

DRAFT PROPOSAL – NOT VALIDATED

### 1. PRESENTATION AND PREPARATION OF Biophen AT(LRT) REAGENTS (#A221111)

Reagents of BIOPHEN AT (LRT) kit are liquid and ready to use.  
BIOPHEN AT (LRT) kit must be stored at 2 - 8 °C, in their original packaging box. It is then stable until the expiration date printed on the box.

	NAME	Packaging	Stability after opening	Stabilization in T°
R1	Factor Xa	4 x 11ml ready for use	3 months at 2-8°C (*) 7 days at room T° (*) Do not freeze	30 mn before any use (**)
R2	SXa-11 Substrate	4 x 4 ml ready for use	3 months at 2-8°C (*) 7 days at room T° (*) Do not freeze	30 mn before any use (**)
Diluent	Physiological Saline or Owren Koller buffer		24 hours <i>on board</i>	

**\*Provided any contamination or evaporation is avoided. Stability can be adjusted according to the exact use conditions.**

**Stabilization:** (\*) After homogenization, let the reagent to stabilize for 30 minutes at room temperature (18-25°C).

**Stabilization of reagents:** (\*\*) It is necessary to let the reagent temperature to stabilize for at least 30 minutes on the automate board before any use.

**Storage 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.

If the reagents are kept on the automate board, take care and use reducers to limit as much as possible any evaporation of the reagents.

**Homogenize the reagents before each use.**

**Any reagent of biological origin must be handled with all the required cautions, as being potentially infectious.**

**Do not interchange the reagents from different lots.**

**Reagents required but not provided:**

- Plasma Calibrator titrated for AT (eg: Biophen Plasma Calibrator #A222101)
- Normal and Abnormal quality control plasmas titrated for AT (ex: BIOPHEN Normal Control Plasma #A223201 and BIOPHEN Abnormal Control Plasma #A223301).
- Diluent.

## 2. CALIBRATION CURVE AND CONTROLS:

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 (**)

\*\*\*Take care avoiding any contamination or evaporation of the reagents. Stability can be adjusted according to the exact use conditions

Reconstitution: (\*) Following reconstitution of calibrators or controls with distilled water, let them to stabilize for 30 minutes at room temperature. It is recommended to run the calibration curve with a freshly reconstituted calibrator.

Storage 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.

**Homogeneize before each use.  
Do not freeze calibrators or controls.**

**Quality controls must be run regularly and a new calibration curve carried out for each new batch of reagents, after an important maintenance of the instrument, or if measured values are not in compliance with the one expected for the method.**

## 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 calibration curve is validated when linearity (r2), as well as measured control values, are in compliance.**

**A new calibration curve must be carried out for each new batch of reagents, after each important maintenance of the instrument, or when measured values for controls are out of the acceptance range for the method (after checking all other parameters for the system).**

**Performances may present slight variations according to the instrument used and to sensitivity adjustment. Validate the expected values in the laboratory working conditions. Performances, as well as values for each new lot of quality controls used, must then be confirmed (and adjusted if necessary) in the laboratory working conditions.**

#### 4. PROGRAMMING THE ANALYZER:

##### 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 ATIII

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 : AT3 Para Code				
Sample.Vol		10	µl	
Diluent Vol	Owren	100	µl	
Rinse	None			
Second Dilution		10 µl		7
Diluent Vol	Owren	10 µl		8
Rinse	None			
Deficient Plasma	None	0µl		9
				4
Rinse(pre/post)	None	None		5
First reagent	FXa	150µl	30 sec	6
Diluent Vol	No	0µl		1
Rinse(pre/post)	None x0/	Clean x 1		2
Second reagent	Substrate	50µl	150 sec	3
Diluent Vol	No	0µl		0
Rinse(pre/post)	None x0	/Clean x 1		Enter
Third reagent	None	0µl	0sec	
Diluent Vol	No	0µl		
Rinse(pre/post)	None x0/	None x0		
Detector	Chromogen for AT III			
Sens/wavelength	Low sens / 405nm Inc			
Maximum time	100 sec			
Select Tests	Name Tests	Special	↑	↓

Detector: 10-60s

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