

PEI Reference Preparation Zika Virus RNA (#11474/16)

Each vial contains 0.5 ml of lyophilized heat inactivated Zika virus (ZIKV), diluted in pooled human plasma. The reference preparation is intended to be used by NAT assays for the detection of ZIKV RNA in human plasma samples.

RECONSTITUTION

Before reconstitution the vial should be allowed to equilibrate to ambient temperature.

Each vial should be reconstituted in **0.5 ml of sterile nuclease-free water** and left for a minimum of 10 minutes with occasional agitation before use.

This reference material was calibrated in the study to establish the 1st World health Organization (WHO) International Standard (IS) for ZIKV RNA (1). The combined qualitative and quantitative mean estimate for 11474/16 was 8.86E+07 units/ml (confidence interval 2.19+E7 to 3.58E+08).

STORAGE

The material is supplied lyophilized and should be stored at or below -20°C. Reference materials should be stored on receipt as indicated on the label. Once, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

DETAILED INFORMATION

The non-WHO reference material for Zika virus (ZIKV) RNA is intended to be used in the standardization of nucleic acid amplification technique (NAT)-based assays for ZIKV. The reference material has been prepared using an Asian strain of ZIKV (PF13/251013-18), isolated from a patient serum in French Polynesia in 2013. The virus strain was kindly provided by Didier Musso at the Institut Louis Malardé. The material has been evaluated in an international collaborative study to evaluate and establish the 1st WHO IS for ZIKV RNA, involving 24 laboratories performing a wide range of ZIKV NAT assays. Further details of the collaborative study are available in the report (1). The sequence of the Zika virus strain has been determined (2) with the following accession number: KX369547.

1. Baylis SA, Hanschmann KMO, Schnierle BS, Trösemeier JH, J. Blümel J. Collaborative Study to Evaluate a Candidate World Health Organization international Standard for Zika Virus for Nucleic Acid Amplification Technique (NAT)-Based Assays WHO/BS/2016.2286.

2. Trösemeier J-H, Musso D, Blümel J, Thézé J, Pybus OG, Baylis SA. Genome Sequence of a Candidate World Health Organization Reference Strain for Zika Virus for Nucleic Acid Testing. Genome Announcements, 2016;4(5). pii: e00917-16.

ORDERING AND SHIPMENT INFORMATION

The PEI Reference Preparation ZIKV RNA (#11474/16) can be ordered by **fax (+49 6103 77 1285)** or **email (Sigrid.Hanitsch@pei.de, Ines.Amberg@pei.de or Christine.Hanker-Dusel@pei.de)**, using the PEI Order Form available from the PEI website:

www.pei.de/pei-reference-material

There is a fee of 40 € per vial, and 15 € for packaging (maximum of 20 vials per box).

If you have any questions, please do not hesitate to contact us:

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