



Manufactured By: HYPHEN BioMed

BIOPHEN HEPARIN 6 ON AMAX 190

Adaptation of BIOPHEN HEPARIN 6 ON AMAX 190

1. Reconstitution of BIOPHEN Heparin 6 (Reference A221006) reagents

Chromogenic determination of the Anti-Xa activity of LMWH, UFH, and Orgaran.

	NAME	Reconstitution	Stability	Stabilization in T°
R1	SXa-11 Substrate	6 ml of distilled water (*)	3 months at 2-8°C * 7 days at room T° Do not freeze	30 mn before any use (**)
R2	Factor Xa	6 ml of distilled water (*)	3 months at 2-8°C * 7 days at room T° Do not freeze	30 mn before any use (**)
Diluent	Distilled Water		24 hours on <i>AMAX 190 board</i>	

Reconstitution:

(*) **After reconstitution with distilled water, respect a stabilization time of 30 minutes at room temperature then 2 hours at 2°-8° C** . In current practice, in order to allow a good standardization, reconstitute these two reagents the evening before and put them at 2°-8°C following the 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 and the Factor Xa temperature to stabilize for at least 30 minutes on the automate before any use. A too low temperature of the reagents can induce an over-estimation. Conversely a too high temperature leads to an under evaluation of heparin.

Foot-note: Do not interchange the reagents coming from different lots of BIOPHEN Heparin.

2. Determination of Heparins UFH and/or LMWH.

NAME	Reconstitution	Stability	Stabilization in T°
Calibration Biophen Heparin Calibrator (ref A222001)	1 ml of distilled water (*)	7 days at 2-8°C 48 hours at room T°	30 minutes <i>on</i> <i>AMAX190 board</i> before any use (**)
Quality controls Biophen UFH Control (ref A223101) Biophen LMWH Control (ref A223001)	1 ml of distilled water (*)	7 days at 2-8°C 48 hours at room T°	30 minutes <i>on</i> <i>AMAX190 board</i> before any use (**)

3. Determination of Orgaran:

The determination of Orgaran requires its own configuration of the AMAX190. This one differs from the configuration used for the *determination* of UFH/LMWH only by the denomination of calibrators and controls.

NAME	Reconstitution	Stability	Stabilization in T°
Calibration Biophen Orgaran ® Calibrator (ref A222201)	1 ml of distilled water (*)	7 days at room T° 48 hours at room T°	** 30 minutes <i>on</i> <i>AMAX190 board</i> before any use (**)
Quality controls Biophen Orgaran ® Control (ref A223501)	1 ml of distilled water (*)	7 days at room T° 48 hours at room T°	** 30 minutes <i>on</i> <i>AMAX190 board</i> before any use (**)

Reconstitution:

(*) After reconstitution of calibrators or controls with distilled water, let them to stabilize for 30 minutes at room temperature. It is better to reconstitute calibrators the very day of calibration.

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.

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

4. Results:

- The calibration curve is of the Log (absorbance) - Lin (concentration) type.
- The values obtained for the patients and controls are directly calculated from the calibration curve.
- The results are expressed in IU/ml.
- When Heparin or Orgaran concentrations are out of the working range, assayed plasma must be diluted in normal plasma, appropriately prepared and platelet poor, in order to keep a sufficient concentration of AT III.
- In presence of low AT III concentrations, as it can be the case in young children, an exogenous source of AT III is necessary, in order to correctly measure the heparin concentration.

5. Programming analyzer AMAX 190:

Set up software and create the program according to:

1. Creat Reagent on AMAX 190

REAGENTS	Disp. Speed	WASHING Cycle	Decont	Decont Intra	Vol min	Vol max
DISTILLED WATER	0	1	NON	NON	200	3000
Substrat	0	4	NON	NON	200	3000
Factor Xa	0	6	OUI	OUI	200	3000

2. Calibration

The unique Calibration in 5 points with Heparin Calibrator makes it possible to measure Heparins UFH/LMWH

3. Programming of test

Name: HEPARIN BIOPHEN
Code HEP

Calibration

Type of curve	9	
Dilution r	0	Curve : data Sec/mE
Data max	2	
standard	0	
ISI Factor	0	
CV maxi	5	
Max Time	100	
Max Time 2	0	
Delay	15	
Impulsion t	0	r :

Procedure

Meas .mode : Chromogène 30-60-90		Pipet mode : 0		
		Mix volume : 0		
Sample.	Reagents	Volume	Incubation	Step after
Patient 15 µl	Distilled Water	45µl	5 sec	S1
S1 react	2R1 Substrat	100	240	S4
S2 React				S
S3 React				S
S4 Start r	R2 FXa	100		

Unit Data

	Unit Data	Normal Range
C T N	UI/ML mDO	

QC/ Statistique

	Eval	Target	2SD	De	Range à
Statistiques	N			0	0
Controls	N	QC1 Auto QC2 Auto QC3 Auto	Auto Auto Auto	Auto Auto Auto	Auto Auto Auto