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Assuring the quality of biological medicines

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SSC/ISTH SECONDARY COAGULATION STANDARD LOT#3

(Version 1 date 12 July 2006)

1 THE STANDARD

The SSC/ISTH Secondary Coagulation Standard Lot #3 has been produced under the auspices of the SSC/ISTH Working Group on Coagulation Standards. 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. Calibration was performed by assay relative to WHO International Standards in multi-centre international collaborative studies involving both manufacturers and clinical laboratories. Details of the values assigned to the SSC/ISTH Secondary Coagulation Standard Lot #3 are given in Table 1.

Table 1 Summary of assigned values

Analyte	Value (IU/vial)	Inter-lab variability (GCV%)	No. of estimates
Factor II	0.86	6.3 %	13
Factor V:C	0.87	3.6 %	23
Factor VII:C	0.87	6.8 %	11
Factor VIII:C	0.80	4.7 %	17
Factor IX	0.94	4.6 %	15
Factor X	0.86	4.1 %	13
Factor XI	0.88	3.1 %	26
Factor XIII	0.71	8.6 %	23
von Willebrand Factor:			
Antigen	1.06	5.7 %	11
Ristocetin Cofactor	0.86	4.9 %	7
Collagen Binding	1.07	11.2 %	9
Protein C			
Antigen	0.89	2.2 %	9
Function	0.89	4.2 %	25
Protein S			
Total antigen	0.85	8.1 %	10
Free antigen	0.88	4.5 %	9
Function	0.78	4.9 %	7
Antithrombin			
Antigen	0.95	2.4 %	5
Function	0.93	2.8 %	12
Fibrinogen	2.58 mg/ml	5.0 %	11

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2 CAUTION

THIS PREPARATION IS NOT FOR ADMINISTRATION TO HUMANS.

This standard has been prepared from normal human blood plasma. Each plasma donation has been tested and found negative for HBsAg, antibodies to HCV and antibodies to HIV-1 and -2. 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 probably will 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 STORAGE, RECONSTITUTION AND OPENING THE VIALS

Store unopened vials between -20 ^{o}C to -70 ^{o}C. Warm the unopened vials to room temperature before opening. Vials have a screw cap and stopper. The cap should be removed by turning anti-clockwise, please note on removal of the cap, the stopper may remain in the vial or be removed with the cap. Care should be taken on removal of cap to prevent the contents escaping. 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. Do not attempt to weigh out any portion of the freeze-dried material. Use the standard as soon as possible after reconstitution. The use of frozen aliquots of the standard is not recommended.

4 BULK MATERIAL AND DISTRIBUTION INTO VIALS

The SSC/ISTH Secondary Coagulation Standard Lot #3 was prepared from normal plasma donations collected by plasmapheresis using 4% (w/v) tri-sodium citrate anticoagulant. Donors were tested and found negative for HBsAg, anti-HCV and anti-HIV -1 and -2. In addition, no viral nucleic acid sequences were found in the pool for HBV, HCV and HIV. The pool was distributed into approximately 58,000 glass vials in November 2003. The accuracy of vial filling was monitored by 45 check-weight vials (15 at the beginning, middle and end of the fill). The mean filling weights and inter-vial variability (CV %) were as follows: beginning (1.108 g; CV 0.263 %), middle (1.100 g; CV 0.122 %) and end (1.100 g; CV 0.143 %). Freeze-drying was performed over 26 hours and the mean residual moisture was 0.101%.

5 PRODUCT LIABILITY

Information emanating from NIBSC is given after the exercise of all reasonable care and skill in its compilation, preparation and issue, but is provided without liability in its application and use. This product is intended for use as a laboratory standard or reference material. It is the responsibility of the user to ensure that he/she has the necessary technical skills to determine the appropriateness of this product for the proposed application. Results obtained from this product are likely to be dependent on conditions of use and the variability of materials beyond the control of NIBSC.

NIBSC accepts no liability whatsoever for any loss or damage arising from the use of this product, whether loss of profits, or indirect or consequential loss or otherwise, including, but not limited to, personal injury other than as caused by the negligence of NIBSC. In particular, NIBSC accepts no liability whatsoever for:-

(i) results obtained from this product; and/or
(ii) non-delivery of goods or for damages in transit.

In the event of any replacement of goods following loss or damage a customer accepts as a condition of receipt of a replacement product, acceptance of the fact that the replacement is not to be construed as an admission of liability on NIBSC's behalf.

6 CITATION

In all publications, including data sheets, in which this material is referenced, it is important that the title of the preparation and the name and address of NIBSC and SSC/ISTH are cited and cited correctly.

7 CUSTOMER FEEDBACK

Feedback from customers on the use of the standard is highly valued and helps to ensure that it continues to fulfill requirements. A Customer Feedback Form is provided on page 5 for your comments.

8 FURTHER INFORMATION

For further information please contact: standards@nibsc.ac.uk

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9 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 Working Group on Coagulation Standards is also highly appreciated.

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MATERIAL SAFETY SHEET

Physical properties (at room temperature)	
Physical appearance	*Freeze-dried powder*
Fire hazard	*None*

Chemical properties			
Stable	*Yes*	Corrosive:	*No*
Hygroscopic	*Yes*	Oxidising:	*No*
Flammable	*No*	Irritant:	*No*
Handling: *This preparation contains material of human origin. The plasma donations included in this product have been tested and found negative for Anti-HCV, Anti-HIV and HBsAg. As with all materials of biological origin, the preparation should be regarded as potentially hazardous to health. The container and its contents should be used and discarded according to your own laboratory procedures. Such procedures probably will include the wearing of protective gloves and avoiding the generation of aerosols. Care should be exercised in opening the container to avoid cuts.*			

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 a viricidal agent. Rinse area with a viricidal agent followed by water. Absorbent materials used to treat spillage should be treated as biologically hazardous waste.

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CUSTOMER FEEDBACK FORM

Contact Details:

Tel:	Fax:	Email:

1. Please indicate which parameters you use the SSC/ISTH standard to measure and for what purpose (eg. Direct calibration of calibrant plasma, quality control check)?

Factor II	
Factor V	
Factor VII	
Factor VIII	
Factor IX	
Factor X	
Factor XI	
Factor XIII	
VWF:Ag	
VWF:RCo	
VWF:CB	
Protein C antigen	
Protein C activity	
Protein S total antigen	
Protein S free antigen	
Protein S function	
Antithrombin antigen	
Antithrombin activity	
Fibrinogen	

2. Are there any new parameters you would like to see attached to the SSC/ISTH standard?

3. Please indicate your opinion of the following:

	Too slow	**Acceptable**	**Good**
Dispatch of orders:			
Response to enquiries:			
Product Information:			

THANK YOU FOR COMPLETING THIS FORM

Please return to: Dr. A R Hubbard, Haemostasis Section, NIBSC, Blanche Lane, South Mimms, Potters Bar, EN6 3QG Hertfordshire, UK FAX: +44 1707 641050 Email: thubbard@nibsc.ac.uk