



**Non WHO Reference Material
SSC/ISTH Secondary Coagulation Standard Lot #5
NIBSC code: SSCLOT5
Instructions for use
(Version 3.0, Dated 03/08/2020)**

This material is not for in vitro diagnostic use.

1. INTENDED USE

The SSC/ISTH Secondary Coagulation Standard Lot #5 was produced under the auspices of the Scientific and Standardisation Committee (SSC) of the International Society on Thrombosis and Haemostasis (ISTH) through the Coagulation Standards Standing Committee. The standard was endorsed by the SSC/ISTH in 2019. The standard is held and distributed by the National Institute for Biological Standards and Control. The preparation consists of screw-capped, rubber-sealed glass vials each containing 1 ml aliquots of pooled normal human plasma, freeze-dried. The standard is calibrated for multiple analytes and is available to manufacturers of coagulation diagnostic reagents and calibrants.

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 following values have been assigned:

Analyte	Value (IU/vial)	Inter-lab variability (GCV%)	n
Factor II	0.95	4.2 %	16
Factor V:			
-clotting	0.87	3.7%	34
-antigen	0.98	1.6%	5
Factor VII:C	1.00	2.7%	17
Factor VIII:C	0.82	5.5%	33
Factor IX	1.09	7.5%	26
Factor X	0.97	4.3%	18
Factor XI	0.87	5.8%	20
Factor XII:C	0.96	5.6%	17
Factor XIII:			
-antigen	0.73	6.2%	9
-function	0.77	6.6%	14
von Willebrand Factor:			
-antigen	1.14	8.7%	18
-ristocetin cofactor	0.82	11.4%	13
-GPIbR	0.95 units/vial	7.0%	14
-GPIbM	0.80 units/vial	7.6%	17
-collagen binding	1.02	9.9%	17
-propeptide	1.03	4.9%	12
Protein C:			
-antigen	0.89	6.4%	11
-function	0.97	4.5%	31
Protein S:			
-total antigen	0.96	5.9%	10
-free antigen	0.98	4.2%	16
-function	0.78	8.7%	18
Antithrombin:			
-antigen	0.94	5.3%	13
-function	0.95	4.1%	26

Fibrinogen 3.19 mg/vial 4.5% 18
GCV - Geometric coefficient of variation; n - number of laboratories in the calibration exercise

Calibration for multiple analytes was performed by assay relative to WHO International Standards in multi-centre international collaborative studies involving manufacturers and clinical laboratories.

4. CONTENTS

Country of origin of biological material: Austria.
The plasma pool from 62 normal donors (166 donations) was distributed into approximately 100,000 glass vials, each containing 1ml, with a coefficient of variation of 0.22% based on volume (calculated by weight and density). The residual moisture after freeze-drying was 0.55%.

5. STORAGE

Store unopened vials between -20 °C to -70 °C. Warm the unopened vials to room temperature before opening.

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.
The vials have a screw cap and an internal rubber stopper. The cap should be removed by turning anti-clockwise.

7. USE OF MATERIAL

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

Warm the unopened vials to room temperature before opening. Reconstitute by adding 1.0 ml of distilled water. Allow the vial to stand for 10 minutes at room temperature and aid reconstitution by gentle swirling. After reconstitution transfer the contents to a plastic tube. Use the standard as soon as possible after reconstitution. The use of frozen aliquots of the standard is not recommended.

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. The standard should not be used after the expiry date of 31st December 2029.

9. REFERENCES

No references

10. ACKNOWLEDGEMENTS

Calibration of the SSC/ISTH Secondary Coagulation Standard would not be possible without the considerable efforts of the participants in the calibration exercises - these laboratories are gratefully acknowledged. The support of the Scientific and Standardisation Committee of ISTH and also the Executive Board of the Coagulation Standards Standing Committee is also highly appreciated.

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): None	
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 viricidal agent. Rinse area with a viricidal agent 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*: Austria * 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: 0.090 g
Toxicity Statement: Non-toxic
Veterinary certificate or other statement if applicable. Attached: No