



**Non WHO Reference Material
Blood Coagulation Factor Xa
NIBSC code: 75/595
Instructions for use
(Version 4.0, Dated 01/04/2008)**

This material is not for in vitro diagnostic use.

1. INTENDED USE

The following is a summary of information supplied by Dr C M Jackson.

2. CAUTION

This preparation is not for administration to humans or animals in the human food chain.

The material is of bovine origin. The material is certified to be obtained from animals taken from a closed herd in the female line since 1980, in which no animal has been clinically suspected of having BSE & which has not been fed rations containing ruminant derived protein during that period. 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 vial of Blood Coagulation Factor Xa, Bovine, 75/595 contains 1.0 unit.

The biological activity of this preparation in various assays systems has not yet been extensively studied. It is claimed that the material gives a linear relationship between clotting time and log concentration in the dilution range 1:2 to 1:100, and gives parallel lines against a preparation of human factor Xa.

4. CONTENTS

Country of origin of biological material: United Kingdom.

Bulk Material: Purified activated bovine factor X (Xa), was prepared at the Washington University School of Medicine, St Louis, Missouri, USA by Dr C M Jackson. The procedure involved barium citrate absorption, QAE Sephadex chromatography, activation of the isolated enzyme of Russell's viper venom and further chromatography on QAE Sephadex. The resulting material gave one major band with a single trace-contaminant on polyacrylamide gel electrophoresis at pH 9.5.

The bovine factor Xa was diluted with 1% pure bovine serum albumin in 0.02 M tris buffer, pH 7.5. The filling-solution was distributed into approximately 2,000 glass vials, freeze-dried and sealed with rubber caps by Dr Jackson at St. Louis.

5. STORAGE

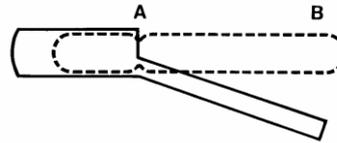
The recommended storage temperature is -20°C or below. At this temperature the percentage loss of activity was found to be less than 0.02% of the original. For use, dissolve the total contents of the vial in 1.0ml distilled water, transfer to a plastic container and use as soon as possible. No attempt should be made to weigh out any portion of the freeze dried material. The diluent recommended for use is 1% pure bovine serum albumin in 0.02 M tris buffer, adjusted to 7.5 with maleic acid.

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

The total contents of the ampoule should be reconstituted at room temperature with 1.0 mL distilled water, dissolved by gentle swirling and transferred immediately to a plastic tube. No attempt should be made to weigh out any portion of the freeze-dried material. The reconstituted standard should be used as soon as possible and should be kept at 4°C during assays.

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.

9. REFERENCES

Kirkwood, T.B.L. Predicting the stability of biological standards and products. *Biometrics* 1977, 33, 736.

10. ACKNOWLEDGEMENTS

Dr C M Jackson, Washington University school of Medicine, St Louis, Missouri, USA

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 white solid	Corrosive: No
Stable: Yes	Oxidising: No
Hygroscopic: Yes	Irritant: Unknown
Flammable: No	Handling: See caution, Section 2
Other (specify):	Contains material of bovine 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: ~50 mg
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable.
Attached: No