

**Non WHO Reference Material  
High titre anti-A in IVIG  
NIBSC code: 14/160  
Instructions for use  
(Version 1.0, Dated 06/07/2015)**

**This material is not for in vitro diagnostic use.**

### 1. INTENDED USE

The passive transfer of anti-A and/or anti-B in IVIG can cause adverse reactions in recipients, including haemolysis. Therefore, there are regulatory requirements in place to control levels of these haemagglutinins. Common WHO-Ph. Eur.-FDA reference preparations are available to improve international harmonisation of the testing of IVIG products, and define the pharmacopoeial limit where this applies. Preparation 14/160 is an IVIG preparation with high titre haemolytic anti-A. Testing by 4 laboratories has shown that the anti-A titre of 14/160 is above that of the Limit Preparation 07/310, which defines the Ph. Eur. and FDA limits (titre of 64 from 5% IVIG for both anti-A and anti-B). Preparation 14/160 was found to have an anti-A titre of 128-256 and an anti-B titre of 32-64 (from 5% IVIG) at NIBSC. It is intended for use in haemolysis assays and as an out-of-specification control for anti-A in haemagglutination titrations.

### 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

N/A

### 4. CONTENTS

Country of origin of biological material: United Kingdom.

### 5. STORAGE

Store unopened ampoules at -20°C or below.

**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 ampoule contents with 1.0 mL distilled or de-ionised water. The reconstituted contents are 10% (w/v) IVIG.

### 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.

NIBSC follows the policy of WHO with respect to its reference materials.

### 9. REFERENCES

N/A

### 10. ACKNOWLEDGEMENTS

N/A

### 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: Lyophilisate	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: Unknown
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains clinical grade human immunoglobulin
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
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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.
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#### 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
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* 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.
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<b>Net weight:</b> 0.08g
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<b>Toxicity Statement:</b> Toxicity not assessed
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<b>Veterinary certificate or other statement</b> if applicable.
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<b>Attached:</b> No
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