HIV 1/2 Rapid Test Verification Panel
Part Number: KZMC029

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 HIV 1/2 Rapid Test Verification Panel is intended for use with *in vitro* assay procedures for the determination of antibodies to HIV 1/2. This panel is for **Research Use Only** and should not be used in diagnostic procedures.

SUMMARY:
The HIV 1/2 Rapid Test Verification Panel is composed of ten members representing donors at various reactivities. Each positive panel member contains 0.25mL and each negative panel member contains 1.75mL of stabilized human plasma. 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 HIV 1/2 test systems.

PRINCIPLES OF THE PROCEDURE:
Verification Panel reagents have been designed for use with *in vitro* assay procedures for the purpose of monitoring assay performance across a wide range of reactivity levels. Verification Panel materials are prepared from human source serum and other non-human components. HIV 1/2 serum has been heat inactivated to reduce infectious risk. Source materials have been processed and treated to eliminate unwanted components and to ensure stability of the final product. The HIV 1/2 Rapid Test Verification Panel members should be evaluated as unknown specimens per the instructions supplied by the manufacturer of the test kit being used.

REAGENTS:
1. Two vials HIV 1/2 Negative (1.75mL each).
2. Four vials HIV-1 Only Positive (0.25mL each).
3. Two vials HIV-2 Only Positive (0.25mL each).
4. Two vials HIV 1/2 Positive (0.25mL each)

HIV 1/2 Rapid Test Verification Panel materials contain proteins derived from human sources.

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.**

HIV 1/2 Rapid Test Verification Panel reagents are prepared from heat inactivated human plasma containing antibodies to HIV 1/2. Each unit of processed normal human plasma used in the preparation of the HIV 1/2 Rapid Test Verification Panel reagents has been tested using FDA cleared tests and found 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 Verification Panel reagents beyond the expiration date.
2. Avoid contamination of reagents when opening and dispensing.

STORAGE INSTRUCTIONS:
1. Store Verification Panel reagents at 2-8°C when not in use.
2. Vials should be stored upright to prevent leakage.
3. When stored as directed, Verification Panel 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 Verification Panel reagents. Solutions, which are visibly turbid, should be discarded.

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

SPECIFIC PERFORMANCE CHARACTERISTICS:
The Verification Panel reagents were tested using commercially available test systems following the procedures provided by the manufacturer for the testing of unknown specimens. Any data provided for this material 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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