Non WHO Reference Material
1st British Reference Preparation for Prekallikrein Activator (PKA)
NIBSC code: 79/572
Instructions for use
(Version 5.0, Dated 23/05/2012)

This material is not for in vitro diagnostic use.

1. INTENDED USE
The 1st British Reference Preparation for Prekallikrein Activator (PKA) was established in 1982. It consists of ampoules each containing (approximately) 5ml plasma protein fraction (PPF). This preparation is intended to be used as a standard in assays to measure PKA activity in solutions of albumin or immunoglobulins.

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. UNTAGE
Each ampoule contains 78.9 units/ml PKA (approximately 400 units in total).

4. CONTENTS
Country of origin of biological material: United Kingdom.

The starting material consisted of a single batch of plasma protein fraction and approximately 2000 ampoules were filled with 5ml aliquots.

5. STORAGE
The preparation should be kept frozen and maintained at -20 ºC or lower until required.

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.

7. USE OF MATERIAL
It is recommended that the contents of an ampoule be divided into aliquots of a volume suitable for the needs of the individual laboratory. These aliquots should be stored at -20°C until required.

8. STABILITY
Reference materials are held at NIBSC within assured, temperature-controlled storage facilities. Reference Materials should be stored on receipt as indicated on the label.

NIBSC follows the policy of WHO with respect to its reference materials. The PKA activity of samples of the 1st British Reference Preparation for Prekallikrein Activator (PKA) which had been stored for five months at 4°C, 20°C, and 37°C were compared with samples of the same material which had been stored at -20°C. From the Arrhenius equation relating degradation rate to absolute temperature, the predicted loss of activity at -20°C is 0.001% per year (upper 95% limit: 0.003% per year). At -20°C the predicted loss is 0.154% in one week and at 37°C this rises to 3.381% per week.

9. REFERENCES
1. Memorandum from Director, Bureau of Biologics, Food and Drug Administration, Bethesda, MD 20205, USA, dated 4th May 1981
2. Biometrics, 1977, 33, 736

10. ACKNOWLEDGEMENTS
Protein Fractionation Centre, Scottish National Blood Transfusion Service, Edinburgh, Scotland, for supply of the material; the participants in the collaborative study for calibrating the 1st British Reference Preparation.

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:
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.
### Physical and Chemical properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Description</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physical appearance: Frozen Liquid</td>
<td>Corrosive:</td>
<td>No</td>
</tr>
<tr>
<td>Stable:</td>
<td>Oxidising:</td>
<td>No</td>
</tr>
<tr>
<td>Hygroscopic:</td>
<td>IRRITANT:</td>
<td>Unknown</td>
</tr>
<tr>
<td>Flammable:</td>
<td>Handling:</td>
<td>See caution, Section 2</td>
</tr>
<tr>
<td>Other (specify):</td>
<td></td>
<td>Contains material of human origin</td>
</tr>
</tbody>
</table>

### 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](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**: 5 g
- **Toxicity Statement**: Toxicity not assessed
- **Veterinary certificate or other statement if applicable**: Attached: No