

Non WHO Reference Material RENIN, Porcine NIBSC code: 65/119 Instructions for use (Version 5.0, Dated 02/05/2013)

This material is not for in vitro diagnostic use.

#### 1. INTENDED USE

Calibrant for renin assays

## 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

The assigned potency is 5.0 units per ampoule.

#### 4. CONTENTS

Country of origin of biological material: United Kingdom.

Each ampoule contains the residue after freeze drying of 1.0ml of a solution that contained:

1mg Extract of porcine kidneys

5mg Sucrose 10 mol/l Phosphate

The material has not been sterilized and contains no bacteriostat.

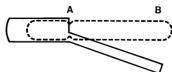
## 5. STORAGE

Store at -20°C or below in the dark

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.

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 minimise loss by surface adsorption.

For economy of use it is recommended that the solution be subdivided into several small containers, which are frozen rapidly to below  $-40^{\circ}$ C and then stored below  $-40^{\circ}$ C in the dark. Repeated freezing and thawing should be avoided.

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

#### 9. REFERENCES

Not Applicable

## 10. ACKNOWLEDGEMENTS

The Renin Standardization Committee of the High Blood Pressure Council and Drs. Haas, Lamfrom and Goldblatt for fractionation and donation of the material.

Dr H Goldblatt, Cleveland, USA and Professor WS Peart, London, for assays.

# 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

National Institute for Biological Standards and Control,

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UK Official Medicines Control Laboratory





Classification in accordance with Directive 2000/54/EC, Regulation (EC) No 1272/2008: Not applicable or not classified

| (EC) No 1272/2008: Not applicable or not classified  |                     |                                      |                      |
|--|---------------------|--------------------------------------|----------------------|
| Physical and Chemical properties   |                     |                                      |                      |
| Physical appearance:   |                     | Corrosive:                           | No                   |
| Freeze-dried powder  |                     |                                      |                      |
| Stable: Yes  |                     | Oxidising:                           | No                   |
| Hygroscopic: Yes   |                     | Irritant:                            | No                   |
| Flammable: No  |                     | Handling:Se                          | e 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 r   | 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 contents should be taken up with absorbent material wetted with an appropriate virucidal agent. Rinse area with an appropriate virucidal agent 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: 6mg

Toxicity Statement: Toxicity not assessed

Veterinary certificate or other statement if applicable.

Attached: No

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