CBER/FDA FSS13025 Zika Virus RNA Reference Reagent, Heat-Inactivated

Catalog No. NR-50723

For research use only. Not for human use.

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Manufacturer:
Center for Biologics Evaluations and Research (CBER), Food and Drug Administration (FDA), Silver Spring, Maryland, USA

Product Description:
FSS13025 Zika virus (ZIKV) RNA reference reagent (ZIKV-RR, FSS13025) is for use in the development and validation of ZIKV nucleic acid testing (NAT). NR-50723 consists of material produced in *Cercopithecus aethiops* kidney epithelial (Vero) cells infected with ZIKV, FSS13025 that has been heat-inactivated at 56°C for 60 minutes, diluted in dialyzed, defibrinated human plasma and lyophilized.[1,2]

The heat-inactivated preparation of ZIKV-RR, FSS13025 (non-lyophilized) was included in a collaborative validation studies for the World Health Organization International Standard for ZIKV (WHO ZIKV IS).[3]

ZIKV, FSS13025, was isolated from the blood of a human in Cambodia in 2010. The complete genomic sequence of ZIKV, FSS13025 has been determined (GenBank: JN860885).[4]

Material Provided:
Each ampule contains lyophilized ZIKV-RR, FSS13025 from approximately 1 mL of heat-inactivated, clarified cell lysate and supernatant from Vero cells infected with ZIKV, FSS13025.

Packaging/Storage:
NR-50723 was packaged aseptically in glass ampules. The product is provided frozen on dry ice and should be stored at -20°C immediately upon arrival. NR-50723 can be reconstituted with 1 mL of sterile distilled water. After rehydration NR-50723 should be stored at -60°C or colder. Freeze-thaw cycles should be avoided.

Citation:
Acknowledgment for publications should read "The following reagent was obtained through the WRCEVA program and BEI Resources, NIAID, NIH: CBER/FDA FSS13025 Zika Virus RNA Reference Reagent, Heat-Inactivated, NR-50723."

Biosafety Level: 2
Appropriate safety procedures should always be used with this material. Laboratory safety is discussed in the following publication: U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, and National Institutes of Health. Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington, DC: U.S. Government Printing Office, 2009; see www.cdc.gov/biosafety/publications/bmbl5/index.htm.

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References:
1. Fares-Gusmao, R., et al. "Production and Characterization of Zika Virus RNA Reference Reagents as a Response to a Public Health Emergency." Transfusion 58 (2018): 2171-2174. PubMed: 30178463.
2. Volkova, E., et al. "Complete Genome Sequences of Zika Virus Strains Used for the Formulation of CBER/FDA RNA Reference Reagents and Lot Release Panels for Nucleic Acid Technology Testing." Genome Announc. 6 (2018): e00572-18. PubMed: 29976606.
3. Baylis, S. A., et al. "Harmonization of Nucleic Acid Testing for Zika Virus: Development of the 1st World

Health Organization International Standard." Transfusion 57 (2017): 748-761. PubMed: 28229462.
4. Haddowi, A. D., et al. "Genetic Characterization of Zika Virus Strains: Geographic Expansion of the Asian Lineage." PLoS Negl. Trop. Dis. 6 (2012): e1477. PubMed: 22389730.

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