



**WHO International Standard  
The 1st International Reference Preparation for ANTI-  
NEWCASTLE DISEASE SERUM  
NIBSC code: NDS  
Instructions for use  
(Version 4.0, Dated 26/04/2013)**

**1. INTENDED USE**

This material has been prepared and characterised by the Veterinary Laboratories Agency, Weybridge, Surrey, UK. With effect from 1st June 1998, the National Institute for Biological Standards and Control (NIBSC), Potters Bar, UK is the custodian and distributor of this material. The package insert from VLA is attached.

**RELEVANT FACTORS**

For details of this International Reference Preparation, please refer to the enclosed package insert from the Veterinary Laboratories Agency. The Distribution statement in the package insert is no longer valid.

**2. CAUTION**

**This preparation is not for administration to humans or animals in the human food chain.**

The material is not of human or bovine origin. 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**

Each ampoule contains 320 International Units

**4. CONTENTS**

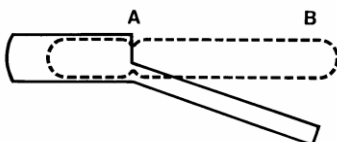
Country of origin of biological material: United Kingdom.  
Each ampoule contains 1ml of a 1 in 10000 dilution of chicken serum containing antibodies to Newcastle Disease Virus

**5. STORAGE**

Vials should be stored at -20°C on receipt.  
**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

Please refer to the package insert from VLA

**8. STABILITY**

Reference materials are held at NIBSC within assured, temperature-controlled storage facilities and they should be stored on receipt as indicated on the label. 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.

**9. REFERENCES**

**10. ACKNOWLEDGEMENTS**

**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: Freeze dried	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains chicken serum



<b>Toxicological properties</b>	
Effects of inhalation:	Not established, avoid inhalation
Effects of ingestion:	Not established, avoid ingestion
Effects of skin absorption:	Not established, avoid contact with skin
<b>Suggested First Aid</b>	
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.
<b>Action on Spillage and Method of Disposal</b>	
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

<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> 1.0g
<b>Toxicity Statement:</b> Non-toxic
<b>Veterinary certificate or other statement</b> if applicable. <b>Attached:</b> 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\\_biologicalstandardsrev2004.pdf](http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biologicalstandardsrev2004.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.



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**INTERNATIONAL REFERENCE PREPARATION OF  
ANTI-NEWCASTLE-DISEASE SERUM (NDS)**

**Description**

The International Reference Preparation of Anti-Newcastle-Disease Serum was established in 1966. It is intended for standardizing the haemagglutination-inhibition test for Newcastle disease.

The International Reference Preparation was prepared from a high-titre serum obtained from vaccinated chickens which had been challenged with the Herts 33 strain of Newcastle disease virus. This serum was diluted to a suitable concentration of 1/10,000. The serum was then dispensed in 1ml amounts into glass ampoules and freeze-dried. The ampoules were sealed in an atmosphere of dry nitrogen at approximately atmospheric pressure. The average weight of dry material per ampoule has been determined as 0.0555g with a standard deviation of  $\pm 2.35\%$ .

**International Unit**

The International Unit is defined as the activity contained in 0.1734mg of the International Reference Preparation. Each ampoule contains 320 International Units.

**Distribution**

The International Reference Preparation is distributed by the International Laboratory for Biological Standards, Ministry of Agriculture, Fisheries and Food, New Haw, Addlestone, Surrey, England on behalf of the World Health Organization. It is available free of charge in limited amounts. If a laboratory needs more than 1 sample every 6 months, it is expected to prepare its own reference preparation and to calibrate it against the International Reference Preparation. A quantity of the latter sufficient for this purpose will be supplied on request.

**Reconstitution of the International Reference Preparation**

The Preparation should be reconstituted immediately before it is to be used.

Ampoules may be opened by scoring with a small saw specifically designed for the purpose, or a hard mineral edge, for approximately one third of the circumference. Application of a piece of red hot glass rod to this scratch will give a clean line of fracture.

If the scoring is made firmly and the glass rod is hot enough, it is possible to produce a fine crack without disturbing the ampoule top until needed. Then slight pressure will complete the separation.

The freeze-dried material in each ampoule may be reconstituted in any convenient volume of a suitable diluent, which will not alter the final pH.

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Fisheries and Food*



Care should be taken to ensure that the entire contents of the ampoule are completely resuspended. This can be achieved by suspending the bulk of the contents of the ampoule in some of the fluid, and using the remainder of the diluent to rinse out the ampoule three times.

A low dilution of the reference preparation, e.g., 1/10, may be stored at about 4°C for up to six months without detectable loss of potency.

#### **National and Laboratory Reference Preparations**

National and laboratory reference preparations should be prepared in a stable form. This may be achieved by freeze-drying aliquots of the reference preparation in neutral-glass ampoules and sealing them in an oxygen-free atmosphere by fusion of the glass. The ampoules should be stored in the dark at a low temperature, e.g. -20°C.

The potency of such a reference preparation relative to that of the International Reference Preparation should be determined by performing a series of comparative haemagglutination-inhibition tests.

After determining the titres of the two sera approximately, the tests should be repeated using dilutions closely spread around the expected end-point e.g., if the end-point is 1/160, dilutions of 1/80, 1/120, 1/160, 1/240 and 1/320 may be used. The dilutions should cover the range from complete inhibition to no inhibition.

The relative potencies of the two sera should be estimated by the usual statistical methods. The number of International Units per ampoule of the proposed reference preparations can thus be calculated. This calculation should be based on a series of at least three tests.

It is suggested that the potency of a national or laboratory reference preparation should be checked against that of a fresh sample of the International Reference Preparation about once a year.

The International Laboratory for Biological Standards at Weybridge is willing to advise and assist laboratories in providing their own reference preparations.

#### **Routine Serological Tests**

Reference preparations can be used to standardize haemagglutination inhibition tests in the following ways:

- (a) Standardization of antigens. Since the reference preparation has already been tested against the local antigen, the titre which the preparation gives under the local test condition is already known. Successive batches of antigen are first standardized approximately according to their haemagglutinating capacity but each is finally checked by titration against the reference preparation. The concentration of the antigen is then adjusted, if necessary, so that the titre of the reference preparation is maintained at the pre-determined level.

This level varies, of course, according to the amount of antigen used and the other conditions of the test. Most laboratories use from 4 - 10 HA units of antigen and find that this is equivalent to 2 - 8 International Units of serum.

- (b) Control of routine tests. To check that the test conditions have remained constant, the reference preparation is titrated along with every batch of tests.
- (c) Expression of results. Since the variables in the test system, such as antigen and red cell concentration, affect the reference preparation and the sera under test equally, the expression of the results in International Units is independent of the particular test system used. Results obtained in different laboratories can thus be compared in a meaningful way.