Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
First WHO International Standard for Lassa virus RNA
NIBSC code: 21/112
Instructions for use
(Version 1.0, Dated 21/04/2022)

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1. INTENDED USE

The First WHO International Standard for Lassa virus RNA for Nucleic Acid Amplification Technique (NAT)-based assays consists of acid-heat inactivated Lineage IV, Josiah isolate of Lassa virus. The preparation has been evaluated in a WHO International Collaborative study (1). The intended use of the International Standard is for the calibration and harmonisation of NAT-based assays for the detection of Lassa virus RNA.

2. CAUTION

This preparation is not for administration to humans or animals

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

The assigned potency of the WHO International Standard for Lassa virus RNA for NAT-based assays is 4.0 Log10 IU/ampoule. After reconstitution in 0.5mL of molecular grade water or PBS, the final concentration of the preparation is 4.3 Log10 IU/mL.

The International Unit (IU) is arbitrary and is not traceable to a copy number.

4. CONTENTS

Each vial of 21/112 contains 0.5mL of lyophilised, non-infectious, Lineage IV, Josiah isolate of Lassa virus (NCBI reference sequence: HQ688672 (S-segment); JN650518 (L-segment)). The virus has been inactivated by a validated method of treatment with acetic acid, followed by 1 hour incubation at 60oC and the batch verified as inactivated by serial blind passage on permissive cells, with full details provided within the study report (1). The material is formulated in universal buffer comprising 10mM Tris-HCL (pH 7.4), 0.5% human serum albumin and 1% D-(+)-Trehalose dehydrate and contains a background of 1x10^5 copies/mL of human genomic DNA.

5. STORAGE

The International Standard 21/112 should be stored at -20°C or below upon receipt.
Please note because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.

6. DIRECTIONS FOR OPENING

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution
The material should be reconstituted in 0.5mL of molecular grade water or PBS. Following addition, the ampoule should be left at ambient temperature for 20 minutes and then mixed thoroughly, avoiding generation of excess foam. Once reconstituted, 21/112 should be diluted in the matrix appropriate to the material/assay being calibrated.
This product requires extraction.

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.

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

9. REFERENCES

(1) Bentley et al., Collaborative Study for the Establishment of a WHO International Standard for Lassa virus RNA. 2022, WHO Expert Committee on Biological Standardization. WHO/BS/2022.2419

10. ACKNOWLEDGEMENTS

We gratefully acknowledge the contributions of the collaborative study participants, particularly in meeting the tight timeframes of this study. We express our thanks to UKHSA for provision of the inactivated Lassa virus. We also thank NIBSC Standards Production and Development for the freeze drying and distribution of the candidate material. This study has been supported by the Foundation for Innovative New Diagnostics (FIND).

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.

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WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

World Health Organization

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: freeze-dried		Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling: See caution, Section 2	
Other (specify):	Material of human origin		

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

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: 0.5 g
Toxicity Statement: Toxicity not assessed
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_biolefstandardsrev2004.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.