



Working Standard
7th British Working Standard
for Blood Coagulation Factors II, IX, X Concentrate
NIBSC code: 15/182
Instructions for use
(Version 1.0, Dated 17/10/2017)

This material is not for in vitro diagnostic use.

1. INTENDED USE

The 7th British Working Standard for Blood Coagulation Factors II, IX, X, Concentrate, was established by the National Institute for Biological Standards and Control in October 2017. This batch of standard, consisting of ampoules (coded 15/182) containing aliquots of freeze-dried blood coagulation factors II, IX, X, concentrate, is intended for the calibration of coagulation factors II and X, Concentrate, 11/126. The assigned potencies after reconstitution with 0.5 ml of distilled water are:

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 for coagulation factors II, IX, X in a collaborative study involving 7 expert laboratories. Potencies were assigned against the 5th International Standard for Blood Coagulation Factor IX, Concentrate, 14/148 and the 4th International Standard for Blood Coagulation Factors II and X, Concentrate, 11/126. The assigned potencies after reconstitution with 0.5 ml of distilled water are:

FI: 6.0 IU/ml; *GCV = 3.4%
FIX: 6.7 IU/ml; GCV = 3.2%
FX: 4.9 IU/ml; GCV = 2.3%

*GCV = Geometric Coefficient of Variation

4. CONTENTS

Country of origin of biological material: Italy.
The standard, 15/182, was prepared at the National Institute for Biological Standards and Control in October 2015. The liquid bulk in 50mM Tris, 150mM NaCl, 2 mg/ml Trehalose, 5mg/ml human albumin, pH 7.4 buffer, was kept between 2 - 8°C throughout the distribution into approximately 11,000 ampoules. The mean liquid fill weight was 0.5191g, with a coefficient of variation of 0.25%

5. STORAGE

Unopened ampoules should be stored in the dark at -20°C or below. 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 manufactures 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

Allow the ampoule to equilibrate at room temperature for 10 minutes. Reconstitute the total content with **0.5 ml distilled water** using gentle agitation. Transfer the content to a plastic tube. Assays should be carried out as soon as possible upon reconstitution. It is not recommended to freeze-thaw aliquots after reconstitution for subsequent use.

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. It is the policy of WHO not to assign expiry dates to international reference materials. They remain valid with the assigned potency and status until withdrawn or amended.

Accelerated degradation studies, using ampoules stored at elevated temperatures relative to ampoules stored at -70°C, have shown that the 7th British Working Standard is stable in unopened ampoules stored at -20°C. The accelerated degradation study and real time monitoring will continue for the lifetime of this standard.

9. REFERENCES

Not applicable.

10. ACKNOWLEDGEMENTS

We are grateful to the participants of the collaborative study, Kedrion S.p.A, Bolognana, Italy for the generous donation of the candidate material.

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: White freeze-dried powder	Corrosive: No



Stable:	Yes	Oxidising:	No
Hygroscopic:	Yes	Irritant:	Unknown
Flammable:	No	Handling:	See caution, Section 2
Other (specify):	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*: 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: 0.015g
Toxicity Statement: Toxicity not assessed
Veterinary certificate or other statement if applicable.
Attached: No