



**Working Standard**  
**Immunoglobulins G, A & M, Human Serum**  
**NIBSC code: 67/099**  
**Instructions for use**  
**(Version 6.0, Dated 30/01/2013)**

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

### 1. INTENDED USE

The preparation code-labelled 67/086 was established in 1969 as MRC Research Standard A\* for Human Serum Immunoglobulins G, A, and M (Rowe et al, 1969 and 1970). Since the supply of preparation 67/086 is limited, another preparation 67/099, derived from the same source pool of serum, but freeze-dried separately, is being issued from NIBSC for general use as a British Working Standard for Human Serum Immunoglobulins G, A and M.

\* MRC Research Standard A, 67/086 for Human Serum Immunoglobulins G, A and M was previously named 'The British Research Standard' and is referred to as such in Bull. Wld. Hlth. Org. (1979) 42, 535-552.

### 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

The weight of freeze dried powder in 67/099 was estimated in 15 ampoules. The mean weight per ampoule was 83.03mg +/- 1.5%. The amount of moisture present was estimated in 12 ampoules, the mean being 0.34% (range 0.12% to 0.48%). The oxygen content of the atmosphere in 3 sealed ampoules of the Standard was determined by mass spectroscopy. A mean content of 14.69% was found.

On this basis, it is estimated that each ampoule of 67/099 will contain on average 102 units of each immunoglobulin G, A and M.

### 4. CONTENTS

Country of origin of biological material: United Kingdom.  
Contains pooled human serum.

### 5. STORAGE

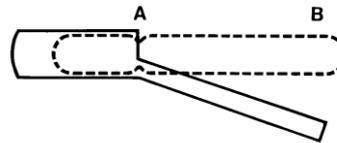
It is recommended that the unopened ampoules be stored at 0°C or below. The stability data relating to MRC Research Standard A, 67/086, cannot be taken to apply to the British Working Standard, 67/099.

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 with de-ionised or distilled water to required volume.

### 8. STABILITY

NIBSC follows the policy of WHO with respect to its reference materials. It is the policy of WHO not to assign an expiry date to its 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 NIBSC.

In addition, once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

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

### 9. REFERENCES

Rowe, D.S., Anderson, S.G and Fahey J.L (1969) A Reference Preparation for Human Serum Immunoglobulins, Immunol. 16. 2. 1969.

Rowe, D.S., Grab, B. and Andersen, S.G (1970) A Research Standard for Human Serum Immunoglobulins G, A and M. Bull. Wld. Hlth. Org. 42, 535.

Rowe, D.S., Grab, B. and Andersen, S.G (1972) An International Reference Preparation for Human Serum Immunoglobulins G, A and M. Content of Immunoglobulins by Weight. Bull. Wld. Hlth. Org. 46, 67.

### 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: 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