

Simplexa™ Dengue Molecular Control (English)

REF MOL3103C
Rev. A



For *in vitro* Diagnostic Use

INTENDED USE

Focus Diagnostics' Simplexa™ Dengue Molecular Control consists of inactivated Dengue virus intended to be used as a control in molecular testing. This control is not intended for use with donor screening tests.

INSTRUCTIONS FOR USE

The Simplexa Dengue Molecular Control should be used at the same volume as unknown samples in a validated molecular test methodology.

MATERIALS PROVIDED

Upon receipt, store at -10 to -30 °C (do not use a frost-free freezer). Appropriately stored controls are stable through the end of the expiration month as indicated on the packaging. After first use, store thawed controls at 2 to 8 °C up to 30 days.

Product Description

Component Name	REF	Description	Cap Color	Number of Vials	Reactions per Vial	Volume per Vial
Dengue Control	MOL3103	Inactivated dengue virus serotypes 1, 2, 3, and 4.	Red	2	various	800 µL

SHELF LIFE AND HANDLING

1. Store controls at -10 to -30 °C (do not use a frost-free freezer).
2. Do not use control beyond the expiration dates.
3. Allow control to thaw at room temperature (approximate range 18 to 25 °C) before use.
4. Once thawed, store the unused control at 2 to 8 °C for no more than 30 days.
5. Do not refreeze.
6. When properly stored, the control is stable through the end of the month indicated on the expiration date on the packaging.

WARNINGS AND PRECAUTIONS

1. All human origin materials should be treated as potentially infectious. Source materials from which this product (including controls) was derived have been screened for Hepatitis B surface antigen, Hepatitis C antibody and HIV-1/2 (AIDS) antibody by FDA-approved methods and found to be negative. However, as no known test methods can offer 100% assurance that products derived from human blood will not transmit these or other infectious agents, all controls, serum specimens and equipment coming into contact with these specimens should be considered potentially infectious and decontaminated or disposed of with proper biohazard precautions. CDC and the National Institutes of Health recommend that potentially infectious agents be handled at the Biosafety Level 2.^{1,2}
2. Follow standard precautions. All controls should be considered potentially infectious and handled accordingly.
3. Wear personal protective equipment, such as (but not limited to) gloves and lab coats when handling controls. Wash hands thoroughly when finished performing the test.
4. Do not pipette by mouth.
5. Do not smoke, drink, eat, handle contact lenses or apply make-up in areas where controls and/or human specimens are being used.
6. Dispose of unused controls and human specimens according to local, state and federal regulations.
7. Contamination of patient specimens or reagents can produce erroneous results. Use aseptic techniques.
8. Pipette and handle reagents carefully to avoid mixing of samples from adjacent wells.
9. Use proper pipetting techniques and maintain the same pipetting pattern throughout the procedure to ensure optimal and reproducible values.

QUALITY CONTROL

Simplexa Dengue Molecular Control is an unassayed control. Control ranges may vary based on testing method. A specific range should be determined for each desired testing method. Each laboratory should establish their own Quality Control ranges and frequency of QC testing based on applicable local laws, regulations and standard good laboratory practice.

LIMITATIONS

1. For *in vitro* diagnostic use.
2. This control is not intended to be used with donor screening tests.
3. This control has been studied using a molecular testing methodology; it is not intended for use with other methodologies.

REFERENCES

1. NCCLS H18-A2. Procedures for the Handling and Processing of Blood Specimens; Approved Guideline. 2nd Ed. (1999).
2. CDC-NIH Manual. (1999) Biosafety in Microbiological and Biomedical Laboratories. 4th ed. And National Committee for Clinical Laboratory Standards (NCCLS). Protection of Laboratory Workers from Instruments, Biohazards and Infectious Disease Transmitted by Blood, Body Fluids and Tissue (NCCLS M29-A).

ORDERING INFORMATION

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TECHNICAL ASSISTANCE

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