Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO Reference Panel
WHO International Reference Panel for Lassa virus RNA
NIBSC code: 22/108
Instructions for use
(Version 2.0, Dated 21/03/2024)

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1. INTENDED USE

The First WHO International Reference Panel for Lassa virus RNA comprises chimeric lentiviral particles (LVPs) in which the Human Immunodeficiency virus (HIV-1) genes have been substituted with those of the Lassa virus S- and L-segment RNA from Lineages II (21/102), III (21/106), V (21/108) and VII (21/104). The panel was evaluated in a WHO International Collaborative study (1) and subsequently further characterized to ensure stability and performance (2). The intended use of the panel is in the development and assessment of Nucleic Acid Amplification Technique (NAT)-based assays detecting Lassa virus RNA.

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

No unitage has been assigned to the panel members. The individual members were formulated to the same target potency based on quantification of a common lentiviral gene. During the WHO International Collaborative study (1) and subsequent performance evaluation (2), it was demonstrated that LASV-specific NAT assays may have discrepancies in quantification of the S- and L-segment which are dependent on assay specific performance for each of the Lineages.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains 0.5mL of lyophilised synthetic Lassa virus RNA packaged within HIV-1 particles. Single nucleotide mutations have been randomly inserted into the Lassa virus RNA sequences to prevent protein expression. The material is an equimolar mix of chimeric LVPs packaging the S-segment and L-segment of Lassa virus RNA and 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.
The plasmid sequences used in production of the chimeric LVPs are deposited to GenBank:

NIBSC Code	Lineage (strain)	NCBI accession number (S- / L-segment)
21/102	Lineage II (Nig08-A37)	OM302259 / OM302260
21/106	Lineage III (Nig08-A19)	OM302261 / OM302262
21/108	Lineage V (AV)	OM302265 / OM302266
21/104	Lineage VII (Togo/2016/7082)	OM302267 / OM302268

5. STORAGE

The Reference Panel should be stored at -20oC 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, the material 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

(2) ADDENDUM to WHO/BS/2022.2419: Collaborative Study for the Establishment of a WHO International Standard and Reference Panel for Lassa virus RNA. 2024, WHO Expert Committee on Biological Standardization. WHO/BS/2024.2468

10. ACKNOWLEDGEMENTS

We gratefully acknowledge the contributions of the collaborative study participants, particularly in meeting the tight timeframes of this study. 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

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory

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: 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

National Institute for Biological Standards and Control,
Potters Bar, Hertfordshire, EN6 3QG. T +44 (0)1707 641000, nibsc.org
WHO International Laboratory for Biological Standards,
UK Official Medicines Control Laboratory