



**WHO International Standard**  
**Alphafoetoprotein, Human, 100,000 IU**  
**NIBSC code: AFP**  
**Instructions for use**  
**(Version 6.0, Dated 11/12/2012)**

## 1. INTENDED USE

This material was prepared from a pool of several hundred cord sera characterised by the Statens Serum Institut (SSI), Copenhagen, Denmark and it was established as the First WHO IS for AFP in 1975 (1). With effect from 1st July 1997, the National Institute for Biological Standards and Control (NIBSC), Potters Bar, UK became the custodian and distributor of this material.

## 2. CAUTION

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

This preparation contains material of human origin. The ampouled material has been tested and found negative for HBsAg and anti-HIV. It gave a positive PCR test for HCV RNA. The preparation should be regarded as potentially hazardous to health. The container and its contents should be used and discarded according to your own laboratory procedures. Such procedures probably will include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening the container to avoid cuts

## 3. UNITAGE

Each ampoule of this preparation contains 100,000 International Units by definition (1,2,3).

Uncertainty: the International unit of AFP is assigned without uncertainty. The uncertainty of the ampoule content of AFP may be considered to be the coefficient of variation, which was determined to be  $\pm 0.42\%$ .

## 4. CONTENTS

Country of origin of biological material: Denmark

The pool was distributed into ampoules in volumes of 2ml and freeze-dried. The ampoules were originally coded 72/225 and contain approx 70 mg of protein each.

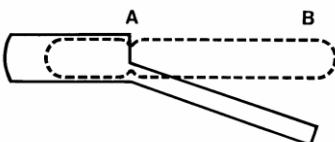
## 5. STORAGE

Unopened ampoules should be stored, in the dark, at  $-20^{\circ}\text{C}$

**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. COLLABORATIVE STUDY

The standard preparation has been investigated in two collaborative studies (3,4) using several assay methods, such as radioimmunoassay, single radial immunodiffusion and immunoelectrophoresis. Six laboratories estimated that one IU approximately equals 1.21 (1.02 – 1.43) nanograms of AFP (3).

## 8. STABILITY

The total contents of an ampoule should be reconstituted in a suitable volume of the solvent to be used in the test. If 10ml of solvent is used, the resulting solution will have a concentration of 10,000 IU/ml. If not used shortly after reconstitution, the solution should be kept in a frozen state.

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 standards@nibsc.ac.uk.

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.

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

- WHO Technical Report Series No.594, 1976, 14
- Sizaret P, Anderson S G, The International Reference Preparation for alphafoetoprotein. J of Biol. Stand., 4, 149, 1976
- Sizaret P et al, Equivalence between international units and mass units of alphafoetoprotein. Report of a collaborative study. Clinica Chimica Acta, 96, 59-65, 1979
- Sizaret P, Breslow N, Anderson S G, and 12 other participants, Collaborative study of a preparation of human cord serum for its use as a reference in the assay of alphafoetoprotein, J Biol. Stand 3, 201-223, 1975

## 10. 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](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)



## 11. 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)

## 12. 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.

## 13. 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 powder	Corrosive:	No		
Stable: Yes	Oxidising:	No		
Hygroscopic: Yes	Irritant:	No		
Flammable: No	Handling:	See caution, Section 2		
Other (specify):	Contains dried material of human origin. <b>It gave a positive PCR test for HCV RNA</b>			
Toxicological properties				
Effects of inhalation:	Not established. Avoid ingestion			
Effects of ingestion:	Not established. Avoid ingestion			
Effects of skin absorption:	Not established. Avoid ingestion			
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.				

## 14. 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.

## 15. INFORMATION FOR CUSTOMS USE ONLY

**Country of origin for customs purposes\***: Denmark

\* 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:** 70mg

**Toxicity Statement:** Non-toxic

**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](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.