will not transmit infection. It is recommended that these reagents and all human specimens be handled in accordance with Universal Precautions.

SAFETY PRECAUTIONS:
1. Clean any spillage immediately and thoroughly using a suitable disinfectant such as 1% bleach solution.
2. Handle and dispose of all specimens, controls and materials used in testing as though they contain infectious agents.

HANDLING PRECAUTIONS:
1. Do not use Influenza Rapid Test Control Pack reagents beyond the expiration date.
2. Avoid contamination of reagents when opening and dispensing.

STORAGE INSTRUCTIONS:
1. Store Influenza Rapid Test Control Pack reagents at 2-8°C when not in use.
2. Vials should be stored upright to prevent leakage.
3. When stored as directed, Influenza Rapid Test Control Pack reagents are suitable for use for up to 60 days after opening.

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION:
1. Alterations in physical appearance may indicate instability or deterioration of Influenza Rapid Test Control Pack reagents.
2. Solutions which are visibly turbid should be discarded.

PROCEDURE:
1. Influenza Rapid Test Control Pack reagents may be included in a test run following the procedure provided by the test kit manufacturer for unknown specimens.
2. Allow Influenza Rapid Test Control Pack reagents to reach room temperature (15-30°C) prior to use. Return to proper storage after use.
3. Mix contents by gentle swirling prior to use. Do not mix by vigorous shaking, avoid foaming.

INTERPRETATION OF RESULTS:
Influenza Rapid Test Control Pack reagent test results should be determined as recommended for unknown specimens in the package insert for each commercially available test kit.

LIMITATION OF THE PROCEDURE:
1. Influenza Rapid Test Control Pack reagents must not be substituted for the positive and negative control reagents provided with some commercially available test kits.
2. Influenza Rapid Test Control Pack reagents are provided for **Research Use Only** and should not be used in diagnostic procedures, for calibration or as primary reference preparations for any test kit.
3. PROCEDURE and INTERPRETATION OF RESULTS provided in package insert of each commercially available test kit must be followed closely when testing the Influenza Rapid Test Control Pack reagents. Deviations from the recommended procedures may produce unreliable results.
4. It is the responsibility of each laboratory to determine the suitability of Influenza Rapid Test Control Pack reagents for its particular use. They also must establish guidelines for the interpretation of results.

SPECIFIC PERFORMANCE CHARACTERISTICS:
The Influenza Rapid Test Control Pack reagents were tested using commercially available test systems following the procedures provided by the manufacturer for the testing of unknown specimens. The data contained in this document is intended to be representative of typical test procedures and should be used for informational purposes only. Each laboratory should establish its own performance characteristics.

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This Product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.
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