

Zika IgM/IgG Control Pack

PRODUCT DESCRIPTION:

The Zika Antibody Control Pack consists of one vial each of IgG, IgM and negative antibody controls. The IgG and IgM controls contain anti-Zika NS1 mouse monoclonal antibody conjugated to purified human IgG or IgM, respectively. All controls are supplied in normal human plasma, 0.09% sodium azide and other stabilizing reagents. These controls are designed to mimic actual Zika positive and negative antibody plasma specimens.

INTENDED USE:

The Zika Antibody Control Pack is intended for use as quality controls with serological tests for the determination of IgG and IgM antibodies to Zika virus. The Zika antibody controls can also be used for validation of clinical assays, development of diagnostic tests, and training of laboratory personnel. These controls are for **Research Use Only** and should not be used in diagnostic procedures.

MATERIALS PROVIDED:

- 1 x 0.25 mL Zika IgG Positive Control
- 1 x 0.25 mL Zika IgM Positive Control
- 1 x 0.25 mL Zika Antibody Negative Control

WARNINGS AND PRECAUTIONS:

Do Not Use in Humans. Not for use in diagnostic procedures. For research use only.

Use Universal Precautions. Handle as if capable of transmitting infectious agents.

These products are intended for research, product development, and quality assurance. These products are NOT intended for use in the manufacture or processing of injectable products subject to licensure under section 351 of the Public Health Service Act or for any other product intended for administration to humans.

Normal human plasma used in the manufacture of this product is treated with 0.09% sodium azide. It was manufactured from materials that have been tested and found non-reactive at the donor level for HIV-1/HIV-2 Antibody, HBsAg and HCV Antibody by FDA licensed donor screening test methods. All materials are also tested for HIV-1 and HCV by FDA approved Nucleic Acid Test (NAT) methods.

SAFETY PRECAUTIONS:

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

STORAGE AND HANDLING INSTRUCTIONS:

- Store at 2-8°C
- Store upright to avoid leakage
- To avoid contamination, use separate pipette tips for all reagents
- Avoid multiple freeze-thaw cycles
- Do not use beyond the expiration date
- Solutions visibly turbid or any other change in physical appearance may indicate deterioration and should be discarded

INSTRUCTIONS FOR USE:

1. Zika antibody controls may be used and treated as specimens following the procedure provided by the test kit manufacturer. **Note: See limitations below.**
2. Allow antibody controls to reach room temperature (15-30°C) prior to use. Return to proper storage after use.
3. Mix vial contents by repeatedly pipetting up and down prior to use.

INTERPRETATION OF RESULTS:

Test results should be determined as recommended for unknown specimens in the package insert for each commercially available test kit. Results may vary with different tests. Each laboratory must establish its own range of acceptable values with a particular test.

LIMITATIONS OF THE PROCEDURE:

Zika antibody positive controls contain Mouse IgG antibody specifically reactive to the Zika antigen NS1. Tests that do not utilize NS1 antigen will yield a negative result. IgM tests that utilize buffers to competitively inhibit human IgG reaction may yield a negative result. It is recommended to reduce the dilution of the IgM control in the assay buffer, i.e., 10-fold instead of 100-fold dilution. Additionally, tests that do not utilize specific detection reagents for human IgG or IgM antibodies may yield false positive results. Do not use in place of positive and negative control reagents provided with commercially available test kits. It is the responsibility of each laboratory to determine the suitability of the Zika antibody controls for its particular use. They also must establish guidelines for the interpretation of the results.

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	Catalog Number		Temperature Limitation
	Batch Code		Expiration Date
	For Research Use Only		Biological Risk
	Manufacturer		