

Non WHO Reference Material
Rec. Single Chain Urinary-Type Plasminogen Activator (SCuPA),
(Non-Glyc.)
NIBSC code: 95/564
Instructions for use
(Version 4.0, Dated 02/04/2008)

This material is not for in vitro diagnostic use.

1. INTENDED USE

This is comprised of a batch of ampoules coded 95/564. Each ampoule contains the residue after freeze drying of an accurately measured 1ml of SCuPA (non-Glyc.) solution which is made up of 50 micrograms of SCuPA in 0.01M phosphate buffer pH7.4, containing 5mgs of pig collagen fraction per ml as stabiliser (Gaffney et al 1996).

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

11,300 IU*/ampoule (by clot lysis assay, Heath & Gaffney, 1990)
8,050 IU*/ampoule (by chromogenic assay)

* This unit has been defined by the standard for high molecular weight (HMW) urinary-type plasminogen activator (u-PA) (Gaffney & Heath, 1990).

4. CONTENTS

Country of origin of biological material: United Kingdom.
The bulk material was supplied by Grunenthal (Germany) through the good offices of Dr W. Gunzler as a frozen liquid. This was diluted to 50 micrograms/ml with 0.01M phosphate buffer, pH7.4, containing 5mgs per ml of a pig collagen fraction (PCF) otherwise known as Prionex (Pentapharm, Basel, Switzerland). This latter stabiliser allowed the reagent to be used as a standard in electrophoretic gels since only the SCuPA was visualised on staining.

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 manufacturers instructions provided with the ampoule breaker.

7. USE OF MATERIAL

No attempt should be made to weigh out any portion of the freeze-dried material prior to reconstitution

The total contents of the ampoule should be reconstituted with 1.0ml distilled water and dissolved gently by swirling to avoid froth. No attempt should be made to weigh out any portion of the freeze dried material. The

reconstituted reagent should be used as soon as possible after reconstitution

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. Following ampouling at +4°C by the procedures outlined by Campbell (1974) the stability was established by indicating no loss in activity at 4°C for 1 year.

9. REFERENCES

Campbell, P.J (1974) J. Biol. Stand. 2: 259-267

Gaffney P.J, Edgell T.A, Dawson P.J, Ford A.W, Stocker, K. J (1996) Pharm. Pharmacol. 48, 896-898

Gaffney, P.J, Heath, A.B. (1990) Thromb. Haemost. 64, 398-401

10. ACKNOWLEDGEMENTS

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: Freeze dried 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	
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*: <i>United Kingdom</i> <i>* 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.</i>
Net weight: <i>10 mg</i>
Toxicity Statement: <i>Toxicity not assessed</i>
Veterinary certificate or other statement if applicable. <i>Attached: No</i>