



**WHO Reference Reagent
WHO IRR for West Nile Virus Lineage-2 (WNV-L2) RNA
Nucleic acid Amplification Techniques
NIBSC code: 18/208
Instructions for use
(Version 2.0, Dated 09/06/2021)**

1. INTENDED USE

The WHO International Reference Reagent for West Nile Virus Lineage-2 (WNV-L2) RNA, NIBSC code 18/208, is intended to be used in the standardization of nucleic acid amplification technology (NAT)-based assays for WNV-L2. The reference comprises a inactivated whole virus preparation of WNV Lineage-2, formulated in negative pooled human plasma. The material has been lyophilized in 1 mL aliquots and stored at -20 °C. The material was evaluated in a worldwide collaborative study involving 19 laboratories performing a range of NAT-based assays for WNV.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The preparation contains material of human origin, and either the final product or the source materials, from which it is derived, have been tested and found negative for HBsAg, anti-HIV and HCV RNA. 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 should include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening ampoules or vials, to avoid cuts.

3. UNITAGE

This material has no assigned unitage.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each vial contains the lyophilized equivalent of 1mL of WNV-L2 in pooled human plasma. The bulk material was inactivated by heat-treatment at 60°C for 1 hour. Inactivation was validated by an absence of plaques on a plaque assay and the absence of CPE after three passages on Vero cells.

5. STORAGE

Vials of lyophilized standard should be stored at -20 °C

Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

Vials have a screw cap; an internal stopper may also be present. The cap should be removed by turning anti-clockwise. Care should be taken to prevent loss of the contents. Please note: If a stopper is present on removal of the cap, the stopper should remain in the vial or be removed with the cap.

7. USE OF MATERIAL

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

The materials should be reconstituted with 1 mL of deionized, nucleasfree molecular-grade water and left for a minimum of 20 minutes with occasional agitation before use. The product should be reconstituted just prior to use, freeze thawing of the product once reconstituted is not recommended.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

Accelerated thermal degradation tests have been carried out at NIBSC and are available in the ECBS report

NIBSC follows the policy of WHO with respect to its reference materials.

9. REFERENCES

ECBS Report 2020 WHO/BS/2020.2397

10. ACKNOWLEDGEMENTS

We thank all the participants that took part in the collaborative study to establish this material as a WHO International Standard

11. FURTHER INFORMATION

Further information can be obtained as follows;

This material: enquiries@nibsc.org

WHO Biological Standards:

<http://www.who.int/biologicals/en/>

JCTLM Higher order reference materials:

<http://www.bipm.org/en/committees/jc/jctlm/>

Derivation of International Units:

http://www.nibsc.org/standardisation/international_standards.aspx

Ordering standards from NIBSC:

<http://www.nibsc.org/products/ordering.aspx>

NIBSC Terms & Conditions:

http://www.nibsc.org/terms_and_conditions.aspx

12. 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 enquiries@nibsc.org

13. CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the preparation's title, its status, the NIBSC code number, and the name and address of NIBSC are cited and cited correctly.

14. MATERIAL SAFETY SHEET

Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

| Physical and Chemical properties | |
|--|---|
| Physical appearance: Lyophilized powder | Corrosive: No |
| Stable: Yes | Oxidising: No |
| Hygroscopic: No | Irritant: No |
| Flammable: No | Handling: See caution, Section 2 |
| Other (specify): | Contains inactivated West Nile Virus Lineage-2 and human plasma |
| Toxicological properties | |
| Effects of inhalation: | Not established, avoid inhalation |
| Effects of ingestion: | Not established, avoid ingestion |
| Effects of skin absorption: | Not established, avoid contact with skin |
| Suggested First Aid | |
| Inhalation: | Seek medical advice |
| Ingestion: | Seek medical advice |



| | |
|--|---|
| Contact with eyes: | Wash with copious amounts of water. Seek medical advice |
| Contact with skin: | Wash thoroughly with water. |
| Action on Spillage and Method of Disposal | |
| Spillage of ampoule 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. | |

15. LIABILITY AND LOSS

In the event that this document is translated into another language, the English language version shall prevail in the event of any inconsistencies between the documents.

Unless expressly stated otherwise by NIBSC, NIBSC's Standard Terms and Conditions for the Supply of Materials (available at http://www.nibsc.org/About_Us/Terms_and_Conditions.aspx or upon request by the Recipient) ("Conditions") apply to the exclusion of all other terms and are hereby incorporated into this document by reference. The Recipient's attention is drawn in particular to the provisions of clause 11 of the Conditions.

16. INFORMATION FOR CUSTOMS USE ONLY

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|---|
| Country of origin for customs purposes*: United Kingdom * Defined as the country where the goods have been produced and/or sufficiently processed to be classed as originating from the country of supply, for example a change of state such as freeze-drying. |
| Net weight: 1 g |
| Toxicity Statement: Non-toxic |
| Veterinary certificate or other statement if applicable. Attached: No |

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised 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 http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biologicalstandardsrev2004.pdf (revised 2004). 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.