Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

International Ref. Preparation
1st WHO International Reference Preparation for HIV-1 CRF's
NIBSC code: 13/214
Instructions for use
(Version 1.0, Dated 02/04/2014)

1. INTENDED USE

It has been known for some time that different subtypes of HIV-1 exist. There is the major group known as M consisting of subtypes A –J and more diverse groups of outliers such as group N, P and O. Initially nucleic acid-based tests had a narrow band of specificity targeting the B clade as this was most predominate in Europe and the US. Improvements have since been made in assay design in an attempt to detect a wider range of subtypes. However, it is recognised that recombination events have lead to a wider diversity of HIV-1 subtypes and in recent years viruses containing one or more subtype sequence within the genome have become evident, these viruses have become known as Circulating Recombinant Forms (CRF's).

It is known from collaborative studies conducted using an HIV-1 NAT panel containing many common subtypes that predominately circulate within in Europe, North America and Asia that some assays are still poor at detecting such subtypes, thus giving a low or negative result on samples that are known to be positive. In order to allow manufacturers of assays and laboratories running in house assays to validate the assays ability to detect CRF's, the WHO endorsed the development of the 1st HIV-1 NAT CRF panel

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

Due to the variation seen in different asays abiliy at detecting some of these panel members, no unitage has been assigned. However in order to guage how each panel member behaved in different assays users are directed to the WHO ECBS report as stated in the reference section

4. CONTENTS

Country of origin of biological material: United Kingdom.

The final material was formulated and produced int he UK, diluent plamsa was from a UK source however inactivated viruses contained within the panel orginated from several different countries

5. STORAGE

On reciept the panel should be placed at -20 until use.
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
Each vial should be reconstivuted with 1ml of molecular grade water just prior to use. Vials should be left for a period of 20 minutes with occasional agitation, a visual check should be made to ensure all contents have fully reconsituted prior to extraction.
The material should be assayed neat or at serial dilutions to determine asasy specificity and sensitivity.

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.

This panel should be used immediately following successul reconsotution. The reconstituted material should not be subjected to further storage or freeze thawing.

9. REFERENCES

WHO ECBS report WHO/BS/2013.2226

10. ACKNOWLEDGEMENTS

We would like to acknowledge the collaborative study group that analysed this panel as part of the establishment of this material.

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: Lyophilised	Corrosive: No
Stable: Yes	Oxidising: 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

Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling:	See caution, Section 2
Other (specify):			

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: 1g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable**.** **Attached:** No