

**CBER/FDA PRVABC59 Zika Virus RNA Reference Reagent, Heat-Inactivated**

**Catalog No. NR-50722**

**Product Description:** PRVABC59 Zika virus (ZIKV) RNA reference reagent (ZIKV-RR, PRVABC59) is for use in the development and validation of ZIKV nucleic acid testing (NAT). NR-50722 consists of material produced in *Cercopithecus aethiops* kidney epithelial (Vero) cells infected with ZIKV, PRVABC59 that has been heat-inactivated at 56°C for 60 minutes, diluted in dialyzed, defibrinated human plasma and lyophilized.

**Lot<sup>1</sup>: ZIKV-PRVABC59**

**Manufacturing Date: SEP2016**

TEST	SPECIFICATIONS	RESULTS
<b>Viral Titer<sup>2</sup></b> Quantitative Real-Time PCR	Report results	5.77 log copies per mL
<b>Virus Inactivation</b> Cell culture safety test for residual virus <sup>2</sup> Cytopathic effect on Vero cells <sup>3</sup> Viral antigen expression by indirect immunofluorescence assay <sup>3</sup> Presence of viral RNA by real-time qPCR after serial passage <sup>3</sup>	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

<sup>1</sup>All tests were completed post-inactivation

<sup>2</sup>Performed 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.

<sup>3</sup>Completed at ATCC<sup>®</sup>. The inactivated virus preparation was plated on Vero E6 cells and incubated for 14 days at 37°C and 5% CO<sub>2</sub>; 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% CO<sub>2</sub>.

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