



**WHO Reference Reagent  
Anti-HPA-1a (minimum potency)  
NIBSC code: 05/106  
Instructions for use  
(Version 2.0, Dated 01/11/2010)**

**1. INTENDED USE**

This 2nd WHO Reference Reagent replaces the first Reference Reagent for anti-HPA-1a minimum potency, coded 93/710. When reconstituted and diluted as described below, it should be used as a reference reagent for minimum acceptable potency for the detection of antibodies against Human Platelet Antigen-1a (HPA-1a). It should not be used for HPA-1a 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. 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-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.

Tap the ampoule gently to collect the material at the bottom (labeled) end. Ensure that the disposable ampoule safety breaker provided is pushed down on the stem of the ampoule and against the shoulder of the ampoule body. Hold the body of the ampoule in one hand and the disposable ampoule breaker covering the ampoule stem between the thumb and first finger of the other hand. Apply a bending force to open the ampoule at the coloured stress point, primarily using the hand holding the plastic collar.

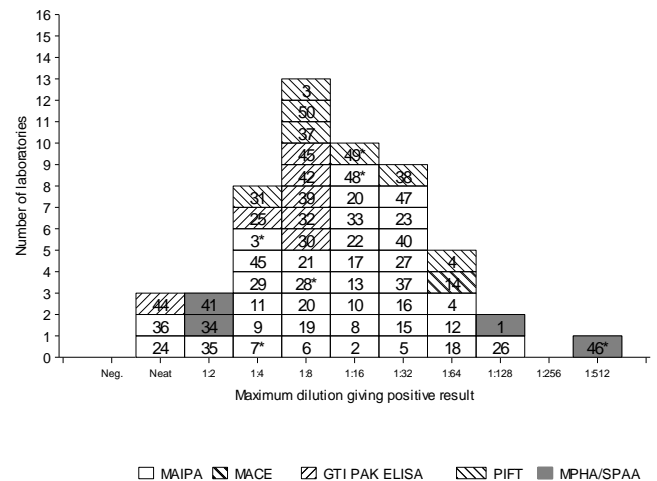
Care should be taken to avoid cuts and projectile glass fragments that might enter the eyes, for example, by the use of suitable gloves and an eye shield. Take care that no material is lost from the ampoule and no glass falls into the ampoule. Within the ampoule is dry nitrogen gas at slightly less than atmospheric pressure. A new disposable ampoule breaker is provided with each DIN ampoule.

**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.

Dilute the reconstituted material immediately before use by adding 1 volume of reconstituted material to 1 volume of phosphate buffered saline containing 0.2% (w/v) bovine serum albumin. Diluted material should then be tested for the presence of IgG anti-HPA-1a antibodies using HPA-1a1a platelets. This dilution (1 in 2) is the minimum dilution expected to be detectable in HPA antibody assays. However, many laboratories can detect the anti-HPA-1a at higher dilutions, as shown in the following histogram which is taken from the WHO collaborative study report.



**Figure 1.** Data from collaborative study: titration of anti-HPA-1a in individual laboratories. Numbers in boxes indicate lab code number only.

**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, 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**

Metcalfe P. et al, An International Reference Reagent (minimum sensitivity) for the detection of anti-HPA-1a. Vox Sanguinis, 96, 146-152.

**10. ACKNOWLEDGEMENTS**

The plasma used to make this material was supplied by National Blood Service, Cambridge.

**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

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 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> 0.08g
<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\\_biol\\_standardsrev2004.pdf](http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biol_standardsrev2004.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.