



**WHO Reference Reagent
Anti-Nuclear Ribonucleoprotein Serum
NIBSC code: W1063
Instructions for use
(Version 2.0, Dated 10/04/2008)**

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.

The package insert from Sanquin is attached.

RELEVANT INFORMATION

For details of this International Standard, please refer to the attached package insert from Sanquin
The preparation is labelled Anti-nuclear ribonucleoprotein (NRNP) autoantibody.

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: Not known.

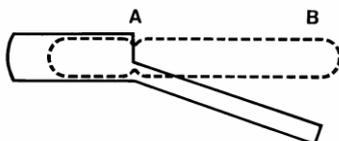
5. STORAGE

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.

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

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.

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

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	Oxidising:	No
Stable: Yes	Irritant:	No
Hygroscopic: No	Handling:	See caution, Section 2
Flammable: No		
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 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: 0.08g
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_biol_efstandardsrev2004.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.



W 1063

W.H.O.
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WHO INTERNATIONAL REFERENCE HUMAN SERUM

for

ANTI-NUCLEAR RIBONUCLEOPROTEIN (nRNP) AUTOANTIBODY

Description and Recommendations for use

INTERNATIONAL UNION OF IMMUNOLOGICAL SOCIETIES
UNION INTERNATIONALE DES ASSOCIATIONS D'IMMUNOLOGIE
STANDARDISATION COMMITTEE





This material has been produced under the joint WHO/IUIS
Programme for the Standardisation of Immunological Reagents.

Reference: WHO/BS/83.1390

Related intermediary sera and FITC labelled conjugates are
as follows:

ANA IgM (HL)
Anti-nuclear ribonucleoprotein (nRNP)
FITC conjugated anti human Ig
FITC conjugated anti human IgG (anti- γ chain)
FITC conjugated anti human IgM (anti- μ chain)

All the above are available from:

International Laboratory for Biological Standards,
Central Laboratory of The Netherlands Red Cross Blood
Transfusion Service,
Plesmanlaan 125,
1066 CX Amsterdam

ANA 66/233

Available from:

The Director, WHO International Laboratory for
Biological Standards,
Statens Seruminstitut,
80 Artager Boulevard,
DK 2300,
Copenhagen S,
Denmark

or from The Director
National Institute for Biological Standards and Control
Holly Hill,
Hampstead,
London, NW3 3RB, England