



Manufactured by Hyphen BioMed.

# BIOPHEN ANTITHROMBIN 2.5 ON OLYMPUS AU400-AU640-AU2700

## DRAFT NO VALIDATED

### Adaptation of BIOPHEN ANTITHROMBIN 2.5 ON OLYMPUS

#### 1. Reconstitution of BIOPHEN ANTITHROMBIN 2.5 (Ref A221102) reagents.

Chromogenic determination of the Antithrombin.

	NAME	Reconstitution	Stability	Stabilization in T°
R1	Factor Xa	2.5 ml TRIS Buffer *	3 months at 2-8°C * 7 days at room T° Do not freeze	** 30 mn before any use
R2	SXa-11 Substrate	2.5 ml of distilled water *	3 months at 2-8°C * 7 days at room T° Do not freeze	** 30 mn before any use

#### Reconstitution:

\* After 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.

-Chose of recipients on Olympus instrument: In order to have a minimum breakeven quantity. Pour the reagents into a long tube with a small diameter. Introduce this tube into a plastic recipient specific to the instrument. Cut the vial neck to introduce easily the tube (the tube must be sufficient longer for attending the bottom of the plastic vial)

#### Stabilization of reagents:

\*\* It is necessary to let the substrate (R2) and the Xa Factor (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.**

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## 2. Determination of ANTITHROMBIN.

NAME	Reconstitution	Stability	Stabilization in T°
Calibration Biophen Plasma Calibrator (réf A222101)	1 ml of distilled water (*)	24 hours at 2-8°C 8 hours at room T°	(**) 30 minutes on CA-1500 board before any use
Quality controls Biophen Normal Control (réf A223201) Biophen Abnormal Control (réf A223301)	1 ml of distilled water (*)	24 hours at 2-8°C 8 hours at room T°	(**) 30 minutes on CA-1500 board before any use

### Reconstitution:

(\*) After 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. Homogenise before each use.

**Foot-note: Do not freeze calibrators or controls.**

Configuration of the analyzer: cf chapter 5.

## 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.

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## 4. Programming of the OLYMPUS instrument

- Test name

Selected: (P) Parameter, (Y) Common test parameter, (A) name of the test.

Selected the tab: "Test Name".

Then selected the function ""Set" and choose a free position.

Set the name of the test.

Then selected: (P) Parameter, (Y) Common test parameter, (C) Tray.

Then select the functions "Set" then "Modified".

Click directly on the test to be added for introducing it into the tray.

- Technical sheet programming

Selected: (P) Parameter, (I) Specific test parameters, Tab "General"

Selected the name of the test in the heading "Test name" using the menu.

Then follow the programming:

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## 5. Calibration

Prediluted the plasma on physiological serum.

The 1:1 dilution plasma corresponds at 100% of activity (or the exact value announced into the Kit).

The 1:2 dilution corresponds at 50% of activity (or at the half of the value announced into the kit).

The 1:4 dilution corresponds at 25% of activity (or the quart of the value announced into the kit).

The physiological serum corresponds at 0% of activity.

## 6. Samples and controls

The samples and controls are tested at the 1:1 dilution.

## 7. Results

The concentration of Antithrombin is expressed in % of activity for normal plasma.

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Specific Test Parameters													
		LIH	ISE	Plage									
Test Name	ATIII	▼	◀	▶	Type			Serum	▼	Exécution	Oui		
Sample :	Volume	2.0	µl	Dilution	0	µl	Predilution rate	1					
Reagents :	R1 Volume	100	µl	Dilution	0	µl	Min OD.		L	-2.0000	Max OD	H	2.5000
	R2 Volume	100	µl	Dilution	0	µl	Reagent OD limit :		First L	-2.0000	First H	2.5000	
Wavelength	Prim.	410	▼	Sec.	Aucun	▼	Dynamic Range		Last L	-2.0000	Last H	2.5000	
Method	Fixe1						Correlation Factor		L	0.00	H	130.00	
Reaction slope	First.	+	▼	Last	15		On-Board stability		A	1.00000	B	0.0000	
Measuring Point 1	First.			Last			period						
Measuring Point 2													
Linearity			%										
No Lag time			▼										
Selected in the list printed with the <u>spacebar</u> or <u>clicking the mouse</u>													
Help	Exit	Impr.	Set										Test number

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- Selected: (P) Parameters, (B) Calibration, and then (C) specific calibration.  
 Selected the test in the printed list « Test Name » using the menu.  
 Selected the function « Set» and follow the programming :

Specific calibration					
General	ISE				
Test Name	ATIII ▼	◀	▶	Type :	Serum ▼
Type of calibration	3AB ▼	Formula	Polygonal ▼	Counts	2
		Process	Conc ▼		
	Cal. No.	OD	CONC	Factor/OD-L	Factor/OD-H
Point 1 :	29**		0.00*	- 0.10	0.10
Point 2 :	30		25	- 0.20	-0.15
Point 3 :	31		50	- 0.40	-0.30
Point 4 :	32		100	- 0.85	-0.65
Point 5 :					
Point 6 :					
Point 7 :					
1-Point Cal. Point		<input type="checkbox"/>	With CONC-0		Advanced calibration
					No
MB Type factor				Calibration Stability Period	

(\*) The concentration of calibrators are done as example

(\*\*) The numbers of calibrators are done also as example: the place are affected as « POSIITON CALIBRATORS »