Influenza Rapid Test Verification Panel I
Part Number: KZMC021

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 Verification Panel I is intended for use with *in vitro* assay procedures to determine the absence or presence of Influenza. This panel is for **Research Use Only** and should not be used in diagnostic procedures.

SUMMARY:
The Influenza Rapid Test Verification Panel I is composed of twenty members representing various influenza strains and a range of reactivities. Each panel member contains 0.5mL of material prepared from inactivated viral culture fluid. This panel can be used for training, lot-to-lot comparison of reagent test kits and to evaluate and compare intra laboratory and inter laboratory performance of Influenza testing platforms.

PRINCIPLES OF THE PROCEDURE:
The Influenza Rapid Test Verification Panel I reagents have been designed for use with *in vitro* assay procedures for monitoring assay performance across a range of reactivity levels. These materials are prepared from inactivated viral culture fluids. Source materials have been processed and treated to eliminate unwanted components and to ensure stability of the final product. The Influenza Rapid Test Verification Panel I members should be evaluated as an unknown specimen per the instructions supplied by the manufacturer of the test kit being used.

REAGENTS:
1. Eight vials Influenza A/B Non-Reactive (0.5mL each).
2. Seven vials Influenza A Reactive (0.5mL each).
3. Five vials Influenza B Reactive (0.5mL each).

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.**

The Influenza Rapid Test Verification Panel I reagents are prepared from inactivated viral culture fluid. Although inactivated, 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 the Influenza Rapid Test Verification Panel I reagents beyond the expiration date.
2. Avoid contamination of reagents when opening and sampling.

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

INDICATIONS OF REAGENT INSTABILITY OR DETERIORATION:
Alterations in physical appearance may indicate instability or deterioration of the Influenza Rapid Test Verification Panel I reagents. Solutions which are visibly turbid should be discarded.

PROCEDURE:
1. The Influenza Rapid Test Verification Panel I reagents may be included in a test run following the procedure provided by the test kit manufacturer for unknown specimens.
2. Allow the Influenza Rapid Test Verification Panel I 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:
The Influenza Rapid Test Verification Panel I 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. The Influenza Rapid Test Verification Panel I reagents must not be substituted for the positive and negative control reagents provided with commercially available test kits.
2. The Influenza Rapid Test Verification Panel I reagents are provided for **Research Use Only** and must not be used 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 Verification Panel I reagents. Deviations from the recommended procedures may produce unreliable results.
4. It is the responsibility of each laboratory to determine the suitability of the Influenza Rapid Test Verification Panel I reagents for its particular use. They also must establish guidelines for the interpretation of results.

SPECIFIC PERFORMANCE CHARACTERISTICS:
The Influenza Rapid Test Verification Panel I 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 use only. Each laboratory should establish its own performance characteristics.

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