



**WHO International Standard  
3rd INTERNATIONAL STANDARD FOR FACTOR IX,  
CONCENTRATE, HUMAN  
NIBSC code: 96/854  
Instructions for use  
(Version 3.0, Dated 01/04/2008)**

#### 1. INTENDED USE

The 3<sup>rd</sup> International Standard for Factor IX, Concentrate, consists of vials coded 96/854, containing aliquots of a high purity single factor IX concentrate, prepared from human plasma. This preparation was established as the 3<sup>rd</sup> International Standard for Factor IX, Concentrate by the Expert Committee on Biological Standardisation of the World Health Organisation in 1996, with a potency of 10.7 IU/vial

#### 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

The standard was calibrated in an international collaborative study involving 38 laboratories in 17 countries, against the 2nd IS for FII, IX, X, Concentrate, 84/683 and the 1st IS for FII, IX, X, Concentrate, 84/681 (indirectly via house standards). The agreed mean potency is 10.7 IU/vial for the 3rd IS FIX, Concentrate, 96/854.

#### 4. CONTENTS

Country of origin of biological material: United Kingdom.  
The 3<sup>rd</sup> International Standard for FIX, Concentrate (approximately 3,500 vials) was donated to the WHO through the good offices of the US FDA. It was part of a large batch of material prepared by a manufacturer was the FDA/EP working standard for FIX concentrate. It is a single Factor IX Concentrate prepared using monoclonal antibody chromatography. Several batches of bulk material were pooled and filled at 15-25°C followed by lyophilisation in rubber-stoppered vials.

#### 5. STORAGE

It is recommended that the unopened vials should be stored at -20°C or below until immediately before use.

**Please note: because of the inherent stability of lyophilized material, NIBSC may ship these materials at ambient temperature.**

#### 6. DIRECTIONS FOR OPENING

Care should be taken to prevent loss of the contents.  
Vials have a 'flip-up' circular cap. Either on the cap or the collar of the vial there is an indication of the point at which to lever off the cap. This exposes an area of the stopper through which reconstitution and withdrawal of the preparation can be made using a hypodermic needle and syringe. If use of a pipette is preferred, then fully remove the metal collar using, for example, forceps, taking care to avoid cuts by wearing appropriate gloves. Remove the stopper for access.

#### 7. USE OF MATERIAL

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

Dissolve the total contents of each vial of the standard with 1.0ml distilled water, using gentle shaking. Do not attempt to weigh out any portion of the freeze-dried material. Transfer the solution to a plastic tube and keep on ice receipt as indicated on the label. Accelerated degradation studies have shown that the standard is stable when stored in unopened vials at -20°C or below, with a predicted loss of 0.026% per month. However, when stored at +20°C, the predicted loss is increased to 0.9% per month.

#### 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. Accelerated degradation studies have shown that the standard is stable when stored in unopened vials at -20°C or below, with a predicted loss of 0.026% per month. However, when stored at +20°C, the predicted loss is increased to 0.9% per month.

NIBSC follows the policy of WHO with respect to its reference materials.

#### 9. REFERENCES

#### 10. ACKNOWLEDGEMENTS

Are made to all the participants in the collaborative study.

#### 11. FURTHER INFORMATION

Further information can be obtained as follows;  
This material: [enquiries@nibsc.org](mailto: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](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](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](mailto: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.

based on the report of the international collaborative study which established their suitability for the intended use.

#### 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: Solid	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 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

<b>Country of origin for customs purposes*:</b> 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.
<b>Net weight:</b> 0.09 g
<b>Toxicity Statement:</b> Toxicity not assessed
<b>Veterinary certificate or other statement</b> if applicable. <b>Attached:</b> No

#### 17. CERTIFICATE OF ANALYSIS

NIBSC does not provide a Certificate of Analysis for WHO Biological Reference Materials because they are internationally recognised primary reference materials fully described in the instructions for use. The reference materials are established according to the WHO Recommendations for the preparation, characterization and establishment of international and other biological reference standards [http://www.who.int/bloodproducts/publications/TRS932Annex2\\_Inter\\_biologicalstandardsrev2004.pdf](http://www.who.int/bloodproducts/publications/TRS932Annex2_Inter_biologicalstandardsrev2004.pdf) (revised 2004). They are officially endorsed by the WHO Expert Committee on Biological Standardization (ECBS)