1st World Health Organization International Reference Reagent for Anti-Ross River Virus Neutralizing Antibodies (IgG)

PEI code 1500/19

(Version 1.1, November 2023)

1. INTENDED USE

The World Health Organization (WHO) International Reference Reagent for anti-Ross River virus (RRV) neutralizing antibodies (IgG) was developed from a pool of five plasma donations from blood donors from Townsville, Australia and evaluated in an international collaborative study. The principal use of the Reference Reagent is for the calibration and harmonization of serological assays for the quantification of anti-RRV neutralizing IgG. The standard can be used as reagent for control for immunoassay performance. Further details of the collaborative study are available in the report (1).

2. UNITAGE

The Reference Reagent has been assigned a unitage of 1,000 units (U)/ml after reconstitution in 0.5 ml sterile, cell culture grade water. The unitage relates to antibody (IgG) neutralization activity for virus neutralization assays.
For other types of immunoassay, the reference reagent may be used as a control reagent (with no assigned unitage) following dilution (dilution to be determined by the user and is assay dependent). The application of the standard is applicable to detection of specific RRV antigenic targets such as envelope proteins, whole virus – it should not be used to compare between groups of assays of different specificity.

3. CONTENTS

Each vial contains the freeze-dried residue of 0.5 ml of human plasma. Each vial contains 500 units of anti-RRV neutralizing antibodies (IgG).

4. CAUTION

THIS PREPARATION IS NOT FOR ADMINISTRATION TO HUMANS.
As with all materials of biological origin, this preparation should be regarded as potentially hazardous to health. The plasma has been for negative for hepatitis B virus, hepatitis C virus as well as human immunodeficiency virus by NAT testing.
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 -20°C. Each vial should be reconstituted in 0.5 ml of sterile nuclease-free water. The product should be reconstituted just prior to use. For virus neutralization assays, the reconstituted material should be heat-inactivated prior to use.

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 -20°C), 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 (1). 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

1. Collaborative study to evaluate a candidate International Reference Reagent for neutralizing antibodies against Ross River virus. WHO Expert Committee on Biological Standardization. WHO/BS/2023.2463

2. 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.

8. ACKNOWLEDGEMENTS

We are grateful to the anonymous donor who provided plasma and to all collaborative study participants.

9. FURTHER INFORMATION

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

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.

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12. **MATERIAL SAFETY SHEET**

Physical properties (at room temperature)		
Physical appearance	Lyophilized powder	
Fire hazard	None	
Chemical properties		
Stable	Yes	Corrosive: No
Hygroscopic	No	Oxidising: No
Flammable	No	Irritant: No
Other (specify)	Material of human origin	
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. 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.

All warranties are excluded to the fullest extent permitted by law, including without limitation that the Goods are free from infectious agents or that the supply of Goods will not infringe any rights of any third party.

The Institute shall not be liable to the Recipient for any economic loss whether direct or indirect, which arise in connection with this agreement.

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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