



# APTT Clotting Assay on STA-R

(using CEPHEN 1, 2.5, 5 or CEPHEN 1LS, 2.5LS reagents)



## 1. Reagents:

NAME	Reconstitution	Stability	Stabilization at the room Temperature
CEPHEN 1 (ACK511K)	Ready to use (about 1 ml per vial)	7 days at room T° (18-25°C)* 3 months at 2-8 °C*	30 mn before any use (**)
CEPHEN 2.5 (ACK512K)	Ready to use (about 2.5 ml per vial)	7 days at room T° (18-25°C)* 3 months at 2-8 °C*	30 mn before any use (**)
CEPHEN 5 (ACK515K)	Ready to use (about 5 ml per vial)	7 days at room T° (18-25°C)* 3 months at 2-8 °C*	30 mn before any use (**)
CEPHEN 1 LS (ACK521K)	Ready to use (about 1 ml per vial)	7 days at room T° (18-25°C)* 3 months at 2-8 °C*	30 mn before any use (**)
CEPHEN 2.5 LS (ACK522K)	Ready to use (about 2.5 ml per vial)	7 days at room T° (18-25°C)* 3 months at 2-8 °C*	30 mn before any use (**)

(\*) **Provided any contamination or evaporation is avoided.**

### **Reagents required but not provided:**

- Calcium chloride 0.025M (ex AAR001A/AAR001K)
- Normal and Abnormal quality control plasmas (ex: BIOPHEN Normal Control Plasma - #A223201 and BIOPHEN Abnormal Control Plasma - #A223301).
- Lupus control sample for Cephen 1 LS or 2.5 LS (lupus sensitive reagent)

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.

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

**Note : Homogenize the reagents before each use.**

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

## 2. Quality control plasmas:

Example:

NAME	Reconstitution	Stability	Stabilization in T°
Biophen Normal Control (ref A223201)	1 ml of distilled water (*)	refer insert	30 minutes <i>on board</i> before any use (**)
<i>Biophen Abnormal Control</i> (ref A223301)	1 ml of distilled water (*)	refer insert	30 minutes <i>on board</i> before any use (**)

Reconstitution: (\*) Following reconstitution of calibrators and controls, let them to stabilize for 30 minutes at room temperature.

Storage of reagents:(\*\*) Following care of strictly respecting the 30 minutes temperature stabilization time for controls at room temperature, then the 30 minutes on the automate, particularly if they were stored at + 2°-8°C.

Homogeneize before each use.

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

**Foot-note: Quality controls must be run regularly, and 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.**

## 3. Results:

- The values obtained for the patients and controls, are expressed in seconds.

**NOTE: Clotting times and performances may present variations according to the instrument used, and to the clot detection 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 STA-R analyzer:

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

TESTS						Configuration		
<b>Method</b>								
IDENTIFICATION								
Abbreviation		aPTT		Last up date				
Name		aPTT		Method		CLOT-BASED		
SAMPLE			DILUENT					
Vol. $\mu$ l	Incu.	Dilution	Id.	Name			Stab. h	Min Vol
50 $\mu$ l	0 sec	1/1	OK	OWREN KOLLER			72	1.5
REAGENTS								
	Id.	Name		Stab. h	Vol. $\mu$ l	Incu. sec	Prec	Continued
Ra	CEP	Cephen reagent		168	50	180	<input type="checkbox"/>	
Rb							<input type="checkbox"/>	
Rc							<input type="checkbox"/>	
Rd	CaCl2	Calcium 0.025M		*	50			

Enter data concerning washing

	Id.	Name	Stab. h	Vol. $\mu$ l	Incu. sec	Prec.	Vial. ml	Min Vol ml
Diluent	OK	OWREN KOLLER	72				25	1.5
Ra	CEP	Cephen reagent	168	50	180	<input type="checkbox"/>	*	0.2 or 0.5*
Rb								
Rc						<input type="checkbox"/>		
Rd	CaCl2	Calcium 0.025M	*	50			*	*
<b>Washing</b>								
	<b>Ra</b>		<b>Rb</b>		<b>Rc</b>		<b>Rd</b>	
Before	No						No	
After	Normal						Normal	
Wash								
Name								
Stab. H								
Vial ml								
Vol in. ml								

\*according to the reagent used

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

TESTS		Configuration							
		<b>I. Result</b>							
METHOD		RESULT							
CLOTTING TIME									
Min. Time	20	Primary Units.	SEC						
Max Time	250	Correction Fact	1.00						
Mean Time	30	Single/Duplicate							
Clot	<input checked="" type="radio"/> Normal <input type="radio"/> weak <input type="radio"/> Mean	<input checked="" type="radio"/> Single <input type="radio"/> Duplicate							
<input checked="" type="checkbox"/> Rd Heating Stirring		Precision (%)	5.00						
		Redilution	Condition						
		1/	<						
			>						
		<table border="1"> <thead> <tr> <th colspan="2">Validation</th> </tr> <tr> <th>Min.</th> <th>Max.</th> </tr> </thead> <tbody> <tr> <td>20</td> <td>250</td> </tr> </tbody> </table>		Validation		Min.	Max.	20	250
Validation									
Min.	Max.								
20	250								

Show the second page and write calibration data.  
No calibration.

**CONFIGURATION – Page 2 / 3**

Calibration						
Mode RAW						
Results in SEC						
Control						
	Id.	Key	Name	Vial. ml	Stab. H	Min Vol ml
Level 1						
Level 2						

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

**CONFIGURATION – Page 3 / 3**

Printout / Transmission					
Units	Convers Factors.	Print	Transmission Test Number	Usual Values	Sec
Main	sec	yes	0	STANDARD	Min. Max.
Aux.1			0		25(*) 40(*)
Aux.2					
Aux.3					
Printout limits		min	20		
		max	250		

\*To be adjusted by the user

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

Controls							
	Id.	Key	Name	Period H	Vial. ml	Stab. H	Min Vol ml
<b>Level 1</b>	(*)	(*)	(*)	(*)	(*)	(*)	(*)
<b>Level 2</b>	(*)	(*)	(*)	(*)	(*)	(*)	(*)
<b>Level 3</b>	(*)	(*)	(*)	(*)	(*)	(*)	(*)

(\*) To be filled by the user. Must be homogeneized and stabilized before each use.