



# LIAPHEN AT ON STA-R

Latex Immunoassay for the quantitative  
determination of AT on STAR

## 1. LIAPHEN AT (# A120002) reagents.

	NAME	Reconstitution	Stability*	T° Stabilization
R1	Latex reagent	Ready to use	6 months at 2-8°C * 7 days at room T° (18-25°C)	** 30 mn on board before any use
R2	Reaction Buffer	Ready to use	6 months at 2-8°C * 7 days at room T° (18-25°C)	

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

**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 (eg: BIOPHEN Normal Control Plasma -#A223201 and BIOPHEN Abnormal Control Plasma #A223301).
- Physiological saline (9g/L NaCl)

## 2. Preparation of the calibration curve and controls/samples:

- Calibration curve:

- Calibration is performed with normal pooled citrated plasma with the assigned value of 100% AT. The assay includes a standard plasma dilution of **1:15 (managed by the automate)**. By definition, this latter dilution of the pool represents the **100% AT**. The dynamic range is from 0 to 150% AT. The **150% AT** is then the **1:10** dilution of the plasma pool.

Or

-Calibration is performed with a commercially available plasma calibrator, with a known AT Concentration **C** (eg **Biophen Plasma Calibrator #A222101**). If **C >100%**, dilute the calibrator to **100% AT** in physiological saline, using the dilution factor **D=C:100**.

The program integrates dilutions of the calibrator (**managed by the STA-R**) at 1:10, 1:15, 1:20, 1:30, 1:60, 0 that correspond by definition to 1.5\*C %, C %, 1.5C/2 %, C/2 %, C/4 % and 0 % of AT (i.e. for C=100%: 150, 100, 75, 50, 25, and 0 % of AT).

- Tested plasmas and controls:

In these conditions, tested plasmas and controls are loaded “undiluted” and assayed at the 1:15 dilution (managed by the STAR).

The control is performed with commercially available control plasmas, titrated for AT. Various control plasmas are available, eg **Biophen Normal Control Plasma (#A223201)**, and **Biophen Abnormal Control Plasma (#A223301)**

Note: For lyophilized calibrators and controls, following reconstitution with distilled water, let the reagent stabilize 30 minutes at room temperature. It is recommended to run the calibration curve with a freshly reconstituted calibrator. It is necessary to let the reagent temperature stabilize for at least 30 minutes onto the automate before any use. Take care avoiding any contamination or evaporation of the reagents. Stability can be adjusted according to the exact use conditions.

**Homogenize before each use.**

**Do not freeze calibrators and quality control plasmas.**

## 3. Results:

- The calibration curve is of the 3<sup>rd</sup> order polynomial regression type.
- The values obtained for patients and controls are directly calculated from the calibration curve (when the standard 1:15 dilution is used for the test).
- The results are expressed as % AT.

The calibration curve is validated when linearity ( $R^2 \geq 0.98$ ), 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).

Note: Performances may present slight variations according to the instrument used. Validate the expected values for controls 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 STA-R analyser:

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

This calibration allows measuring concentrations in the range of about 0 - 150% of AT

TESTS								Configuration
<b>Method</b>								
<b>IDENTIFICATION</b>								
Abbreviation		LIAPHAT			Last up date			
Name		LIAPHEN AT			Method		Immu. 2pts	
<b>SAMPLE</b>				<b>DILUENT</b>				
Vol. µl	Incu.	Dilution	Id.	Name			Stab. h	Continued
60 µl	0 sec	1/15	SP	Physiological			(*)	
<b>REAGENTS</b>								
	Id.	Name		Stab. h	Vol. µl	Incu. sec	Prec.	
Ra	R2	Buffer		(*)	200	240	<input type="checkbox"/>	
Rb				(*)			<input type="checkbox"/>	
Rc							<input type="checkbox"/>	
Rd	R1	Latex		(*)	50			

Enter data concerning washing

<b>REAGENTS</b>								
	Id.	Name	Stab. h	Vol. µl	Incu. sec	Prec.	Vial. ml	Min.Vol ml
Diluent	SP	Physiological	(*)				20	1
Ra	R2	Buffer	(*)	200	240	<input type="checkbox"/>	10	0.5
Rb						<input type="checkbox"/>		
Rc						<input type="checkbox"/>		
Rd	R1	Latex	(*)	50			2.1	0.3
<b>Washing</b>								
	Ra		Rb		Rc		Rd	
Before	No						No	
After	Normal						Intensive	
Wash								
Name								
Stab. H								
Vial ml								
Vol in. ml								

(\*) To be filled by the user, according to the instructions of the insert, and to the exact use conditions.

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

TESTS		Configuration	
		<b>Result</b>	
<b>METHOD</b>		<b>RESULT</b>	
2 point kinetics		Primary Unit	%
First Point	30	Correction factor	1.00
Second Point	300	Single/Duplicate	<input checked="" type="radio"/> Single
			<input type="radio"/> Duplicate
		Precision (%)	5.00
		Redilution	Condition
		1/	<
		1/	>
<input type="checkbox"/> Rd Heating			
<input checked="" type="checkbox"/> X Stirring			
		<b>VALIDATION %</b>	
		Min.	Max.
		0*	150*

\*To be adjusted by the user.

TESTS		Configuration			
		<b>Calibration</b>			
MODE :		polynomial 3 <sup>rd</sup> order	Determination		
		Single	<input checked="" type="checkbox"/> X Duplicate		
<b>ASSAYS</b>		<b>Concentrations</b>			
SCALE :	<input checked="" type="checkbox"/> X Linear	Log	<input checked="" type="checkbox"/> X Linear    Inverse    Log		
	Id.	Key	Name	Stab. H	Dilution
Std 1	CAL1	C1	Plasma cal	*	1/10**
Std 2	CAL1	C1	Plasma cal	*	1/15
Std 3	CAL1	C1	Plasma cal	*	1/20
Std 4	CAL1	C1	Plasma cal	*	1/30
Std 5	CAL1	C1	Plasma cal	*	1/60
Std 6	SP	SP	Physiological	*	1/1
Ctrl, Niv. 1					
Ctrl, Niv. 2					

\*According to the calibrator used (homogenize before each use).

\*\*The concentration corresponding to the 1:10 dilution must not exceed 150% AT.

Click on the icon **Printout/Transmission software** for the **manager program** and create the program according to:

TESTS						Configuration
					Printout/Trans.	
<b>PARAMETERS</b>						
	Units	Factor Convers	Print	Transmission Test numbers	Usual Values Min.          Max.	
Main	%		v	0	80(*)	120(*)
Aux1	DOD		v	0	0	3
Aux2						
Aux3						
<b>Printout Limits</b>						
Min.	<input type="text" value="0"/>	Max.	<input type="text" value="200"/>			

(\*) to be adjusted by the user.

Show the last page and enter data concerning the quality control.

TESTS						Configuration
					Q.C	
<b>LEVEL 1</b>						
	Id.	Key	Name	Stab. h	Vial. ml	Min Vol ml
Control	BNC		BN CONT	24	1	0.2
<b>LEVEL 2</b>						
	Id.	Key	Name	Stab. h	Vial. ml	Min Vol ml
Control	BAC		BA CONT	24	1	0.2
<b>LEVEL 3</b>						
	Id.	Key	Name	Stab. h	Vial. ml	Min Vol ml
Control	*		*	*	*	*
Period :	<input type="text"/>	hours	<input type="text"/>	Tests	<input type="text"/>	Vial

\*According to the controls used (homogenize before each use).