



**Non WHO Reference Material**  
**Rheumatoid Arthritis Serum, 2nd British Standard**  
**NIBSC code: 64/003**  
**Instructions for use**  
**(Version 2.0, Dated 15/06/2023)**

This material is not for in vitro diagnostic use

### 1. INTENDED USE

The 2<sup>nd</sup> British Standard (product code 64/003) is intended for use in the calibration of serological assays used in diagnosis of Rheumatoid Arthritis. The proposed standard was characterised in a large International Collaborative Study and was shown to have comparable behaviour and potency to the Rheumatoid Serum: 1<sup>st</sup> WHO International Standard (code: W1066) and 1<sup>st</sup> British Standard (code: 64/002), both of which were derived from the same serum pool as 64/003. [1]

The ampouled material has been tested and found negative for HBsAg and anti-HIV. New, highly sensitive techniques have now shown this preparation to be positive for HCV RNA by PCR.

### 2. CAUTION

**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 and anti-HIV, and positive for HCV RNA.**

**This preparation is not for administration to humans or animals.**

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

100 International Units per ampoule

The preparation, 64/003, was evaluated by 36 laboratories in 13 countries and was assayed in agglutination and ELISA immunoassays against the 1<sup>st</sup> IS Rheumatoid Arthritis Serum (W1066). The preparation was immunologically similar to the 1<sup>st</sup> IS in the majority of assays and demonstrated adequate stability in accelerated degradation studies.

### 4. CONTENTS

Country of origin of biological material: United Kingdom.  
This Standard is produced from freeze-dried sera from patients with Rheumatoid Arthritis.

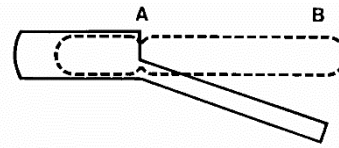
### 5. STORAGE

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**

The contents of each ampoule may be reconstituted by the addition of 1ml of either distilled water or buffered saline, mix gently until fully reconstituted. This solution will contain 100 IU per ml.

### 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.

Accelerated degradation studies have indicated that this material is suitably stable, when stored at -20°C. Once reconstituted, diluted or aliquoted, users should determine the stability of the material according to their own method of preparation, storage and use.

### 9. REFERENCES

1. Anderson, S.G., et al., International reference preparation of rheumatoid arthritis serum. Bull World Health Organ, 1970. 42(2): p. 311-8.

### 10. ACKNOWLEDGEMENTS

We thank the participants of the collaborative study.

### 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

**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:<br>Freeze dried powder   | Corrosive: No   |
| Stable: Yes   | Oxidising: No   |
| Hygroscopic: No   | Irritant: No  |
| Flammable: No   | Handling: See caution, Section 2                          |
| Other (specify):  | Contains material of human origin<br>Positive for HCV RNA |
| 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](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**

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|---|
| <b>Country of origin for customs purposes*:</b> United Kingdom<br>* 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> 0.02g  |
| <b>Toxicity Statement:</b> Non-toxic  |
| <b>Veterinary certificate or other statement</b> if applicable.   |
| <b>Attached:</b> No   |