

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

Catalog No. NR-50723

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.

Lot¹: ZIKV-FSS13025

Manufacturing Date: SEP2016

TEST	SPECIFICATIONS	RESULTS
Viral Titer² Quantitative Real-Time PCR	Report results	5.3 log copies per mL
Virus Inactivation Cell culture safety test for residual virus ² Cytopathic effect on Vero cells ³ Viral antigen expression by indirect immunofluorescence assay ³ Presence of viral RNA by real-time qPCR after serial passage ³	No recovered virus No viable virus detected No viable virus detected No viable virus detected	No recovered virus No viable virus detected No viable virus detected No viable virus detected

¹All tests were completed post-inactivation

²Performed at Center for Biologics Evaluations and Research (CBER), Silver Springs, Maryland, USA. For additional information, please refer to 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.

³Completed at ATCC[®]. The inactivated virus preparation was plated on Vero E6 cells and incubated for 14 days at 37°C and 5% CO₂; cell lysate and supernatant from these cultures was passaged on fresh monolayers of Vero E6 cells and again incubated for 14 days at 37°C and 5% CO₂.

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