



**Non WHO Reference Material
Thyroid Stimulating Hormone, beta subunit
NIBSC code: 85/522
Instructions for use
(Version 5.0, Dated 23/09/2010)**

This material is not for in vitro diagnostic use.

1. INTENDED USE

The preparation consists of a batch of ampoules (coded 85/522) containing purified β -Subunit of human TSH.

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 probably will 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

Nominal ampoule content is 2.5 μ g per ampoule.

4. CONTENTS

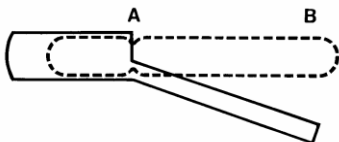
Country of origin of biological material: United Kingdom.
Each ampoule contains the freeze-dried residue of 1ml of a solution containing TSH β -Subunit in 0.05 M sodium phosphate, 0.5% trehalose, pH7.4.

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

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

For all practical purposes each ampoule contains the same amount of the same materials. Dissolve the total contents in a known amount of suitable buffer solution with carrier protein (free of peptidase), where extensive dilution is required, to minimize loss of surface adsorption.

No attempt should be made to weigh out portions of the freeze-dried powder.

For economy of use, it is recommended that the solution be subdivided into several small containers, which are frozen rapidly to below -70°C and then stored below -30°C in the dark.

Repeated freezing and thawing should be avoided.

The material has not been sterilized and contains no bacteriostat.

Suitable precautions should be taken in the use and disposal of the ampoule and its contents.

8. PREPARATION OF AMPOULES

The batch of ampoules coded 85/522 was prepared according to the procedures used for international biological standards (WHO, 1978). A weighed portion of the TSH β -Subunit, without further drying, was dissolved in a sterile solution containing 0.05M sodium phosphate, 0.5% trehalose, pH7.4. This solution was passed through a membrane filter (mean pore diameter 0.4 μ m) and distributed in 1.0ml aliquots into ampoules. The ampouled solution was lyophilized and after secondary desiccation, the ampoules containing pure dry nitrogen were sealed by heat fusion of the glass and have since been stored at -20°C in the dark.

9. STABILITY

In the absence of stability data, users should assume the reference preparation to exhibit the potency as described at establishment.

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

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.

Users who have data supporting any deterioration in the characteristics of any reference preparation are encouraged to contact NIBSC.

10. REFERENCES

WHO Expert Committee on Biological Standardization, 29th Report.
WHO Technical Report Series No. 626, (1978).

11. ACKNOWLEDGEMENTS

Acknowledgements are made to Dr A. F Parlow, who kindly donated the bulk TSH β -Subunit preparation.

12. 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



13. 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

14. 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.

15. 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: Solid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: No
Flammable: No	Handling: See caution, Section 2
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 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.	

16. 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.

17. 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: 6mg
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. Attached: No