



Manufactured by Hyphen BioMed.

BIOPHEN Protein C5 ON THROMBOLYSER

Adaptation of BIOPHEN PROTEIN C 5 ON THROMBOLYSER

1. Reconstitution of BIOPHEN PROTEIN C .5 (Ref A221205) reagents.

Chromogenic determination of Protein C.

	NAME	Reconstitution	Stability	Stabilization in T°
R1	Protac	5 ml of distilled water (*)	3 months at 2-8°C 3 days at room T° Do not freeze	30 mn before any use (**)
R2	SAPC-21 Substrate	5 ml of distilled water (*)	3 months at 2-8°C 3 days at room T° Do not freeze	30 mn before any use (**)

Reconstitution:

(*) Following reconstitution with distilled water, let the R1 and R2 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 let the substrate (R2) and the Protac (R1) 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 Protein C.

NAME	Reconstitution	Stability	Stabilization in T°
Calibration Biophen Plasma Calibrator (ref A222101)	1 ml of distilled water (*)	24 hours at 2-8°C 8 hours at room T°	30 minutes <i>on STA board</i> before any use (**)
Quality controls Biophen Normal Control (ref A223201) Biophen Abnormal Control (ref A223301)	1 ml of distilled water (*)	24 hours at 2-8°C 8 hours at room T°	30 minutes <i>on STA board</i> before any use (**)

Reconstitution:

(*) Following reconstitution of calibrators or controls with distilled water, let them to stabilize for 30 minutes at room temperature.

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. Homog enize before each use.

Foot-note: Do not freeze calibrators or controls.

3. Results.

- The calibration curve is of the Lin (absorbance) - Lin (concentration) type.
- The values obtained for the patients and controls are directly calculated from the calibration curve.
- The results are expressed in % activity.
The 100% activity is that of reference normal pooled citrated plasma.

4. Programming STA Analyzer

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

Parameters : BIOPHEN Protein C	
Reagents	: BIOPHEN Protein C 5
N° of lot	:
Volume (ml)	: 5
Date	:
Unit	: %
Double	: Yes
Tolerance	: 10%
Incubation	: 300
Read 1	: 15
Read 2	: 80
Min Simple	: 0.001
Max Simple	: 3.000
Normal range Min	: 1.00
Normal range Max	: 150.00
Latence Time	: normal
Algorithme	: Reg.Linear
Type of graph	: LIN/LIN
Val of calib Min	: 0.100 $\delta A/min$
Val of calib Max	: 0.300 $\delta A/min$
Calib dilution	: 0
Test after	:
Test driv	:
With test dp	: no
Type coag	: C-lin405
Dilut.rpt	: 1
Distribution Time	: 180
Factor of calculation	: 1.00

REAGENT	CP	UP	Down	Wash	Clean	Wash	Pi-Ty	Inc
PL	H	40	24	250	0	0	norm	0
RE G	H	110	100	250	300	1200	norm	0
SU G	L	110	100	250	300	1200	norm	0
Double								
PL	H	60	24	250	0	0	norm	0
PL	H	24	24	250	0	0	norm	0
RE G	H	110	100	0	0	0	norm	0
RE G	H	110	100	250	300	1200	norm	0
SU G	L	110	100	0	0	0	norm	0
SU G	L	110	100	250	300	1200	norm	0