



Manufactured by Hyphen BioMed.

BIOPHEN HEPARIN 3 ON SYSMEX CA 1500

Adaptation of BIOPHEN HEPARIN 3 on SYSMEX CA 1500

1. Reconstitution of the reagent, BIOPHEN Heparin 3 (Reference A221003).

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

	NAME	Reconstitution	Stability	Stabilization in T°
R1	SXa-11 Substrate	3,0 ml of distilled water (*)	3 months at 2-8°C * 7 days at room T° Do not freeze	30 mn <i>on board</i> SYSMEX CA 1500 before any use (**)
R2	Factor Xa	3,0 ml of distilled water (*)	3 months at 2-8°C * 7 days at room T° Do not freeze	30 mn <i>on board</i> SYSMEX CA 1500 before any use (**)
Diluent	Distilled Water		24 hours <i>on board</i> SYSMEX CA 1500	

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 board</i> SYSMEX CA 1500 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 board</i> SYSMEX CA 1500 before any use (**)

3. Determination of Orgaran:

The determination of Orgaran requires its own configuration of the CA 1500. 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 board</i> SYSMEX CA 1500 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 board</i> SYSMEX CA 1500 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. INSTRUMENT SETTING FOR SYSMEX CA 1500

Click on the window Set up software for the “manager program” and create the program according to: Chromogen for AT3

Change the data with the data indicated on the table below

Use the program and create the name for the reagents, Calibration plasmas and control plasmas

System		Ready			
Parameter : HEP Chr Para Code					
Sample.Vol			15	µl	
Diluent Vol	Dist Water		45	µl	
Wash	Without			15	
Second Dilution	No	0µl		7	
Diluent Vol	No	0µl			8
Wash		Without			9
Deficient Plasma	No			4	
Wash	Without	x0/	Without x0		5
First reagent	SUB 100µl 60 sec			1	
Diluent Vol	No	0µl			2
Wash	Without	x0/	Clean x 1	3	
Second reagent	Xa	100µl	300 sec	0	
Diluent Vol	No	0µl			Enter
Wash	Without	x0/	Off /Clean x 3	Detector	
Third reagent	Without				
Diluent Vol	No Util	0µl			
Wash	Without	x0/	Without x0	Sens/wavelength	
Detector	Chromogene for AT III				
Read time	80 sec			Special	
Select Tests	Name Tests				
		↑	↓		

System		Ready																						
. Detection choice.																								
Test Name	% End Point (%)	Read time																						
B Hep		20 ≈ 60	<table border="1"> <tr> <td>7</td> <td></td> <td>8</td> <td></td> <td>9</td> </tr> <tr> <td>4</td> <td></td> <td>5</td> <td></td> <td>6</td> </tr> <tr> <td>1</td> <td></td> <td>2</td> <td></td> <td>3</td> </tr> <tr> <td>0</td> <td></td> <td></td> <td></td> <td>Enter</td> </tr> </table>		7		8		9	4		5		6	1		2		3	0				Enter
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