



# Biophen AT anti-IIa on ACL Elite

## Chromogenic determination of AT anti-IIa activity

**PRELIMINARY DRAFT PROPOSAL – NOT VALIDATED**

**NOTE: reconstitution and stabilization: usual cautions according to the specific technical insert D.750.02/BI/1122.**

### BIOPHEN AT (anti-IIa) (#A221122) on ACL Elite

#### Reagents

Reagent 1: Bovine Thrombin : reconstitute with 2,5 ml distilled water (AT\_Throm)

Reagent 2: SIIa-01: reconstitute with 2,5 ml water (SIIa)

Reagent 3: Dilution buffer ready to use (AT-buffer)

#### Instrument settings

**Test ID : AT-IIa**  
 Extended Name : Biophen AT(anti IIa)  
 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
SIIa	v	Complete possible and advise
AT_Throm	v	Complete possible and advise
Cleaning A	v	Complete possible and advise
AT-buffer	v	Complete possible and advise

#### Loading Step 1 Scope: Sample

	Sample Line	Reagent Line
Loading Type	In-cup dilution	No loading
Predispensed	AT-buffer 110.0 µl	--
Diluent	AT-buffer 118.0 µl	--
Diluted	Plasma 12.0 µl	--
Outer Ring		
Washing	1	
Replicates N°	1	
Washing Reference	Enabled	Enabled
Intermediate Rinse	Enabled	Enabled
Washing between loading	1	1
Washing at step completion	3	3
Timing Constraint	--	
Mixing	--	

#### Loading Step 2 Scope: Opt. Ref.

	Sample Line	Reagent Line
Loading Type	No dilution	No dilution
Liquid ID	AT-buffer 80.0 µl	AT_Throm 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 3 Scope: Sample**

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	No dilution	No dilution
Liquid ID	Prep. plasma 50.0 µl	AT_Throm 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	60 s
Mixing	--	

**Loading Step 4 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	SIIa 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	
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
SIIa	v	Complete possible and advise
AT_Throm	v	Complete possible and advise
Cal Plasm	v	Complete possible and advise
Cleaning A	v	Complete possible and advise
AT-buffer	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	AT-buffer 110.0 µl	--
Diluent	AT-buffer 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	--	

Biophen AT anti-IIa on ACLElite 2/4 D.750.07/BI/1122/ACLElite

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**Loading Step 2 Scope: Std 3**

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	In-cup dilution	No loading
Predispensed	AT-buffer 110.0 µl	--
Diluent	AT-buffer 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: Std 1**

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	In-cup dilution	No loading
Predispensed	AT-buffer 110.0 µl	--
Diluent	AT-buffer 118.0 µl	--
Diluted	Cal Plasm 12.0 µl	--
Outerr Ring		
Washing	1	
Replicates N°	4	
Washing Reference	Enabled	Enabled
Intermediate Rinse	Enabled	Enabled
Washing between loading	0	0
Washing at step completion	1	1
Time constraint	--	
Mixing	--	

**Loading Step 4 Scope: Std 2**

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	In-cup dilution	No loading
Predispensed	AT-buffer 110.0 µl	--
Diluent	AT-buffer 118.0 µl	--
Diluted	Prep. cup 12.0 µl	--
Outer Ring		
Washing	1	
Replicates N°	4	
Washing Reference	Enabled	Enabled
Intermediate Rinse	Enabled	Enabled
Washing between loading	0	0
Washing at step completion	1	1
Time constraint	--	
Mixing	--	

**Loading Step 5 Scope: Std 3**

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	In-cup dilution	No loading
Predispensed	AT-buffer 110.0 µl	--
Diluent	AT-buffer 118.0 µl	--
Diluted	Prep. cup 12.0 µl	--
Outer Ring		
Washing	1	
Replicates N°	4	
Washing Reference	Enabled	Enabled
Intermediate Rinse	Enabled	Enabled
Washing between loading	0	0
Washing at step completion	1	1
Time constraint	--	
Mixing	--	

**Loading Step 6 Scope: Opt. Ref.**

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	No dilution	No dilution
Liquid ID	AT-buffer 80.0 µl	AT_Throm 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 7 Scope: Std 1, Std 2, Std 3**

	<u>Sample Line</u>	<u>Reagent Line</u>
Loading Type	No dilution	No dilution
Liquid ID	Prep. cup 50.0 µl	AT_Throm 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	60 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	SI1a. 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 ul
Cycles n.	3	
Washing at completion	3	3
Sequential Flag	Disabled	

**Acquisition Parameters**

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:  $\Delta$  Abs      Check CV: Enabled      Outlier EnabledFinal Unit: %  
X = x      Y = y

Curve	Start	End	F(X)	G(Y)	q' Translat.	Slope Check	r <sup>2</sup> check
1 <sup>st</sup>	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