SeroDetect HIV-Ab Range Verification Panel
Part Number: KZMC024
Lot Number: 1607-272-0007

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 SeroDetect HIV-Ab Range Validation Panel is intended for use with *in vitro* assay procedures for the determination of antibodies to Human Immunodeficiency Virus (HIV). This panel is for **Research Use Only** and should not be used in diagnostic procedures.

SUMMARY:
The SeroDetect HIV-Ab Range Validation Panel is composed of ten members representing a titration of an HIV-Ab reactive donor. Each panel member contains 1.5mL of material prepared from 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-Ab test systems.

PRINCIPLES OF THE PROCEDURE:
SeroDetect 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. SeroDetect materials are prepared from human source plasma and other non-human components. HIV-Ab plasma has been heat inactivated to reduce infectious risk (1). Source materials have been processed and treated to eliminate unwanted components and to ensure stability of the final product. The SeroDetect HIV-Ab Range Validation 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 SeroDetect HIV-Ab Negative (1.5mL each).
2. Eight vials SeroDetect HIV-Ab Positive (1.5mL each).
SeroDetect HIV-Ab Range Validation Panel materials contain proteins derived from human sources, antimicrobial agents and stabilizers.

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.**

SeroDetect HIV-Ab Range Validation Panel reagents are prepared from heat inactivated human plasma containing antibodies to HIV. Each unit of processed normal human plasma used in the preparation of SeroDetect HIV-Ab 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 Biosafety Level 2 practices as described in the CDC NIH publication, Biosafety in Microbiological and Biomedical Laboratories (2), or other equivalent guidelines (3,4).

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 (2-4).

HANDLING PRECAUTIONS:
1. Do not use SeroDetect Panel reagents beyond the expiration date.
2. Avoid contamination of reagents when opening and dispensing.

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

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

SPECIFIC PERFORMANCE CHARACTERISTICS:
The SeroDetect Panel 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.

PIKZMC024 Rev02
Effective Date:04/02/2020

This Product was manufactured in a facility which has a Quality Management System that is ISO 13485 certified.
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Representative Levels of Reactivity
SeroDetect HIV-Ab Range Verification Panel
Expiration Date: 01/23/2022

Panel Member	Ortho Vitros ECi A-HIV 1+2 Test Date: 01/23/2020
	S/Co
1	0.17
2	0.47
3	3.44
4	6.83
5	29.5
6	47.7
7	87.0
8	98.9
9	107
10	111

*Positive Result S/Co ≥ 1.00 and Negative Result S/Co ≤ 1.00

This data is intended to be representative of typical test procedures and should be used for informational purposes only.
They are not intended to represent performance specifications.

REFERENCES:

1. ZeptoMetrix Corporation Validation Protocol Number PRO 01-012-0209-00 Validation of Heat Inactivation of the HIV-1 Virus in Human Source Plasma.
2. U.S. Department of Health and Human Services. Biosafety in Microbiological and Biomedical Laboratories. HHS Publication (NIH) 93-8395. Washington: U.S. Government Printing Office, May, 1993.
3. National Committee for Clinical Laboratory Standards. Protection of Laboratory Workers from Infectious Disease Transmitted by Blood, Body Fluids and Tissue – Second Edition, Tentative Guideline. NCCLS Document M29-T2. Villanova, PA: NCCLS, 1991.
4. National Committee for Clinical Laboratory Standards. Clinical Laboratory Waste management; Approved Guideline> NCCLS Document GP 5-A. Villanova, PA: NCCLS, 1993.

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