Medicines & Healthcare products Regulatory Agency

NIBSC Confidence in Biological Medicines

WHO Reference Reagent
Anti-HPA-5b (Minimum Potency)
NIBSC code: 99/666
Instructions for use
(Version 5.0, Dated 21/12/2007)

1. INTENDED USE

This preparation, when reconstituted and diluted as described below, should be used as a reference reagent for minimum acceptable potency for the detection of antibodies against Human Platelet Antigen-5b (HPA-5b). It should not be used for HPA-5b typing or 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 reagent was prepared was tested and found negative for HBsAg, anti-HIV 1 and 2, anti-HCV and HCV RNA by PCR. However, as with all preparations of human origin, this preparation cannot be assumed to be free of all infectious agents. Suitable precautions should be taken in the use and disposal of the ampoule and its contents.

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 units are assigned to this material.

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 two donors immunised against HPA-5b. The immunoglobulin class of the anti-HPA-5b 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. 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.
Dilute the reconstituted material immediately before use by adding 1 volume of reconstituted material to 1 volume of phosphate buffered saline containing 1% (w/v) bovine serum albumin. Diluted material should then be tested for the presence of IgG anti-HPA-5b antibodies using HPA-5a5b platelets. This dilution (1 in 2) is the minimum dilution expected to be detectable in HPA antibody assays (e.g. MAIPA, PIFT and ELISA assays). However, many laboratories can detect the anti-HPA-5b at higher dilutions, as shown in the following histogram which is taken from the publication indicated in Section 9.

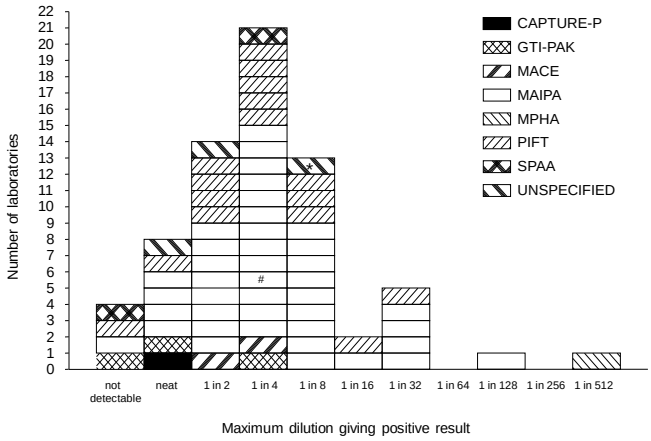

Figure 1. Data from collaborative study: titration of anti-HPA-5b in individual laboratories, boxes indicate maximum dilution giving a positive result. # dilution reported as <1 in 5. * dilution reported as 1 in 10.

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 -20ºC or below, for the assigned values to remain valid until the material is withdrawn or replaced. These studies have also shown that the material is suitably stable for shipment at ambient temperature without any effect on the assigned values.
Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

9. REFERENCES

The following publication describes the International Collaborative Study which was carried out in order to characterise the reagent; *P Metcalfe, WH Ouwehand, D Sands & TW Barrowcliffe. Collaborative studies to establish the first WHO reference reagent for detection of human antibody against HPA-5b. Vox Sanguinis 2003,* ***84****, 237-240.*

10. ACKNOWLEDGEMENTS

The plasma used to make this material was supplied by National Blood Service, Cambridge and International Blood Group Reference Laboratory, Bristol.

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

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

World Health Organization

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: Pale yellow freeze-dried powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
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: Toxicity not assessed
Veterinary certificate or other statement if applicable**.**

Attached: No

17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Refe because they are internationally recognised primary reference materials fully instructions for use. The reference materials are established according Recommendations for the preparation, characterization and establishment of i other biological reference http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biolefstand (revised 2004). They are officially endorsed by the WHO Expert Committe Standardization (ECBS) based on the report of the international collaborati established their suitability for the intended use.

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

World Health Organization