

DRAFT PROPOSAL – NOT VALIDATED

NOTE 1: usual cautions according to the specific technical insert D.750.02/BI/1102, with AAR103A (special buffer without heparin).

NOTE 2: this adaptation is a method derived from Biophen AT2.5(#A221102). It can be adjusted if needed for derived use of Biophen AT5 (#A221105), as per the specific technical insert D.750.02/BI/1105.

**Method derived from BIOPHEN AT 2.5 (#A221102) on ACL Elite:
AT Progressive Assay**

Reagents

FXa: reconstitute with 2,5 ml Tris Buffer **without heparin (eg AAR103A)**
SXA-11: reconstitute with 2,5 ml water

Instrument settings

Test ID : AT (P)
Extended Name : Biophen AT prog
Enable Parallelism : Disabled
Calibration mode : Dedicated
Import Calibration from : None
Import raw data from : None
Test Code : xxx
Test revision : 1.00
Library Version : 1.01
Test code for host : xxx
IL Test : no

Session type: ANALYSIS Double samples: Disabled

-----Material Check-----		
Liquid ID	Check Presence	Action if short
SXa	v	Complete possible and advise
F (Xa) P		Complete possible and advise
Cleaning A		Complete possible and advise
Factor Dil	v	Complete possible and advise
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Loading Step 1 Scope: Opt. Ref.

	Sample Line	Reagent Line
Loading Type	No dilution	No dilution
Liquid ID	Factor Dil 80.0 µl	F (Xa) P 80.0 µl
Washing Reference	Enabled	Enabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	0	0
Washing at step completion	1	1
Time constraint	--	--
Mixing	--	--

Loading Step 2 Scope: Sample

	Sample Line	Reagent Line
Loading Type	In line dilution	No dilution
Diluent	A Factor Dil 37.5 µl	--
Diluted	plasma 12.5 µl	F (Xa) P 50.0 µl
Washing Reference	Enabled	Enabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	1	1
Washing at step completion	3	3
Time constraint	Set timer	300 s
Mixing	--	--

Loading Step 3 Scope: Ref.

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	No dilution	No dilution
Liquid ID	Washing R 90.0 µl	Washing R 90.0 µ
Washing Reference	Enabled	Enabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	0	0
Washing at step completion	1	1
Time constraint	Wait until timer has expired	
Mixing	ramp	Enabled
	inter-ramp interval	3 s
	centrifugation time	11 s

Loading Step 5 Scope: Sample

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	No dilution	No loading
Liquid ID	SXa 50.0 µl	--
Washing Reference	Disabled	Disabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	0	0
Washing at step completion	2	2
Time constraint	Step length	95 s
Mixing	--	

Cleaning

	<u>Sample line</u>	<u>Reagent Line</u>
Diluent	None	None
Diluted	None	Cleaning A 140.0 µl
Cycles n.	3	3
Washing at completion	3	3
Sequential Flag	Disabled	

Acquisition Parameters

Ramp	Enabled	Acquisition Time	30 s
Inter-ramp interval	1	Sampling Rate	100 msec
Acquisition Delay	0 s	Acquisition Channel	Chrom 405nm
		Speed	1200 rpm

Data Reduction

Results Unit	Normal Range	Test Range	Scale Range
Δ Abs		0.00000 – 2.00000	0.00000 – 99.0000
%		15.0000 – 150.000	0.00000 – 900.000

Normalization: 2* log (R/S)

Algorithm: Delta Algorithm for: Sample

Parameters

Smooth:

Reaction Curve: First part: Offset 10 POINTS Final part: Final 10 POINTS

Curve check parameters:

Check saturation Enabled

Session type: Calibration

Number of replicates: 4

Material Check

Liquid ID	Check Presence	Action if short
AT Sub	v	Complete possible and advise
AT_F (Xa)		Complete possible and advise
Cal Plasm	v	Complete possible and advise
Cleaning A		Complete possible and advise
Factor Dil	v	Complete possible and advise

Loading Step 1 Scope: Std 2

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	In-cup dilution	No loading
Predispensed	Factor Dil 110.0 µl	--
Diluent	Factor Dil 10.0 µl	--
Diluted	Cal Plasm 120.0.0 µl	--
Inner Ring		
Washing	1	
Replicates N°	1	
Washing Reference	Enabled	Enabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	0	0
Washing at step completion	1	1
Time constraint	--	
Mixing	--	

Loading Step 2 Scope: Std 3

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	In-cup dilution	No loading
Predispensed	Factor Dil 110.0 µl	--
Diluent	Factor Dil 70.0 µl	--
Diluted	Cal Plasm 60.0.0 µl	--
Inner Ring		
Washing	1	
Replicates N°	1	
Washing Reference	Enabled	Enabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	0	0
Washing at step completion	1	1
Time constraint	--	--
Mixing	--	--

Loading Step 3 Scope: Opt. Ref.

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	No dilution	No dilution
Liquid ID	Factor Dil 80.0 µl	F (Xa) P 80.0 µl
Washing Reference	Enabled	Enabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	0	0
Washing at step completion	1	1
Time constraint	--	--
Mixing	--	--

Loading Step 4 Scope: Std 1

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	In line dilution	No dilution
Diluent	A Factor Dil 37.5 µl	--
Diluted	Cal Plasm 12.5 µl	F (Xa) P 50.0 µl
Washing Reference	Enabled	Enabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	1	1
Washing at step completion	3	3
Time constraint	Set timer	300 s
Mixing	--	--

Loading Step 5 Scope: Std 2

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	In line dilution	No dilution
Diluent	A Factor Dil 37.5 µl	--
Diluted	Prep. cup 12.5 µl	F (Xa) P 50.0 µl
Washing Reference	Enabled	Enabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	1	1
Washing at step completion	3	3
Time constraint	Set timer	300 s
Mixing	--	--

Loading Step 6 Scope: Std 3

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	In line dilution	No dilution
Diluent	A Factor Dil 37.5 µl	--
Diluted	Prep. cup 12.5 µl	F (Xa) P 50.0 µl
Washing Reference	Enabled	Enabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	1	1
Washing at step completion	3	3
Time constraint	Set timer	300 s
Mixing	--	--

Loading Step 8 Scope: Ref

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	No dilution	No dilution
Liquid ID	Washing R. 90.0 µl	Washing R. 90.0 µl
Washing Reference	Enabled	Enabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	0	0
Washing at step completion	1	1
Time constraint	Wait until timer has expired	
Mixing	ramp	Enabled
	inter-ramp interval	3 s
	centrifugation time	11 s

Loading Step 9 Scope: Std 1, Std 2, Std 3

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	No dilution	No loading
Liquid ID	SXa. 50.0 µl	--
Washing Reference	Disabled	Disabled
Intermediate Rinse	Disabled	Disabled
Washing between loading	0	0
Washing at step completion	2	2
Time constraint	Step length	95 s
Mixing	--	--

<u>-----Cleaning-----</u>			
	<u>Sample line</u>		<u>Reagent Line</u>
Diluent	None	None	
Diluted	None	Cleaning A	140.0 ul
Cycles n.	3		
Washing at completion		3	3
Sequential Flag	Disabled		

<u>-----Acquisition Parameters-----</u>			
Ramp	Enabled	Acquisition Time	30 s
Inter-ramp interval	1	Sampling rate	100msec
Acquisition Delay	0 s	Acquisition Channel	Chrom 405 nm
		peed	1200 rpm

Calibration Calculation:

Calibration Std	Dilution Ratio %	CV
Std 1	100.00	8.0%
Std 2	50.00	6.0%
Std 3	25.00	4.0%

Response Type: Δ Abs Check CV: Enabled Outlier Enabled

Final Unit: %
X = x Y = y

Curve	Start	End	F(X)	G(Y)	q' Translat.	Slope Check	r^2 check
1 st	Std 1	Std 3	x	y	v Std 1	-2000. 0 to 0.0000	>= 0.980

Define as Mandatory: Std 1 Std 2 Std 3

Normalization: $2 * \log (R./S)$
Algorithm: Delta Algorithm
for: Std 1 Std 2 Std 3

Parameters

Smooth:

Reaction Curve: First part: Offset 10 POINTS Final part: Final 10 POINTS

Curve Check Parameters:

Check saturation Enabled