

WHO International Standard
Anti-c Incomplete Blood Typing Serum, Human
NIBSC code: W1007
Instructions for use
(Version 2.0, Dated 04/04/2008)

#### 1. INTENDED USE

This material was previously distributed by Sanquin Diagnostic Services, the Netherlands. With effect from 1st February 2007, the National Institute for Biological Standards and Control (NIBSC), Potters Bar, UK, is the custodian and distributor of this material.

#### RELEVANT INFORMATION

For details of this International Standard, please refer to the enclosed package insert from Sanquin

The preparation is labelled 1st International Standard, Anti-c incomplete blood typing serum, human.

#### 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

64 IU/ampoule.

## 4. CONTENTS

Country of origin of biological material: United Kingdom.

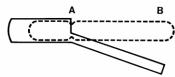
## 5. STORAGE

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

Tap the ampoule gently to collect the material at the bottom (labelled) end. Ensure ampoule is scored all round at the narrow part of the neck, with a diamond or tungsten carbide tipped glass knife file or other suitable implement before attempting to open. Place the ampoule in the ampoule opener, positioning the score at position 'A'; shown in the diagram below. Surround the ampoule with cloth or layers of tissue paper. Grip the ampoule and holder in the hand and squeeze at point 'B'. The ampoule will snap open. Take care to avoid cuts and projectile glass fragments that enter eyes. Take care that no material is lost from the ampoule and that no glass falls into the ampoule.



Side view of ampoule opening device containing an ampoule positioned ready to open. 'A' is the score mark and 'B' the point of applied pressure.

#### 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 0.5ml distilled/deionised water.

#### 8. STABILITY

It is the policy of WHO not to assign an expiry date to their international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label. For information specific to a particular biological standard, contact the Technical Information Officer or, where known, the appropriate NIBSC scientist.

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

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

## 9. REFERENCES

N/A

## 10. ACKNOWLEDGEMENTS

10. 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.

## 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:		Corrosive:	No
Lyophilisate			
Stable:	Yes	Oxidising:	No
Hygroscopic:	No	Irritant:	No
Flammable:	No	Handling: See	e caution, Section 2
Other (specify):	Contains material of human origin		



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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	Seek medical advice		
Ingestion: Seek	Seek medical advice		
Contact with eyes: Wash with copious amounts of water. Seek medical advice			
Contact with skin: Wash	h 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

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: 0.039g

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 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.





leaflet





designated by WHO as international laboratory for biological standards





central laboratory of the netherlands red cross bloodtransfusion service

World Health Organization
1st Standard Preparation

Anti-c incomplete blood-typing serum, human

Each ampoule contains 64 IU.

Form in which available:
- ampoules containing 39.0 mg of freeze-dried
human anti-c blood-typing serum diluted in
AB serum.

From: "BIOLOGICAL SUBSTANCES, International Standards and Reference Reagents", WHO, Geneva, 1986, page 50.

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