Rotavirus Rapid Test Control Pack
Part Number: KZMC036

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 Rotavirus Rapid Test Control Pack is intended for use with *in vitro* rapid tests for the determination of the presence or absence of Rotavirus. This control pack is for **Research Use Only** and should not be used in diagnostic procedures.

SUMMARY:
The Rotavirus Rapid Test Control Pack is composed of two members representing Rotavirus positive and negative samples. Each panel member contains 1.5mL of artificial nasal matrix and inactivated Rotavirus. 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 Rotavirus rapid test systems.

PRINCIPLES OF THE PROCEDURE:
The Rotavirus Rapid Test Control Pack has been designed for use with *in vitro* rapid tests for monitoring assay performance. The Rotavirus Rapid Test Control Pack is prepared from human and non-human components. Rotavirus has been inactivated to reduce infectious risk. The Rotavirus 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 Rotavirus (WA) Positive (1.5mL).
2. One vial Rotavirus 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.**

Rotavirus Rapid Test Control Pack reagents are prepared from inactivated Rotavirus. All materials used in the preparation of the Rotavirus 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 Rotavirus Rapid Test Control Pack reagents beyond the expiration date.
2. Avoid contamination of reagents when opening and dispensing.

STORAGE INSTRUCTIONS:
1. Store Rotavirus 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, Rotavirus 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 Rotavirus Rapid Test Control Pack reagents.
2. Solutions which are visibly turbid should be discarded.

PROCEDURE:
1. Rotavirus 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 Rotavirus 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:
Rotavirus 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. Rotavirus Rapid Test Control Pack reagents must not be substituted for the positive and negative control reagents provided with some commercially available test kits.
2. Rotavirus 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 Rotavirus 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 Rotavirus Rapid Test Control Pack reagents for its particular use. They also must establish guidelines for the interpretation of results.

SPECIFIC PERFORMANCE CHARACTERISTICS:
The Rotavirus 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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