



Manufactured By: HYPHEN BioMed

BIOPHEN FACTOR VII ON STA, STA-C

Adaptation of BIOPHEN Factor VII on STA and STA-C

1. Reconstitution of BIOPHEN Factor VII (Ref A221304) reagents.

Chromogenic determination of the Factor VII.

	NAME	Reconstitution	Stability	Stabilization in T°
R1	F.X	4 ml of distilled water *	72 hours at 2-8°C * 8 hours at room T° Do not freeze	** 30 mn before any use
R2	Thromboplastin	2 ml of distilled water *	48 hours at 2-8°C * 8 hours at room T° Do not freeze	** 30 mn before any use
R3	SXa-11	4 ml of distilled water	3 months at 2-8°C * 7 days at room T° Do not freeze	** 30 mn before any use
R4	TRIS-BSA	Ready to use	Stable until the expiration date at 2-8°C	** 30 mn before any use

Reconstitution:

* After reconstitution with distilled water, leave the R1, R2 and R3 reagents to stabilize for 30 minutes at room temperature .

Conservation of reagents:

Take care of putting up the specific caps back on the bottles before storing them at 2°-8° C and of strictly respecting the temperature stabilization time of 30 minutes before using the reagents on the automate.

Stabilization of reagents:

** It is necessary to leave the substrate (R3), (R2) (R1) and (R4) temperature to stabilize for at least 30 minutes on the automate before any use

Foot-note: Do not interchange the reagents from different lots.

2. Determination of Factor VII :

Reconstitution:

After reconstitution of calibrators or controls with distilled water (normal pool plasma or plasma Calibrator with a known Factor VII concentration), leave them to stabilize for 30 minutes at room temperature.

All the samples, calibration and control plasmas are prediluted 1:50 before use.

Foot-note: A calibration curve must be carried out for each new batch of reagents.

Conservation of reagents:

** Take care of strictly respecting the 30 minutes temperature stabilization time for *calibrators* and *controls* at room temperature, then the 30 minutes on the automate, particularly if they were stored at + 2°- 8°C. Homogenize before each use.

Foot-note: Do not freeze calibrators or controls.

Configuration of the analyzer: cf chapter 5.

4. Results:

- The calibration curve is of the Log (absorbance) - Log (concentration) type.
- The values obtained for the patients and controls are directly calculated from the calibration curve.
- The results are expressed in % activity

5. Programming the STA analyser :

Click on the icon **set up software** for the **manager program** and create the program according to :

All the samples, calibration and control plasmas are prediluted 1:50 before use.

CONFIGURATION – Page 1 / 3

Identification										
Abbreviation		Name			Method			Date		
B F.VII		BIOPHEN F.VII			Colo-two points					
Sample				Diluent						
Volume	Incu	Dil.	Id.	Name			vial.	stab	Vol. min.	
100µl	0 sec	1/20	R4	R4 VII			5 ml	8 h	0.2 ml	
reagents										
Id.		Name		Incu sec	Vol. µl	Vial ml	Stab h	Vol min. ml	Washing	
									front	afterwards
Ra	R1VII	R1 VII		0	100	4	8	0.2	no	Normal
Rb	R2VII	R2 VII		420	50	2	8	0.2	no	Spécial
Rc										
Rd	R3VII	R3 VII			100	4	8	0.2	no	Intensive
Analyze			Result				Acceptance (%)			
Linearity min	0.80		Major Unit		%		Standard	min	max	
First point	20 sec		Correction Fact.		1.00			0	200	
Last point	300 sec		Determination		single					
Rd Heating	yes		SD max		5%					
Mixed	yes		Redil. Critere							
			<							
			>							

Enter data concerning washing.

Washing				
	Ra	Rb	Rc	Rd
Front	No			No
After	Normal	Special		Intensive
Wash		12227		
Name		STA-DESORB U		
Stab. H		120		
Vial ml		15		
Vol in. ml		0.9		

Show the second page and write calibration data.

CONFIGURATION – Page 2 / 3

Calibration										
Method graph – linear regression						Manual Validation				
Calibrators				Vial ml	Stab. H	Vol. mini ml	Range Determination Concentration Assay	LOG LOG Single		
Id.	Key	Name	Dil.							
VIICAL		VIICAL	1/10	1	8	0.2				
VIICAL		VIICAL	1/20	1	8	0.2				
VIICAL		VIICAL	1/40	1	8	0.2				
VIICAL		VIICAL	1/80	1	8	0.2				
VIICAL		VIICAL	1/200	1	8	0.2				
Control										
	Id.	Key	Name	Vial. ml	Stab. H	Vol min. ml				
Level 1										
Level 2										

Show the last page and enter data concerning the quality control.

The STA can manage 3 levels of quality control. For exemple : the following configuration is possible.

CONFIGURATION – Page 3 / 3

Edition / Transmission							
		Factor convers.	Edition	Range transmission	Usual Range		%
Major Unit	%			0	STANDARD	Min.	Max.
Aux.1	OD/min			0		10	200
Aux.2							
Aux.3							
Range data		min		0			
		max		200			
Controls							
	Id.	Key	Name	Time H	Vial. ml	Stab. H	Volume min. ml
Level 1	NC		N CONT	24	1	8	0.2
Level 2	AC		AB CONT	24	1	8	02
Level 3							