

DRAFT PROPOSAL

1. Reconstitution of Hemoclot PS (# ACK041K) reagents.

	NAME	Reconstitution	Stability*	T° Stabilization
R1	PS deficient plasma	1 ml of distilled water *	Refer to the insert	** 30 mn on board before any use
R2	Activator	1 ml of distilled water *		

*The stability data claimed on the insert were obtained on reconstituted vials, kept closed, protected from and provided any contamination or evaporation is avoided. Stability must be controlled, and can be adjusted and validated if required, according to the exact use conditions for each laboratory.

Reconstitution: (*) After reconstitution with distilled water, let the reagent to stabilize for at least 15 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.

Homogenise 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 PS (e.g.: Biophen Plasma Calibrator #A222101)
- Normal and Abnormal quality control plasmas titrated for PS (ex: BIOPHEN Normal Control Plasma -#A223201 and BIOPHEN Abnormal Control Plasma #A223301).
- Distilled water, preferentially sterile.
- Calcium chloride 0.025M (e.g.: # AAR001A/AAR001K).
- Imidazole buffer (e.g.: #AAR021A/AAR021K/AAR021L);

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% PS. The assay includes a standard plasma dilution of **1:10 (managed by the automate)**. By definition, this later dilution of the pool represents the **100% PS activity**. If the standard is less than 100%, it is possible to adjust its concentration by using a lower dilution factor.

Or

-Calibration is performed with a commercially available plasma calibrator, with a known PS Concentration (eg **Biophen Plasma Calibrator #A222101, to be titrated, in progress**). The **1:10 (managed by the automate)** corresponds to the indicated PS concentration ("C%").

Nota: If the standard is less than 100%, it is possible to adjust its concentration by using a lower dilution factor.

- **Tested plasma and controls:**

In these conditions, tested plasmas and controls are loaded "undiluted" and assayed at the **1:10 dilution (managed by the STAR)**. Samples expected at a normal concentration (>100%, can be assayed at the 1:20 dilution (test dependent).

Controls: The control is performed with commercially available control plasmas, titrated for PS.

Various control plasma are available (**to be titrated, in progress**): **Biophen Normal Control Plasma (#A223201)**, and **Biophen Abnormal Control Plasma (#A223301)**

Nota : For lyophilized calibrators and controls, following reconstitution with distilled water, let the reagent to 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 to 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.

Homogenise before each use.

Do not freeze calibrators and quality control plasmas.

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 for the method.

Performances may present slight variations according to the instrument used. Validate the expected values in the exact laboratory working conditions.

Check the validity of the series by including quality control plasmas at different levels in each one.

1. Results:

- The calibration curve (working range) is of the Log (CT, in seconds) – Lin (PS concentration, in %) type.
- The values obtained for patients and controls are directly calculated from the calibration curve (when the standard 1:10 dilution is used for the test).
- The results are expressed as % PS 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).

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.

Material definition report

Material name: PS deficient R1
Index material : type of vial : 4 ml
Manufacturer : HBM

Category : reagent
Type of material : Intermediary reagent
Comments :

Lot informations

Volume control :
Alert volume : 0.30ml

Following expiration : Disabled

Stability on board (chilled) : Disabled

Stability on board (ambient) : N/A
Test not done, stability exceeded : Activated

Informations : Agitation, rinsing & cleaning
Rinsing : Disabled
Rinsing & cleaning :
Number of cleaning and rinsing : 1

Cleaning cycle
Cleaning solution system
Cycle number of aspiration: 1
Air rins/clean: 15µl
Volume of cleaning solution : 130µl
Air transportation : 0µl
Total volume : 145µl
Residence time : 0 sec
Agitation : Disabled

Cleaning solution for all cycles : 130µl

Rinsing cycles :
Frequency : only change of vials
Rinsing after cleaning : 1 sec
Agitations Rinsing : Disabled

Agitation : Disabled

Following lot
Lot used, etc,

Material definition report

Material name: aPC R2
Index material : type of vial : 4 ml
Manufacturer : HBM

Category : reagent
Type of material : Intermediary reagent
Comments :

Lot informations

Volume control :
Alert volume : 0.30ml

Following expiration : Disabled

Stability on board (chilled) : Disabled

Stability on board (ambient) : N/A
Test not done, stability exceeded : Activated

Informations : Agitation, rinsing & cleaning
Rinsing : Disabled
Rinsing & cleaning :
Number of cleaning and rinsing : 1

Cleaning cycle
Cleaning solution system
Cycle number of aspiration: 1
Air rins/clean: 15µl
Volume of cleaning solution : 130µl
Air transportation : 0µl
Total volume : 145µl
Residence time : 0 sec
Agitation : Disabled

Cleaning solution for all cycles : 130µl

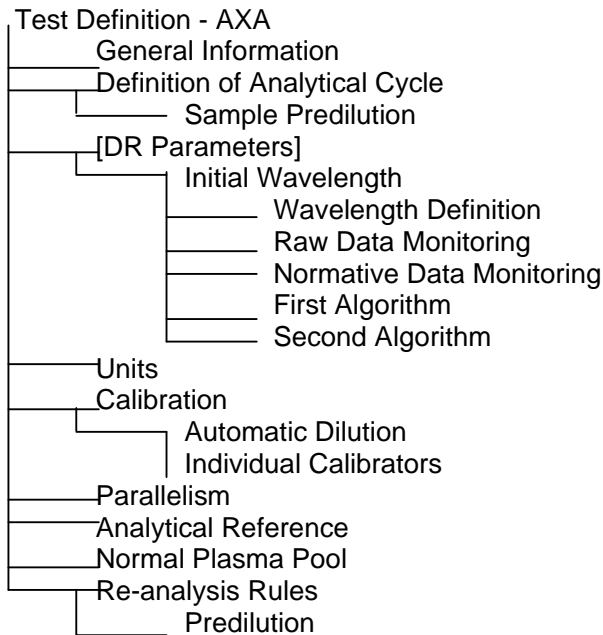
Rinsing cycles :
Frequency : only change of vials
Rinsing after cleaning : 1 sec
Agitations Rinsing : Disabled

Agitation : Disabled

Following lot
Lot used, etc,

V. ANALYZER PROGRAMMING

Follow order of analyzer tree to program



General Information

Test Code	<input type="text" value="HEMOCLOT PS"/>	Test Number	<input type="text"/>
Test Name	<input type="text" value="Protein S"/>	QC Number	<input type="text"/>

Test

Initial Test Version

Modified Test Version

User Comments

Enable drift test

[Parent Test]	<input type="text"/>	↓
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Enable matched-pair test

Master Test	<input type="text"/>	↓
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Enable dependence test

Definition of Analytical Cycle

Wavelength Acquisition

Initial Wavelength

W-671

↓
↑

nm

Acquisition Duration

Acquisition Duration	200	↓ ↑	S
Time	35	↓ ↑	S

Extended Acquisition Duration

Extended Acquisition Duration	500	↓ ↑	S
[OC Number]		Test Code	Hemoclot PS

Load Cycle

Number of Repetitions

1

↓
↑

<input checked="" type="checkbox"/>	Name of Material	Type	[Volume Loaded]	Incubation Limit
	Sample		50	
	R1 deficient PS	Intermediary. reagent	50	119-121
	R2 aPC	Intermediary. reagent	50	179-181
	R3 CaCl2	Triggering reagent	100	

Total volume in cuvette

250

μl

Sample Predilution

Enable sample predilution

General	Mixture/Sample	Diluent
---------	----------------	---------

Dilution Parameterization

Parts, sample	1	↓ ↑	
Parts, diluent	9	↓ ↑	
Minimum sample volume	10	↓ ↑	μl

Sample	Mixture	Diluent
Volume	Volume	Volume
12	0	108

12	0	108	Total Volumes
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Enable mixing

Mixture volume	60	↓ ↑	%	Number of cycles	1	↓ ↑
				— Rinsing after mixing	1	↓ ↑

Enable sample predilution

General	Mixture/Sample	Diluent
---------	----------------	---------

Volumes

Head space volume	0	↓ ↑	μl
Air volume	15	↓ ↑	μl
[Transport air volume]	30	↓ ↑	μl
Head space volume	0	↓ ↑	μl

Rinsing

Duration	1	↓ ↑	
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Enable sample predilution

General	Mixture/Sample	Diluent
---------	----------------	---------

Volumes Material

NaCl 0.9%		↓	
Head space volume	0	↓ ↑	μl
Air volume	15	↓ ↑	μl
[Transport air volume]	30	↓ ↑	μl

Head space volume	0	↓ ↑	μl
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Wavelength Definition

Initial Wavelength Enable alerts

Enable errors

Enable reference method

Hz	1.000	↓ ↑
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Enable normalization method

Absorbance	↓
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Smoothing Method: Sliding Smoothing

<input checked="" type="checkbox"/> Enable smoothing 1	Number of points	10	↓ ↑
<input checked="" type="checkbox"/> Enable smoothing 2	Number of points	5	↓ ↑
<input type="checkbox"/> Enable smoothing 3	Number of points	0	↓ ↑

Raw Data Monitoring

<input checked="" type="checkbox"/> Enable raw data monitoring	
<input checked="" type="checkbox"/> Enable first monitoring point	<input checked="" type="checkbox"/> Enable clipping
Error threshold <input type="text" value="50"/> ↓ ↑	% maximum delta <input type="text" value="25"/> ↓ ↑
Alert threshold <input type="text" value="50"/> ↓ ↑	% maximum rejected points <input type="text" value="1"/> ↓ ↑
<input type="checkbox"/> Enable last monitoring point	<input checked="" type="checkbox"/> Enable substitution method
Error threshold <input type="text"/> ↓ ↑	Extrapolation <input type="text"/> ↓
Alert threshold <input type="text"/> ↓ ↑	

<input checked="" type="checkbox"/> Enable control signal	<input type="checkbox"/> Enable basic analysis AND sliding
Minimum signal <input type="text" value="0.003"/> ↓ ↑	% time <input type="text" value="5,00"/> ↓ ↑ %
Maximum signal <input type="text" value="1.200"/> ↓ ↑	Window size <input type="text" value="1,000"/> ↓ ↑ s

% max. rejected values ↓
↑ %

Enable method of Extrapolation ↓

Enable sequential curve monitoring
Min. and then max. ↓

Normative Data Monitoring

Enable normalized delta checks

Enable normalized delta curve

Enable calibrated delta check results

Min. Limit Error	25,00	↓ ↑
Min. Limit Alert	25,00	↓ ↑

Max. Tolerance	0.000	↓ ↑	%
Max Tolerance Alert	0.000	↓ ↑	%

Baseline check	Endpoint check
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Enable baseline check

Hz	1,000	↓ ↑
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Enable mean control

Target Value	0.000	↓ ↑
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Error Tolerance	10	↓ ↑	%	Error Limit	0.000	0.000
Alert Tolerance	10	↓ ↑	%	Alert Limit	0.000	0.000

Enable monitoring AND

Error Limit	5,000	↓ ↑	Alert Limit	5,000	↓ ↑
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First Algorithm

<input type="checkbox"/> Enable secondary algorithm <input type="radio"/> End point <input type="radio"/> Kinetics <input type="radio"/> Threshold <input type="radio"/> 1st drift <input checked="" type="radio"/> 2nd drift <input type="radio"/> Delta <input type="radio"/> End-Initial <input type="radio"/> Statistical	1st drift		2nd drift				
	Smoothing						
	Method	Slope	↓	<input checked="" type="checkbox"/> Enable smoothing 1	Number of points	5	↑ ↓
	Number of points	3	↓ ↑	<input type="checkbox"/> Enable smoothing 2	Number of points		↑ ↓
	Peak Search Method			<input type="checkbox"/> Enable smoothing 3	Number of points		↑ ↓
	Last maxima peak		↓				
	Delta checks		Peak checks		Post-processing checks		
	<input checked="" type="checkbox"/> Max. Delta Peak						
	Error Limit	10.000	↓ ↓				
	Alert Limit	10.000	↓ ↑				
<input type="checkbox"/> Max. Delta Peak %							
Error Limit	10	↓ ↑					
Alert Limit	10	↓ ↑					

First Algorithm

<input type="checkbox"/> Enable secondary algorithm <input type="radio"/> End point <input type="radio"/> Kinetics <input type="radio"/> Threshold <input type="radio"/> 1st drift <input checked="" type="radio"/> 2nd drift <input type="radio"/> Delta <input type="radio"/> End-Initial <input type="radio"/> Statistical	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">1st drift</td> <td style="width: 50%; padding: 2px;">2nd drift</td> </tr> <tr> <td colspan="2" style="text-align: center; padding: 2px;">Smoothing</td> </tr> <tr> <td style="padding: 2px;">Method</td> <td style="padding: 2px;">Slope ↓</td> </tr> <tr> <td style="padding: 2px;">Number of points</td> <td style="padding: 2px;">3 ↓ ↑</td> </tr> <tr> <td colspan="2" style="padding: 2px;">Peak Search Method</td> </tr> <tr> <td style="padding: 2px;">Last maxima peak</td> <td style="padding: 2px;">↓</td> </tr> <tr> <td colspan="2" style="padding: 2px;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="padding: 2px;"><input checked="" type="checkbox"/> Enable smoothing 1</td> <td style="padding: 2px;">Number of points</td> <td style="padding: 2px;">3 ↓ ↑</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Enable smoothing 2</td> <td style="padding: 2px;">Number of points</td> <td style="padding: 2px;">↓ ↑</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Enable smoothing 3</td> <td style="padding: 2px;">Number of points</td> <td style="padding: 2px;">↓ ↑</td> </tr> </table> </td> </tr> <tr> <td colspan="2" style="padding: 2px;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%; padding: 2px;">Delta checks</td> <td style="width: 33%; padding: 2px;">Peak checks</td> <td style="width: 33%; padding: 2px;">Post-processing checks</td> </tr> <tr> <td style="padding: 2px;"><input type="checkbox"/> Max. 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Units

Unit Parameterization Results

✓	Unit	Unit Type	Label	<input type="checkbox"/>	[dec]	Normal Limits	Therapeutic Limits	Linearity Limit	Test Limits
	Seconds	Measured	S	<input type="checkbox"/>	1			10-200	
	%	Calibrated	%	<input type="checkbox"/>	1			10-150	
				<input type="checkbox"/>					
				<input type="checkbox"/>					
				<input type="checkbox"/>					
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<p>Unit selection test results</p> <p>Unit 1 <input type="text" value="Seconds"/> ↓</p> <p>Unit 2 <input type="text" value="%"/> ↓</p> <p>Unit 3 <input type="text"/> ↓</p> <p>Unit 4 <input type="text"/> ↓</p>	<p>Primary unit configuration</p> <p>Primary unit <input type="text" value="%"/> ↓</p> <p><input checked="" type="checkbox"/> Enable Max. Difference</p> <p>Max. Difference <input style="width: 50px; text-align: center;" type="text" value="10"/> ↓ ↑ %</p>	<p>Reactional curve visualization parameters</p> <p><input checked="" type="checkbox"/> Enable automatic scale</p> <p><input type="checkbox"/> Raw data</p> <p><input type="radio"/> Normalized (absorbance)</p> <p>Min. Y-axis <input style="width: 50px; text-align: center;" type="text" value="0.000"/> ↓ ↑</p> <p>Max. Y-axis <input style="width: 50px; text-align: center;" type="text" value="3000.000"/> ↓ ↑ mAbs</p>
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Calibration

Calibrations

General	Frequency	[DR Parameters]
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General

Number of repetitions ↓ ↑

Cal. Unit ↓

Calibration Mode

Cal. by automatic dilution

Individual calibrators

Enable cal. importation

Imported Test ↓

Type imported ↓

Imported Unit ↓

Calibrations

General	Frequency	[DR Parameters]
---------	-----------	-----------------

Enable off-range point auto-deletion

Enable extrapolation

Enable CV control

Mathematical Model

Linear Regression Spline

High Limit	0.000	↓ ↑
Low Limit	0.000	↓ ↑

Linear Regression

X-Axis Transformation

Non-transformed ↓

Y-Axis Transformation

Log10(y) ↓

Enable slope control

Theoretical Slope ↓ ↑ Tolerance ↓ ↑ % limits -

Enable control intercept point

Theoretical Intercept Point ↓ ↑ Tolerance ↓ ↑ limits -

Enable [R2 control]

R2 minimum

↓ ↑

Automatic Dilution

General	Calibrator	Diluent
----------------	-------------------	----------------

Dilutions

- Define points by dilution %
- Define points by concentration

- Direct
- unique dilution
- Serie
- Dilution cascade

Calibrator Value	62**	↓	↑	%
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** depend of the calibrator concentration used (e.g. : 62% à at 100% of dilution)

% dilution	Target Value	Min. replicates	% CV max	Calibrator Volume	Mixture Volume	Diluent Volume
200%	124	1	5	88		
150%	93	1	5	83		
50%	31	1	5	68		68
25%	15.5	1	5		58	58
12.5%	7.8	1	5		39	39

Predilution Volume		
Sample Volume	Mixture Volume	Diluent Volume
23		92
18		102
12		108
12		108
12		108

- Enable mixing

Mixture		↓	↑	%
Number of cycles	1	↓	↑	
Rinsing after mixing	0.000	↓	↑	s

Sample Volume		
1	↓	↑

- 1ere dilution 2nd Dilution

Re-analysis Rules

a

Enable re-analysis

Result Limits	[DR Error]
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Verification Unit:	%	↓
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Rule	Same Test	Extended Test	Re-analysis Dilution
High Normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Normal	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
High Therapeutic Limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Therapeutic Limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
High-Linearity Limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low-Linearity Limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test: high limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Test: low limit	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
High Limit of Test: Unit of Measure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Limit of Test: Unit of Measure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
High Limit of Calibration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Low Limit of Calibration	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Result limits	DR error
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Error of result

Rule	Same test	Extended test	Alternative pre-dilution
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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Aspiration sample error (base line)	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Error of liquid detection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>