



**WHO International Standard  
Follicle Stimulating Hormone (FSH), Human, Recombinant, For  
Immunoassay  
NIBSC code: 92/510  
Instructions for use  
(Version 3.0, Dated 23/01/2008)**

### 1. INTENDED USE

This consists of a batch of ampoules (coded 92/510) containing highly purified human recombinant follicle stimulating hormone obtained from Chinese hamster ovary cells. It was established as the First International Standard for Follicle Stimulating Hormone, human recombinant, for immunoassay by the Expert Committee on Biological Standardization of the World Health Organisation at its forty eighth meeting in 1997 (1). It is intended for use in calibration of preparations of FSH by immunoassay.

### 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

This preparation has been assigned a unitage of 60 International Units per ampoule.

### 4. CONTENTS

Country of origin of biological material: United Kingdom.

Each ampoule contains the residue, after freeze drying, of 1ml of a solution which contained:

rDNA-derived human FSH approx	10 µg
Human plasma albumin	2mg
Mannitol	10mg
Sodium chloride	15.4mM

### 5. STORAGE

Unopened ampoules should be stored at -20°C

**Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.**

### 6. DIRECTIONS FOR OPENING

DIN ampoules have an 'easy-open' coloured stress point, where the narrow ampoule stem joins the wider ampoule body. Various types of ampoule breaker are available commercially. To open the ampoule, tap the ampoule gently to collect material at the bottom (labelled) end and follow manufactures instructions provided with the ampoule breaker.

### 7. USE OF MATERIAL

For practical purposes each ampoule contains the same amount of the same materials. Dissolve all the contents in a known amount of buffer solution. No attempt should be made to weigh portions of the freeze dried powder.

The material has not been sterilised and contains no bacteriostat.

### 8. COLLABORATIVE STUDY

This preparation was evaluated by International Collaborative study involving 27 laboratories in 12 countries. It was compared with the second IRP for FSH and LH (in ampoules coded 78/549) in a variety of immunoassay systems and with other current and candidate International Standards in a range of in vivo and in vitro bioassay systems. The assigned unitage was derived from the geometric mean of all laboratory means from immunoassays only. It should be noted that there exists a discontinuity of unitage between the activity obtained by immunoassay and that obtained by in vivo bioassay and this preparation with its assigned unitage should be considered as a standard for the calibration of immunoassays only. This material was subsequently evaluated independently by UK NEQAS with this assigned value.

The results of the above studies indicated that the preparation in ampoules coded 92/510 was adequately stable and suitable to act as an International Standard for the calibration of immunoassays. The assigned unitage does not represent a formal calibration of 92/510 in terms of 78/549 but does maintain an approximate continuity of unitage which is hoped to be acceptable to users of earlier preparations.

This preparation was therefore established as the First International Standard for Follicle Stimulating Hormone, human for immunoassays with an assigned unitage of 60 IU per ampoule by the Expert Committee on Biological Standardization of WHO at its meeting in 1997.

### 9. 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.

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.

### 10. REFERENCES

1. WHO Tech Rep Series No.889,1999.

### 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](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: White lyophilised powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
Other (specify): Contains material of human origin. Can react with oxidising materials. Avoid contact with acids and alkalis.	
Toxicological properties	
Effects of inhalation: No adverse effects reported for this material.	
Effects of ingestion: No adverse effects reported for this material.	
Effects of skin absorption: No adverse effects reported for this material.	
Suggested First Aid	
Inhalation: Remove from exposure	
Ingestion: Wash mouth thoroughly with water	
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

<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> 13mg
<b>Toxicity Statement:</b> Non-toxic
<b>Veterinary certificate or other statement</b> 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.