



**Non WHO Reference Material
Parathyroid Hormone, Human-Type, Synthetic (1-34) fragment
NIBSC code: 82/508
Instructions for use
(Version 4.0, Dated 05/12/2007)**

This material is not for in vitro diagnostic use.

1. INTENDED USE

Note that there is now an International Standard for human PTH 1-34, 04/200, (see Catalogue).
The reagent consists of a batch of ampoules (coded 82/508).

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 of the reagent contains 355 UNITS.

NOTE

Ampoules were included in an international collaborative study on the proposed replacement international standard for bovine parathyroid hormone. The study also included ampouled bovine 1-34 PTH fragment.

Estimates of biological potency relative to intact bovine PTH varied with different assay systems and a single potency value, relative to International Units of bPTH, cannot be assumed.

In the intravenous dose, one hour chick hypercalcaemia bioassay, ampoules of 82/508 assayed at 355 units (95% confidence limits 325-388) relative to a previous house standard for synthetic h1-34 PTH, ampoule code 75/596 originally assigned a value of 500 'units', and which was also included in the collaborative study.

The bulk preparation, lot T036-205, RHCG 3989 was assumed to contain approx 80% peptide, by weight. Analysis by HPLC at NIBSC showed that the bulk material was not homogenous

4. CONTENTS

Country of origin of biological material: United Kingdom.

Important note

Based on calculations using data supplied with the bulk material and the volume of the solution in which it was diluted for filling, each ampoule was originally assigned a mass content of approx 34µg. However, subsequent analyses by HPLC, conducted both in-house and external to NIBSC have demonstrated that each ampoule contains the residue after freeze-drying of 1 ml of a solution which contained:

h1-34 PTH	approx 8 µg
Mannitol	approx 2mg

The assigned unitage of 355 UNITS remains the same.

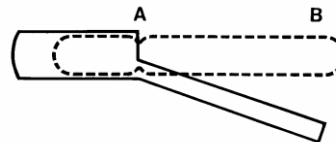
5. STORAGE

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 of reagent contains the same quantity of the substances listed above. Dissolve the total contents of the ampoule in a known volume of a suitable solvent (distilled water, saline or buffer) with carrier protein where extensive dilution is required. No attempt should be made to weigh out any portion of the freeze-dried material.

For economy of use, it may be possible that the solution be sub-divided into several small containers and stored at -40°C or below for approx. 3 months. Conditions of storage should be monitored carefully to ensure that activity is retained.

The ampoules do not contain bacteriostat and solution of the reagent should not be assumed to be sterile.

8. PREPARATION OF AMPOULES

Ampoules were prepared according to the procedures recommended for international biological standards (Annex 4, 29th Report of the Expert Committee on Biological Standardisation of the World Health Organisation), 1978).

9. STABILITY

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.

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. ACKNOWLEDGEMENTS

Approximately 100mg of a synthetic preparation of human 1-34 fragment of parathyroid hormone (1-34 PTH), Lot T036-205, RHCG 3989, synthesised at Revlon Health Care, Tuckahoe, NY, USA, was donated to NIBSC through the good offices of Dr J.P. Dailey, Revlon Health Care Group.

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: Powder	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: No	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.	

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: 2mg
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable.
Attached: No