



**WHO Reference Reagent  
2nd WHO International Reference Panel Preparation for HIV-1  
Subtypes for NAT (Main)  
NIBSC code: 12/224  
Instructions for use  
(Version 5.0, Dated 22/12/2017)**

### 1. INTENDED USE

HIV-1 exhibits substantial genetic diversity and several different genotypes of HIV-1 exist. There is a major group (group M), consisting of subtypes A-K, and a more diverse collection of outliers have been referred to as groups N and O. Many of the early nucleic acid-based tests (NAT) had a fairly narrow band of specificity targeted mainly at subtype B viruses, as these predominated in the Western World. Greater awareness of the HIV genetic diversity and the desire to detect as many strains of HIV as possible has led to a number of improvements in assay design. However, it has been recognised that some assays are still poor at detecting certain subtypes, occasionally giving low or negative results for samples that are clearly positive in other assays.

in 2000 the WHO agreed that there was a need for a well characterised reference panel of different HIV-1 subtypes for use in regions of the world where non-B subtypes of HIV-1 predominate and by laboratories involved in NAT diagnosis and by kit manufacturers. The 1st International Reference panel for HIV-1 RNA (Code 01/466) was provided for use in qualitative and quantitative HIV-1 RNA assays.

This panel consists of the same viruses at the same concentrations as was used in the 1<sup>st</sup> WHO panel, however the virus has been heat inactivated using prior to spiking into negative human plasma. All preparations have been lyophilised.

The Panel consists of 10 samples representing different HIV-1 subtype - A, B, C, D, AE, F, G, AG-GH, group N and group O.

### 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 any panel member

### 4. CONTENTS

Country of origin of biological material: United Kingdom.  
The final material was formulated and produced in the UK, diluent plasma was from a UK source however inactivated viruses contained within the panel originated from several different countries.

### 5. STORAGE

This panel should be stored at -20°C upon receipt.

**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 panel member should be reconstituted in 1ml of molecular grade water and left for approximately 20 minutes with occasional gentle agitation. ensure the the lyophilised pellet is fully reconstituted prior to use.

The panel is intended to be used in nucleic acid-based techniques and should be treated as a patient sample, i.e is intended to go through the extraction process.

### 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.

Real time stability studies are on going at NIBSC, accelerated degradation studies showed no loss in potency when stored the material was stored at +20C for upto one year.

### 9. REFERENCES

Morris C L, Wigglesworth E, Heath AB.

Report on an International Collaborative Study to Establish the 2nd WHO International Subtype Reference panel for HIV-1 NAT Assays WHO ECBS report 2012 WHO/BS/ 2012.2209

### 10. ACKNOWLEDGEMENTS

### 11. FURTHER INFORMATION

Further information can be obtained as follows;

This material: [enquiries@nibsc.org](mailto: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](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](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](mailto: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

<b>Physical and Chemical properties</b>	
Physical appearance: Lyophilised	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	
<b>Toxicological properties</b>	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin
<b>Suggested First Aid</b>	
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.
<b>Action on Spillage and Method of Disposal</b>	
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](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

<b>Country of origin for customs purposes*:</b> 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.
<b>Net weight:</b> 1g
<b>Toxicity Statement:</b> Toxicity not assessed
<b>Veterinary certificate or other statement</b> if applicable. <b>Attached:</b> 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\\_bi\\_olefstandardsrev2004.pdf](http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_bi_olefstandardsrev2004.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.