

DRAFT

Adaptation of BIOPHEN Plasminogen on STA

1. Reconstitution of BIOPHEN plasminogen (Ref A221502) reagents.

Chromogenic determination of plasminogen activity.

	NAME	Reconstitution	Stability	Stabilization in T°
R1	Activator (SK)	2.5 ml of distilled water (*)	1 month at 2-8°C * 7 days at room T° Do not freeze	30 mn before any use (**)
R2	Substrate	2.5 ml of distilled water (*)	1 month at 2-8°C * 7 days at room T° Do not freeze	30 mn before any use (**)

Reagents required but not provided:

Physiological saline (9 g/L NaCl)

Reconstitution:

(*) After reconstitution with distilled water, let the reagent to stabilize 30 minutes at room temperature.

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.

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.

Foot-note: Do not interchange the reagents from different lots.

NOTE: Use microcups when running the assay, to improve management of the reagents volumes by the automate.

Preparation of the calibrators

- Calibration is performed with normal pooled citrated plasma with the assigned value of 100% Plasminogen. The assay includes a standard plasma dilution of 1:20. By definition, this later dilution of the pool represents the 100% Plasminogen activity. The dynamic range is from 0 to 200% Plasminogen. The 200% Plasminogen activity is the 1:10 dilution of the plasma pool.

Or

-Calibration is performed with plasma calibrator commercially available, with a known Plasminogen concentration. The 1:20 dilution corresponds to the indicated Plasminogen concentration, and the 1:10 to twice this concentration.

Tested plasma:

In these conditions, the tested plasmas and controls are assayed at the 1:20 dilution.

A calibration curve must be carried out for each new batch of reagents.

Controls

The control is performed with commercially available control plasmas, titrated for Plasminogen.

Nota : Following reconstitution with distilled water, let the reagent to stabilize 30 minutes at room temperature. It is necessary to let the reagent temperature to stabilize for at least 30 minutes onto the automate before any use.

Do not freeze quality control plasmas

4. Results:

- *CALIBRATION RANGE (0 to 200 %)*: The calibration curve (working range) 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 as % Plasminogen activity (100 % being equivalent to 1 Unit/ml)

5. Programming the STA analyser:

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

Concentration working range : 0 -200% of Plasminogen

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Identification										
Abbreviation		Name			Method			Date		
BPLG		BIOPHEN PLG			Chro-kinetics OD/min o					
Sample				Diluent						
Volume	Incu	Dil.	Id.	Name			Vial.	stab	Min.Vol.	
100µl	0 sec	1/20	PH	PHYSAL			5 ml	8 h	0.2 ml	
reagents										
Id.		Name		Incu sec	Vol. µl	Vial ml	Stab h	Min.Vol. ml	Washing	
Ra R1PLG		R1 PLG		180	100	3	168	0.35	before	after
Rc										
Rd R2PLG		R2 PLG			100	3	168	0.35	no	Intensive
Analysis			Result				Validation (%)			
Linearity min	0.80	Primary Units		%		Standard	min	max		
First point	15 sec	Corrector		1.00			0	250		
Second point	90 sec	Single/Duplicate		single						
Rd Heating	Yes	Precision		5%						
Stirring	no	Redil. Condition								
				<						
				>						

Enter data concerning washing.

Washing				
	Ra	Rb	Rc	Rd
Front	No	No		No
After	Special			Intensive
Wash	12227			
Name	STA-DESORB U			
Stab. H	120			
Vial ml	15			
Vol in. ml	0.9			

Show the second page and write calibration data.

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Calibration										
Mode graph – linear regression						Scale				
Calibrators				Vial ml	Stab. H	Min.Vol. ml	Raw Data Concentration Single/Duplicate	Lin Lin Single		
Id.	Key	Name	Dil.							
PH		PHYSAL	1/1	5	8	0.2				
PLGCAL		PLGCAL	1/10	1	8	0.2				
PLGCAL		PLGCAL	1/20	1	8	0.2				
PLGCAL		PLGCAL	1/40	1	8	0.2				
PLGCAL		PLGCAL	1/80	1	8	0.2				
Control										
	Id.	Key	Name	Vial. ml	Stab. H	Min.Vol. ml				
Level 1										
Level 2										

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

The STA can manage 3 levels of quality control. For example: the following configuration is possible.

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Printout / Transmission							
	Units	Factor convers.	Print	Transmission Test number	Usual Values		%
Main	%		Yes	0	STANDARD	Min.	Max.
Aux.1	OD/min		Yes	0		70	120
Aux.2							
Aux.3							
Printout limits			min	0			
			max	250			
Controls							
	Id.	Key	Name	Period H	Vial. ml	Stab. H	Min.Vol. ml
Level 1	(*)	(*)	(*)	(*)	(*)	(*)	(*)
Level 2	(*)	(*)	(*)	(*)	(*)	(*)	(*)
Level 3	(*)	(*)	(*)	(*)	(*)	(*)	(*)

(*) To be filled by the user