1st World Health Organization International Standard for Chikungunya virus RNA for Nucleic Acid Amplification Techniques (NAT)-Based Assays

PEI code 11785/16

(Version 2.0, Dated 23/10/2017)

1. INTENDED USE

The World Health Organization (WHO) International Standard for Chikungunya virus (CHIKV) RNA is intended to be used in the standardization of nucleic acid amplification technique (NAT)-based assays for CHIKV. The standard has been prepared using an East/Central/South African (ESCA) strain of CHIKV (R91064), isolated from a patient returning from India to the U.S. in 2006 (1). The material has been lyophilized in 0.5 mL aliquots and stored at -20°C. The material has been evaluated in an international collaborative study involving 25 laboratories performing a wide range of CHIKV NAT assays. Further details of the collaborative study are available in the report (2).

2. UNITAGE

This reagent has been assigned a unitage of 2,500,000 International Units/mL.

3. CONTENTS

Each vial contains 0.5 mL of lyophilized material containing inactivated CHIKV. The virus has been diluted in human negative plasma and lyophilized. The material is intended for dilution in a diluent appropriate for the assay matrix being tested (e.g. plasma).

4. CAUTION

THIS PREPARATION IS NOT FOR ADMINISTRATION TO HUMANS.

The preparation contains heat inactivated CHIKV.

As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. It should be used and discarded according to your own laboratory's safety procedures. Such safety procedures probably will include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

5. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution.

The material is supplied lyophilized and should be stored at or below -20ºC. Each vial should be reconstituted in 0.5 mL of sterile nuclease-free water. The product should be reconstituted just prior to use. The product should be used for the calibration of secondary reference preparations for CHIKV RNA. If not all the material is used immediately, laboratories may aliquot the remaining material into suitable single use volumes which should be stored at or below -70ºC.

6. STABILITY

As the stability studies with accelerated conditions indicate high stability of the lyophilized reference material under the recommended storage conditions (at or below -20ºC), there is no expiry date assigned to the International Standard. This approach complies with the recommendations for the preparation, characterization and establishment of international and other biological reference standards (3). The reference material is held at the Paul-Ehrlich-Institut (PEI) within assured, temperature-controlled storage facilities. During its life cycle the stability is monitored at regular intervals. The international standard remains valid with the assigned potency and status until withdrawn or amended.

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.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact PEI.

7. REFERENCES

The accession number for the CHIKV virus strain is KJ941050 (4).

1. Lanciotti RS, Kosoy OL, Laven JJ, Panella AJ, Velez JO, Lambert AJ, Campbell GL. 2007. Chikungunya virus in U.S. travelers returning from India, 2006. Emerg. Infect. Dis. 13:764-767.

2. Kreß JA, Hanschmann KMO, Chudy M. Collaborative Study to Evaluate a Candidate World Health Organization International Standard for Chikungunya Virus for Nucleic Acid Amplification Technique (NAT)-Based Assays WHO/BS/2017.2330.

3. World Health Organization. Recommendations for the preparation, characterization and establishment of international and other biological reference standards (revised 2004). WHO Technical Report Series 2006. 932, 73-131.

4. Añez G, Heisey DA, Rios M. 2014. Complete coding region sequence of a chikungunya virus strain used for formulation of CBER/FDA RNA reference reagents for nucleic acid testing. Genome Announc. 2(4):e00587-14.

8. ACKNOWLEDGEMENTS

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9. FURTHER INFORMATION

Further information for this material can be obtained as follows: *http://www.pei.de/who-reference-material* or *whoccivd@pei.de*
WHO Biological Reference Preparations:
http://www.who.int/biologicals/reference_preparations/en/

10. CUSTOMER FEEDBACK

Customers are encouraged to provide feedback on the suitability or use of the material provided or other aspects of our service. Please send any comments to: *whoccivd@pei.de*.

Paul-Ehrlich-Institut
Paul-Ehrlich-Str. 51-59
63225 Langen, Germany

Email: whoccivd@pei.de
Web: http://www.pei.de

11. CITATION

In any circumstance where the recipient publishes a reference to PEI materials, it is important that the correct name of the preparation, the PEI code number, the name, and the address of PEI are cited correctly.

12. MATERIAL SAFETY SHEET

Physical properties (at room temperature)
Physical appearance: Lyophilized powder
Fire hazard: None
Chemical properties
Stable: Yes
Hygroscopic: No
Flammable: No
Corrosive: No
Oxidising: No
Irritant: No
Other (specify): Contains inactivated CHIKV
Handling: See caution, section 4
Toxicological properties
Effects of inhalation: Not established - avoid
Effects of ingestion: Not established - avoid
Effects of skin absorption: Not established - avoid
Suggested First Aid
Inhalation: Seek medical advice
Ingestion: Seek medical advice
Contact with eyes: Wash thoroughly with water. Seek medical advice
Contact with skin: Wash thoroughly with water. Seek medical advice
Action on Spillage and Method of Disposal
Spillage of vial contents should be taken up with absorbent material wetted with an appropriate disinfectant. Rinse area with an appropriate disinfectant followed by water. Absorbent materials used to treat spillage should be treated as biological waste.

13. CERTIFICATE OF ANALYSIS

PEI does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognized primary reference materials fully described in the instructions for use.
The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards (3). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS) based on the report of the international collaborative study which established their suitability for the intended use.

14. LIABILITY AND LOSS

Information provided by the Institute is given after the exercise of all reasonable care and skill in its compilation, preparation and issue, but it is provided without liability to the Recipient in its application and use.

It is the responsibility of the Recipient to determine the appropriateness of the materials supplied by the Institute to the Recipient ("the Goods") for the proposed application and ensure that it has the necessary technical skills to determine that they are appropriate. Results obtained from the Goods are likely to be dependent on conditions of use by the Recipient and the variability of materials beyond the control of the Institute.

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The total liability of the Institute in connection with this agreement, whether for negligence or breach of agreement or otherwise, shall in no event exceed 120% of any price paid or payable by the Recipient for the supply of the Goods.
If any of the Goods supplied by the Institute should prove not to meet their specification when stored and used correctly (and provided that the Recipient has returned the Goods to the Institute together with written notification of such alleged defect within seven days of the time when the Recipient discovers or ought to have discovered the defect), the Institute shall either replace the Goods or, at its sole option, refund the handling charge provided that performance of either one of the above options shall constitute an entire discharge of the Institute's liability under this Condition.

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