Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO International Standard
Anti-HPA-1a standard (100 IU)
NIBSC code: 03/152
Instructions for use
(Version 4.0, Dated 21/12/2007)

1. INTENDED USE

This preparation, when reconstituted should be used in quantitative assays to construct a standard curve for the determination of anti-HPA-1a activity in unknown samples. It should not be used for any other purpose.

2. CAUTION

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

This preparation contains material of human origin. Each individual donation from which the Standard was prepared was tested and found negative for HBsAg, anti-HIV 1 and 2 and anti-HCV. 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

Following an international collaborative study, and with the agreement of the participants, this preparation has been assigned an arbitrary unitage of 100 international units (IU) per ampoule.

4. CONTENTS

Country of origin of biological material: United Kingdom.
Each ampoule contains the residue after freeze-drying of 1 mL pooled human plasma. The plasma was collected from six donors immunised against HPA-1a. The immunoglobulin class of the anti-HPA-1a antibodies is IgG. Antibodies against other HPA antigens or HLA Class I antigens have not been detected in this preparation

5. STORAGE

Unopened ampoules should be stored at -20°C.
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.
Reconstitute the contents of one ampoule with 1.0 ml distilled water using gentle mixing. The ampoules do not contain bacteriostat and the preparation should not be assumed to be sterile.
Prepare replicate serial doubling dilutions of both the reconstituted anti-HPA-1a standard and the test samples in PBS, 0.1% v/w BSA (pH 7.5) from neat to 1:1024, then test all samples in a quantitative assay for anti-HPA-1a.
Construct a standard curve using the mean value (e.g. optical density or fluorescence value) for each dilution, identify the linear portion of the curves and use this to calculate the activity in arbitrary units of the test sample compared to the standard (100 IU).

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 NIBSC and WHO not to assign expiry dates to reference materials. Accelerated degradation studies have indicated that this standard is suitably stable, when stored at -20°C or below, for the assigned values to remain valid until the standard is withdrawn or replaced. These studies have also shown that the standard is suitably stable for shipment at ambient temperature without any effect on the assigned values.

9. REFERENCES

The following publication describes the International Collaborative Study which was carried out in order to characterise the reagent; *D Allen, P Rigsby, H Bessos, J Berry, D Wilson, W Ouwehand, S Urbaniak, & P Metcalfe: Collaborative study to establish the first International Standard for quantitation of anti-HPA-1a. Vox Sanguinis 2005,* ***89****, 100-104.*

10. ACKNOWLEDGEMENTS

N/A

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:	Pale yellow freeze-dried powder	Corrosive:	No
Stable:	Yes	Oxidising:	No
Hygroscopic:	Yes	Irritant:	No
Flammable:	No	Handling: Section 2	See caution,
Other (specify):	Contains 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: 0.08g
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_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.