

DRAFT - NOT VALIDATED

Chromogenic determination of the anti-Xa activity

of LMWH, UFH, and ORGARAN®

1. Reconstitution of the BIOPHEN Heparin 6 reagent, (Reference A221006)

Chromogenic determination of the Anti-Xa activity of LMWH, UFH, and Orgaran.

	NAME	Reconstitution	Stability	Stabilization in T°
R1	SXa-11 Substrate	7.5 ml of distilled water (*)	3 months at 2-8°C ** 7 days at room T° Do not freeze	30 mn <i>on board</i> before any use(***)
R2	Factor Xa	7.5 ml of distilled water (*)	3 months at 2-8°C * * 7 days at room T° Do not freeze	30 mn <i>on board</i> before any use (***)
Diluent	Physiological Saline		24 hours on board	

2. Reconstitution of the BIOPHEN Heparin 3 reagent, (Reference A221003)

Chromogenic determination of the Anti-Xa activity of LMWH, UFH, and Orgaran.

	NAME	Reconstitution	Stability	Stabilization in T°
R1	SXa-11 Substrate	3.75 ml of distilled water (*)	3 months at 2-8°C * * 7 days at room T° Do not freeze	30 mn <i>on board</i> before any use(***)
R2	Factor Xa	3.75 ml of distilled water (*)	3 months at 2-8°C ** 7 days at room T° Do not freeze	30 mn <i>on board</i> before any use (***)
Diluent	Physiological Saline		24 hours on board	

Recommendations for reconstitution:

Reconstitution (*): Reconstitute each vial with distilled water. Shake thoroughly (vortex). Let to homogenize for 30 minutes at room temperature (18-25 °C), while shaking the vial from time to time (vortex), until complete dissolution of the content. Check the absence of any solid at the bottom of the vial.

In current practice, in order to allow a good standardization, reconstitute these two reagents the evening before and put them at 2°-8°C following the 30 minutes at room temperature.

Note: In all cases, before use, check the absence of solids at the bottom of the vial, which confirms that dissolution is complete. If necessary, incubate for 1 hour at RT or better at 37°C, while shaking (vortex) from time to time. If required, then additionally incubate overnight at RT.

Storage of reagents: ()** Stability indicated are validated provided any evaporation or contamination of reconstituted reagents avoided. They must be adjusted according to the actual laboratory working conditions

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 24H/24H, take care to limit as much as possible any evaporation of the reagents by using a chimney or mini-reducer.

Stabilization of reagents: (***) It is necessary to let the substrate and the Factor Xa temperature to stabilize for at least 30 minutes on the automate before any use. A too low temperature of the reagents can induce an over-estimation. Conversely a too high temperature leads to an under evaluation of heparin.

Homogenize 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.

If necessary use microcups when running the assay, to improve management of the reagents volumes by the automate

3. Determination of Heparins UFH and/or LMWH.

NAME	Reconstitution	Stability	Stabilization in T°
Calibration Biophen Heparin Calibrator (ref A222001)	1 ml of distilled water (*)	7 days at 2-8°C 48 hours at room T°	30 minutes <i>on the automate board</i> before any use (**)
Quality controls Biophen UFH Control (ref A223101) Biophen LMWH Control (ref A223001)	1 ml of distilled water (*)	7 days at 2-8°C 48 hours at room T°	30 minutes <i>on the automate board</i> before any use (**)

4. Determination of Orgaran:

The determination of Orgaran requires its own configuration of the MDA This one differs from the configuration used for the *determination* of UFH/LMWH only by the denomination of calibrators and controls.

NAME	Reconstitution	Stability	Stabilization in T°
Calibration Biophen Orgaran ® Calibrator (ref A222201)	1 ml of distilled water (*)	7 days at room T° 48 hours at room T°	30 minutes <i>on the automate board</i> before any use (**)
Quality controls Biophen Orgaran ® Control (ref A223501)	1 ml of distilled water (*)	7 days at room T° 48 hours at room T°	** 30 minutes <i>on the automate board before any use (**)</i>

Reconstitution:

(*) After reconstitution of calibrators or controls with distilled water, let them to stabilize for 30 minutes at room temperature. It is better to reconstitute calibrators the very day of calibration.

Conservation of reagents:

(**) Take care of strictly respecting the 30 minutes temperature stabilization time for *calibrators* and *controls* at room temperature, then the 30 minutes on the automate, particularly if they were stored at + 2°-8°C. Homogenize before each use.

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.

Homogenize before each use.

Do not freeze calibrators and quality control plasmas.

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).

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

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

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.

5. Results:

- The calibration curve is of the Log (absorbance) - Lin (concentration) type.
- The values obtained for the patients and controls are directly calculated from the calibration curve.
- The results are expressed in IU/ml.
- When Heparin or Orgaran concentrations are out of the working range, assayed plasma must be diluted in normal plasma, appropriately prepared and platelet poor, in order to keep a sufficient concentration of AT III.
- In presence of low AT III concentrations, as it can be the case in young children, an exogenous source of AT III is necessary, in order to correctly measure the heparin concentration.

Nota: Biophen Heparin reagents are developed for measuring homogeneously Unfractionated heparin (UFH) and Low Molecular Weight Heparin (LMWH), using the same calibration curve.

The superimposition conditions are susceptible to slightly vary according to the combination of reagents and lots used, and the technical characteristics and specific adjustment of each apparatus.

Therefore, this superimposition has to be verified and validated in the exact laboratory working conditions and for each machine, by establishing the calibration curve using Biophen Heparin calibrators (LMWH, ref A222001), and by assaying the homogeneous system of associated Biophen UFH calibrators (ref A222301), UFH control plasmas (ref A223101), and LMWH control plasmas at high and low levels (ref A223001, A223701).

The linearity (r^2) is expected to be ≥ 0.98 for the calibration curve.

Controls must be measured in compliance.

Measured values for calibrators are acceptable when:

Measured value = target value ± 0.10 IU/ml for levels ≤ 0.50 IU/ml (better ± 0.05 IU/ml)

Measured value = target value ± 0.15 IU/ml for levels > 0.5 IU/ml (better 90-110% of the target value, or ± 0.10 IU/ml for levels between 0.5 and 1.0 IU/ml)

Should the superimposition not be obtained, a separate calibration curve must be used for each type of heparin, and validated by assaying the homogeneous quality control system (controls measured in compliance and close to the assigned target value).

The calibration curve is validated when linearity (r^2), 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).

Performances may present slight variations according to the instrument used. 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.

Nota: The 3 months stability at 2-8°C and the 7 days stability at room temperature (18-25°C) claimed are validated on reconstituted vials kept closed, protected from any evaporation or contamination.

For your information, stability data on STAR board tested in our laboratory working conditions are:

- 7 days for reconstituted vials loaded on STAR during working time, using mini reducers or chimneys then closed and stored at 2-8 °C overnight.
- 5 days for reconstituted vials left loaded continuously on STAR.

Stabilities of reagents on each automate must be controlled, adjusted and validated under each exact laboratory working conditions.

PROGRAMMING ANALYZER MDA

- **Test creation:**

Enter the utility menu.

System Configuration.

Test Configuration: to be completed according to the instructions. The easiest way is to start from a pre-existing test and to update the parameters according to the following instructions.

- **Creation of the reagents codes**

Enter the utility menu.

Database Management.

Write in reagents and deficient plasma.

Chose the test.

Warning : the « triggering » reagent is always proposed.

If new lot : enter the « new lot » menu and fill in all yellow fields.

If same reagent lot, but new lot for controls or calibrator : enter the test and “reagent lot”.

Chose calibrator or control and write in the new lot.

Warning : the corresponding target value has to be defined.

- **Reagents bar code :**

Enter the « reagents » menu.

Write in the reagents codes indicated in the configuration.

Print the bar codes.

- **Startup:**

- a) **Load the reagents in « reagents menu»:**

- Add the reagents.

- Unlock the keyboard.

- Load the reagents in the loading areas:

 - X controls A

 - X physiological saline (serum phy) in B

 - X substrate in C

 - X Factor Xa

- Close again the shield.

- b) **Start Menu**

 - Begin again the operations

- c) **Test Menu to launch the controls and the calibration if required.**

- Chromogenic

- Test

If a calibration is needed: enter the test and start the calibration, then save.

If controls are directly tested: save.

- **Samples creation**

- Test Menu

- Test patients = identification then chose the test.

- Save.

Check the test report.

TEST REPORT

Date

Hour

Tests Parameters

Test : Biophen Heparin
Id of the Test : xxxxx
Use in the menu : Y
Menu : Chromogenic
Priority by defect : 2
Wavelength : 405
Latency Time : 18
Reading time : 60
Normalisation target : 3000

Report heading

Mean heading : Mean (1000)
Result Unit : U/ml
Unit X : U/ml
Unit Y : mDO

Test Well

Detection Bilirubin : N
Detection Hemolysis : N
Temperature Tubes : N
Detection lipemia : N

Reagents

Reagent(s) Lot : Biophen Heparin
Manufacturer : Hyphen
Needle B : Serum Phy
Needle C : Substrat Biophen
Needle D : Xa Biophen

End point method Parameters

Endpoint Algorithm	: Log Rate
Enable Compression	: N
Compression Factor	: 1
Compression min Delta	: 0.00000
Fitline max Residuals	: 0.003000
Fitline min Correlation	: 0.00000
FibrTime Branching Delta	: 0.00000
FibrTime 99% Intersect factor	: 0.00000
FibrTime 99% Fibr-calib slope	: 0.50000
FibrTime 99% Fitline-calib Intcp	: 0.50000
FibrTime Fitline Rng Slope	: 0.20000
FibrTime Fitline Rng Intcp	: 0.00000
Rate decision Slope	: 0.00800
Rate max residuals	: 0.0030000
Rate Max diff Ratio	: 1.000000
Rate log-transform Flag	: Y
TTmetric Smallest Delta	: 0.00000
TTMetric Largest Delta	: 0.00000
TTmetric Delta-Add Factor	: -10.00000
TTMetric Calib Slope	: 0.00000
TTMetric Calib Intcp	: -10.00000
AuxRng threshold-det slope	: 0.00000
AuxRng threshold-det Intcp	: -2.00000
AuxRng required interval	: 1
Always use AuxRng Flag	: N
Noclot Min Delta	: 0.00000
Fitting rng adj slope	: -2.00000
Fitting rng adj Intcp1	: -50.00000
Fitting rng adj Intcp2	: 10
Fitting rng adj Intcp3	: 10
GaussJordan Trips Subtractor	: 0
Two-Hump time-Diff limit	: 0.00000
APTT normal upper Clottime	: 8.00000
Lupus Time-Diff limit	: -240.00000
Clottime Fraction Flats Check	: 0.00000
Wavedefect No-chg interval	: 75
Max Number of repairs	: 1

More Endpoint parameters

Min Delta	: 0.00000
Max Delta	: 1.10000
Min Start Waveform Slope	: -1.00000
Max Start Waveform Slope	: 1.00000
Min End Waveform Slope	: -1.00000
Max End Waveform Slope	: 1.00000
Min 1 st Derivative Index	: 0.00000
Max 1 st Derivative Index	: 1200.00000
Min 1 st Derivative Amp	: -1.00000
Max 1 st Derivative Amp	: 1.00000
Min Alt-Derivative Index	: 0.00000
Max Alt-Derivative Index	: 1200.00000
Min Alt-Derivative Amp	: -1.00000
Max Alt-Derivative Amp	: 1.00000
Min 2 nd Alt-Derivative Index	: 0.00000
Max 2 nd Alt-Derivative Index	: 1200.00000
Min 2 nd Alt-Derivative Amp	: -1.00000
Max 2 nd Alt-Derivative Amp	: 1.00000
Min Blank Time	: 1
Max Blank Time	: 18
Min Reagent-Add offset Time	: 0
Max Reagent-Add offset Time	: 200
Min Data Points in Waveform	: 0
Max Data Points in Waveform	: 1200
Min zero Data Points	: 0
Max zero Data Points	: 10
Min repairs	: 0
Max repairs	: 51
Padded Peak Diff factor	: 0.22000
Slope Offset	: 1.000000
Intcp offset	: 0.000000
Enable Smart Bottom	: N
Early Clot Detect	: 0.900000

Plasma type parameters

Plasma identification name :	: sample
Determinations	: 1
Limit accuracy in duplicate	: 20% (end point mode) 0.0% (calibrator)
Limit CV inter dilution	: 0.0
Usual low value	: 0.00 High: 0.00
Dilutions in simple	
1 st dilution	: 2 Activated : Y

Substitution values : Y

Macro parameters: Simple 1

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30 PV : 15
RINSEP	v800	v0	v0		PV	

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15 CT: 1
RINSEC	v800	v0	v0			PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75
DELREAGENT	m1250				PV	

WASH	v800	v10	v135			PV
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Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75
DELOPTICS	m2250					PV

BLEACH2	v800	v20	v135			PV
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SCRUBME	v800	v10	v135			PV
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Macro parameters: Simple 2

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30 PV : 15
RINSEP	v800	v0	v0		PV	

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15 CT: 1
RINSEC	v800	v0	v0			PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75
DELREAGENT	m1250				PV	

WASH	v800	v10	v135			PV
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Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75
DELOPTICS	m2250					PV

BLEACH2	v800	v20	v135			PV
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SCRUBME	v800	v10	v135			PV
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Macro parameters: Simple 3

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30 PV : 15
RINSEP	v800	v0	v0		PV	

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15 CT: 1
RINSEC	v800	v0	v0			PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75
DELREAGENT	m1250				PV	

WASH	v800	v10	v135			PV
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Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75
DELOPTICS	m2250					PV

BLEACH2	v800	v20	v135			PV
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SCRUBME	v800	v10	v135			PV
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Macro parameters: Simple 4

Needle : A
VFSTASP2C m1000 dLKUP v5 v15 v0 RV : 30 PV : 15
RINSEP v800 v0 v0 PV

Needle : B
FETCHDEL m1500 dLKUP v15 v5 PV : 15 CT: 1
RINSEC v800 v0 v0 PV

Needle : C
FETCH1 m1250 dLKUP v75 v5 PV : 75
DELREAGENT m1250 PV
WASH v800 v10 v135 PV

Needle : D
FETCH1 m2250 dLKUP v75 v5 PV : 75
DELOPTICS m2250 PV
BLEACH2 v800 v20 v135 PV
SCRUBME v800 v10 v135 PV

Macro parameters: Simple 5

Needle : A
VFSTASP2C m1000 dLKUP v5 v15 v0 RV : 30 PV : 15
RINSEP v800 v0 v0 PV

Needle : B
FETCHDEL m1500 dLKUP v15 v5 PV : 15 CT: 1
RINSEC v800 v0 v0 PV

Needle : C
FETCH1 m1250 dLKUP v75 v5 PV : 75
DELREAGENT m1250 PV
WASH v800 v10 v135 PV

Needle : D
FETCH1 m2250 dLKUP v75 v5 PV : 75
DELOPTICS m2250 PV
BLEACH2 v800 v20 v135 PV
SCRUBME v800 v10 v135 PV

Macro parameters: Simple 6

Needle : A
VFSTASP2C m1000 dLKUP v5 v15 v0 RV : 30 PV : 15
RINSEP v800 v0 v0 PV

Needle : B
FETCHDEL m1500 dLKUP v15 v5 PV : 15 CT: 1
RINSEC v800 v0 v0 PV

Needle : C
FETCH1 m1250 dLKUP v75 v5 PV : 75
DELREAGENT m1250 PV
WASH v800 v10 v135 PV

Needle : D
FETCH1 m2250 dLKUP v75 v5 PV : 75
DELOPTICS m2250 PV
BLEACH2 v800 v20 v135 PV
SCRUBME v800 v10 v135 PV

Macro parameters: Simple 7

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30 PV : 15
RINSEP	v800	v0	v0		PV	

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15 CT: 1
RINSEC	v800	v0	v0			PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75
DELREAGENT	m1250				PV	
WASH	v800	v10	v135			PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75
DELOPTICS	m2250					PV
BLEACH2	v800	v20	v135			PV
SCRUBME	v800	v10	v135			PV

Macro parameters: Simple 8

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30 PV : 15
RINSEP	v800	v0	v0		PV	

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15 CT: 1
RINSEC	v800	v0	v0			PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75
DELREAGENT	m1250				PV	
WASH	v800	v10	v135			PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75
DELOPTICS	m2250					PV
BLEACH2	v800	v20	v135			PV
SCRUBME	v800	v10	v135			PV

Macro parameters: Simple 9

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30 PV : 15
RINSEP	v800	v0	v0		PV	

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15 CT: 1
RINSEC	v800	v0	v0			PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75
DELREAGENT	m1250				PV	
WASH	v800	v10	v135			PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75
DELOPTICS	m2250					PV
BLEACH2	v800	v20	v135			PV
SCRUBME	v800	v10	v135			PV

Macro parameters: Simple 10

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0		PV		

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0			PV	

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250				PV		
WASH	v800	v10	v135			PV	

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250					PV	
BLEACH2	v800	v20	v135			PV	
SCRUBME	v800	v10	v135			PV	

Plasma type parameters

Plasma identification name : Control
Determinations : 1
Limit accuracy in duplicate : 20% (end point mode) 20% (calibrator)
Limit CV inter dilution : 20.0
Dilutions in simple
1st dilution : 2 Activated: Y

Extended Parameters

Test name : Biophen Heparin
Plasma identification name : Control
Substitution values : Y

Expiration Criteria

Time Intervall : 3000 (hours)
Counter Intervall : 30000

Macro parameters: Simple 1

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v135				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 2

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v135				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 3

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v135				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 4

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v135				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 5

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v135				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 6

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v135				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 7

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v135				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 8

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v135				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 9

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v135				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 10

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v135				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Réactif

Needle A : Heparin Ctl 1

Needle A : Heparin Ctl 2

Règles de CQ

Règle 1 : 1-1-3s

Plasma type parameter

Plasma identification name : Calibrator
Determinations : 2
Chosen Dilution : 0.50000
Limit accuracy in duplicate : 20% (end point mode)

Dilutions in simple

1st dilution : 2 Activated: Y

Extended Parameters

Test name : Biophen Heparin

Plasma identification name : Calibrator

Substitution values : Y

Expiration Criteria

Time Intervall : 3000 (hours)

Warning – the calibration will expire : 24 (hours)

Counter Intervalle : 30000

Curve Criteria

Lowest Limit for R² : 0.9800

Extrapol. High activated : N Value : 2.0 U/ml message éc : N

Extrapol. Low activated : N Value : 0.00 U/ml message éc. : N

Macro parameters: Simple 1

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v125				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 2

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v125				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 3

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v125				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 4

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5			PV : 15 CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5			PV : 75
DELREAGENT	m1250						PV
WASH	v800	v10	v125				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5			PV : 75
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 5

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5			PV : 15 CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5			PV : 75
DELREAGENT	m1250						PV
WASH	v800	v10	v125				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5			PV : 75
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 6

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5			PV : 15 CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5			PV : 75
DELREAGENT	m1250						PV
WASH	v800	v10	v125				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5			PV : 75
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 7

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v125				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 8

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v125				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 9

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v125				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Macro parameters: Simple 10

Needle : A

VFSTASP2C	m1000	dLKUP	v5	v15	v0	RV : 30	PV : 15
RINSEP	v800	v0	v0				PV

Needle : B

FETCHDEL	m1500	dLKUP	v15	v5		PV : 15	CT: 1
RINSEC	v800	v0	v0				PV

Needle : C

FETCH1	m1250	dLKUP	v75	v5		PV : 75	
DELREAGENT	m1250						PV
WASH	v800	v10	v125				PV

Needle : D

FETCH1	m2250	dLKUP	v75	v5		PV : 75	
DELOPTICS	m2250						PV
BLEACH2	v800	v20	v135				PV
SCRUBME	v800	v10	v135				PV

Reagents

Needle A	: Heparin Ref 1
Needle A	: Heparin Ref 2
Needle A	: Heparin Ref 3
Needle A	: Heparin Ref 4

Curve Definition

Curve definition name	: Biophen Heparin Ref
Segments	: 1
Slope	: Neg
Ordinate, Abscissa in	: Y-Axe
	: Segment 1
Curve Structure	: Polynomial 2 nd degree
Transformation of X	: Linear
Transformation of Y	: Log

