



**WHO International Standard
HIV (antibody), 1st International Reference Panel
NIBSC code: 02/210
Instructions for use
(Version 5.0, Dated 11/12/2012)**

1. INTENDED USE

The 1st International Reference Panel for Anti-HIV (NIBSC code 02/210), contains representative plasma samples of anti-HIV from individuals infected with HIV of different genetic subtypes and groups. This panel was established as the 1st International Reference Panel for Anti-HIV by the Expert Committee on Biological Standardisation of the World Health Organisation in October 2006.

The 1st International Reference Panel for Anti-HIV may be used with a range of EIA, agglutination, Western blot and rapid assays. This panel can be used to compare the sensitivity and specificity of a range of assays able to detect antibodies to HIV.

2. CAUTION

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

These preparations contain dilutions of solvent-detergent treated human plasma samples known to contain antibodies to HIV and a normal human serum diluent. The plasma samples have been tested and found negative for HBsAg, anti-HCV 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 this panel.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Each vial contains the residue after freeze-drying of 0.5ml of a solution containing:

- Solvent-detergent treated human plasma containing antibodies to HIV
- Normal human serum
- 0.05% Bronidox as a preservative

The International Reference Panel contains 1:40 dilutions of HIV-positive plasma samples corresponding to:

- anti-HIV-1 subtype A (Group M)
- anti-HIV-1 subtype B (Group M)
- anti-HIV-1 subtype C (Group M)
- anti-HIV-1 subtype E (now referred to as CRF01_AE) (Group M)
- anti-HIV-1 Group O
- anti-HIV-2
- diluent control

Normal human serum (donated by BBI Inc, USA and shown to be anti-HIV, anti-HCV, HBsAg and HCV RNA negative) was used as diluent. The HIV-positive plasma samples were virally inactivated using a well established and validated solvent-detergent (1% TNBP/1% Triton X-100) method (Horowitz B. et al, 1992, Blood 79: 826-831) before freeze-drying. Furthermore, Bronidox preservative was added to the final mixture prior to freeze-drying (final concentration 0.05%v/v).

5. STORAGE

Unopened vials should be stored at -20°C. Reference materials are held at NIBSC within assured, temperature-controlled storage facilities.

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 'flip-up' circular cap. Either on the cap or the collar of the vial, there is an indication of the point at which to lever off the cap. This exposes an area of the stopper through which reconstitution and withdrawal of the preparation can be made using a hypodermic needle and syringe. If use of a pipette is preferred, then fully remove the metal collar using, for example, forceps, taking care to avoid cuts by wearing appropriate gloves. Remove the stopper for access. Care should be taken to prevent loss of the contents.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the material

To reconstitute the material, tap the vial gently to ensure the freeze-dried pellet is at the bottom of the vial. Carefully remove the tear-off metal crimp seal and rubber stopper and reconstitute the pellet using 0.5ml sterile distilled water. Ensure the contents are fully dissolved before use. The material should be used immediately after reconstitution. If it is necessary to store the material, this should be at +2-8°C. DO NOT FREEZE.

8. STABILITY

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities and they should be stored on receipt as indicated on the label. It is the policy of WHO not to assign an expiry date to their international reference materials. Accelerated degradation studies have indicated that this material is suitably stable, when stored at -20°C or below until the material is withdrawn or replaced. These studies have also shown that the material is suitably stable for shipment at ambient temperature without loss of performance.

Data generated at NIBSC indicate that the reconstituted material will remain active for up to 3 months following reconstitution when stored at +2-8°C.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

ECBS Report Reference: WHO/BS/06.2032.

Wigglesworth et al, Journal of Virological Methods, 163 (2010) 101-108

10. ACKNOWLEDGEMENTS

Not applicable.

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.

In all publications (or data sheets for kits) in which this preparation is used as an assay calibrant, it is important that the title of the preparation, vial code 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 pellet | Corrosive: No |
| Stable: Yes | Oxidising: No |
| Hygroscopic: No | Irritant: Yes (contains Bronidox) |
| Flammable: No | Handling: See caution, Section 2 |
| Other (specify): Contains solvent-detergent treated human plasma with antibodies to HIV. | |
| 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 vial 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: 0.5g per vial. 3.5g per panel. |
| 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_biol_efstandardsrev2004.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.