



# PRODUCT CATALOG



Last update March 2023



## PRODUCT OVERVIEW



As a dedicated company to *in vitro* diagnostic reagents, HYPHEN BioMed offers to clinical and specialized laboratories, pharmaceutical industry, or medical research, a wide range of *in vitro* diagnostic and research reagents for the exploration of thrombosis, hemostasis, fibrinolysis and autoimmunity.

### HYPHEN BIOMED OFFER

Based on advanced techniques, the company offers certified hemostasis reagents with high added value for being used with the various automated systems; manual or semi-automated applications are available.

To facilitate your work, HYPHEN BioMed's team has developed a wide range of laboratory reagent lines to meet all your requirements.

#### Functional assays, using clotting or chromogenic methods:

- **HEMOCLOT™**

A range of clotting assays designed with highly purified coagulation factors for IVD and research use, as well as for pharmaceutical industry applications.

- **BIOPHEN™**

Innovative chromogenic assays, calibrators, and controls (traceable to international standards), for IVD and for research and pharmaceutical applications.

#### Enzyme immunoassays:

- **ZYMUTEST™**

Complete line of highly sensitive, accurate and specific Enzyme Immunoassays (Elisa) which remains the reference methods for the exploration of proteins involved in thrombotic diseases, fibrinolysis, autoimmunity, or drug induced complications such as HIT.

#### Latex enhanced turbidimetric assays:

- **LIAPHEN™**

A range of turbidimetric latex immunoassays, fully automatable, for the quantitative determination of different analytes and biomarkers on citrated human plasma.

#### Bio immunoassays:

- **ZYMUPHEN™**

Proprietary bio-immunoassays, highly specific, for testing rare protein activities in coagulation and fibrinolysis (such as tPA, PAI-1, TF, TAFI, EVs...), with high sensitivity.

#### Aggregometry assays:

- Aggregometry line offering an extended range of platelet functional assays.

### PRODUCTS LIST CODIFICATION

Product range	Reference Codification
LIAPHEN™	12
BIOPHEN™	22
ZYMUPHEN™	52
Aggregometry	AG
Auxiliary Reagents	AR
Bovine Enzymes	BE
Bovine Proteins	BP
Clotting Kit	CK
Deficient Plasma	DP
Human Enzymes	EZ
Purified Proteins	PP
Recombinant Proteins	RE
ZYMUTEST™	RK
Recombinant Human proteins	RP
Standards & Controls	SC

#### CUSTOMIZED RESEARCH PRODUCTS

Looking for a specific reagent? A calibrator? A control?

HYPHEN BioMed develops customized products, matching specifically with your needs.

As an *in vitro* reagent expert in the field of hemostasis, thrombosis, fibrinolysis and autoimmunity, HYPHEN BioMed is well acknowledged by clinical laboratories, as well as by research organizations, pharmaceutical industry, and the scientific community.

HYPHEN BioMed develops and produces in-house its major raw materials to provide you with efficient and robust solutions to optimize the diagnosis.

In addition, through its dedicated specialized protein purification equipment and enzyme engineering, its cell culture and recombinant protein unit, its high-capacity manufacturing equipment and its freeze-dryers, HYPHEN BioMed can provide you with on-demand customized products. HYPHEN BioMed's team can offer highly purified proteins and enzymes extracted from plasma or biological concentrates or recombinant, monoclonal or polyclonal antibodies, immunoconjugates, as well as dedicated raw materials and substrates under flexible presentations for home-made clotting, chromogenic or immunological assays.

With HYPHEN BioMed's technical support, you can build complete and adjusted solutions for your research and development projects, and design applications on the various coagulation analyzers.



● ● ● ● ● **A SUPPORT FOR EQA (EXTERNAL QUALITY ASSESSMENT)**

With the company's recognized experience, its offer for a full range of calibrators and controls, and its high-capacity manufacturing equipment, HYPHEN BioMed can provide you with lyophilized plasma materials for external quality assessment (EQA) organizations.

HYPHEN BioMed can meet your expectations with normal or pathological samples for routine hemostasis assays, or anticoagulation monitoring (e.g. heparins and heparin-like spiked samples, direct anti-Xa or anti-IIa inhibitors spiked in plasma, ...).

HYPHEN BioMed offers a complete and flexible line of assayed parameters, at targeted levels, and pre-titrated samples, which can be used on the major automated coagulation analyzers.

● ● ● ● ● **REGULATORY STATUS (RS)**

**RUO** For Research Use Only. Should not be used for patient diagnosis or treatment.

**CE-IVD** CE marked product In-Vitro Diagnostic use.

**510(k)** United States marked product for IVD use

● ● ● ● ● **QUALITY SYSTEM**

One of the company's major objectives is to achieve excellence in the quality of products, services and support by adhering to international quality standards. HYPHEN BioMed is certified for: ISO 13485:2016, MDSAP (Medical Device Single Audit Program) by TÜV Rheinland, and the company started the transition to the European regulation (EU) 2017/746.

All basic objectives and commitments of each HYPHEN BioMed employee are dedicated to deliver to customers full satisfaction through the quality of products and services.

HYPHEN BioMed develops and markets diagnostic reagents, many of which are CE marked and 510(k) cleared. They concern clotting, chromogenic and immunological assays for measuring all anticoagulant drugs, blood extracts and monitoring substitutive therapies, as well as all which is needed for thrombosis check-up and hemostasis laboratory applications.

● ● ● ● ● **SYSTEMS**

HYPHEN BioMed's assays can be applied to all current coagulation analyzers such as Sysmex CA series, CS series, CN series or Werfen ACL TOP® Family, Stago STA® R Family.

HYPHEN BioMed provides Application Guides for defined coagulation analyzer families. The Application Guides contain analyzer/assay specific handling and performance information and supersede the information from the Instructions for Use.



CS-1600



CS-2400  
CS-2500



CS-5100



CN Series



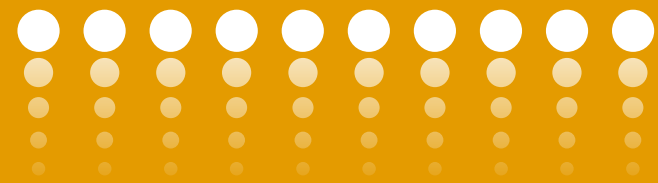
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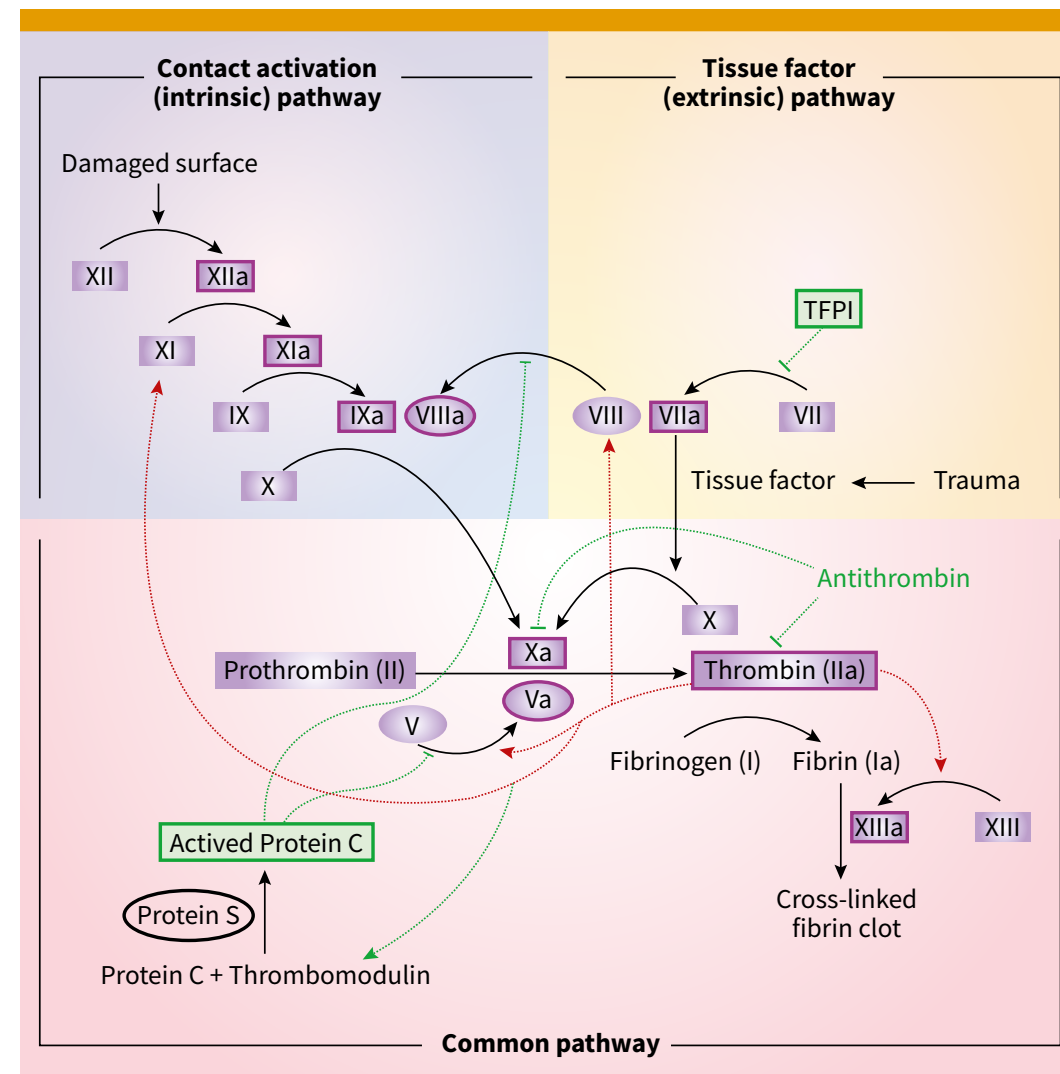


# GLOBAL & ROUTINE TESTS

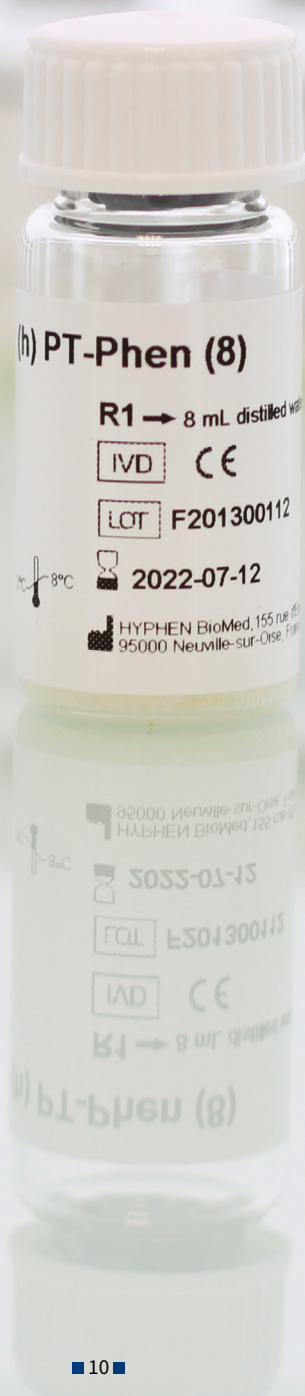


Coagulation screening tests are necessary to explore patients with hemostasis disorders.

The global measurement of intrinsic and extrinsic pathways help to clearly highlight the dysfunction of the coagulation cascade exposing patients to bleeding.



Coagulation pathways



## PROTHROMBIN TIME (PT)<sup>(1)</sup>

PT explores the coagulation extrinsic pathway and can be used for investigating some congenital or acquired bleeding disorders, liver diseases, vitamin K deficiency and vitamin K antagonists therapy.

It allows exploration of so-called vitamin K dependent coagulation factors.

This is the most widely used coagulation assay for laboratory monitoring of anticoagulant therapy with Vitamin K Antagonists (VKA).

### PT – Phen™

Determination of prothrombin time (PT).

REAGENT				CALIBRATORS		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• (h)PT-Phen™	CE-IVD	CK581	12 x 4 mL	• PT Calibrator Set	SC084K	• BIOPHEN™ Normal Control Plasma	223201
		CK582	12 x 8 mL			• BIOPHEN™ Abnormal Control Plasma	223301
		CK583	12 x 18 mL			• EASYPLASMA™ Calibrator	226601
• PT-Phen™ LRT Liquid and Ready to use	CE-IVD	CK584K	6 x 5 mL	• PT Calibrator Set	SC084K	• BIOPHEN™ Normal Control Plasma	223201
		CK584L	12 x 5 mL			• BIOPHEN™ Abnormal Control Plasma	223301
		CK586K	6 x 20 mL			• EASYPLASMA™ Control Set	225601
		CK586L	12 x 20 mL				

## ACTIVATED PARTIAL THROMBOPLASTIN TIME (aPTT)<sup>(1)</sup>

Explores the intrinsic pathway of coagulation and is a screening test to investigate some congenital or acquired deficiencies, especially hemophilia A and B, or coagulation inhibitors such as Lupus Anticoagulant (LA) or autoantibodies against coagulation factors.

### CEPHEN™

Determination of aPTT.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• CEPHEN™ Liquid aPTT Ready to use	CE-IVD	CK511K	6 x 1 mL	-	-	• LA Control Plasma	SC081K
		CK512K	6 x 2.5 mL			• LA Control Plasma Weak	SC082K
		CK515K	8 x 5 mL			• LA Control Plasma High	SC083K
		CK515L	12 x 5 mL			• BIOPHEN™ Normal Control Plasma	223201
						• BIOPHEN™ Abnormal Control Plasma	223301
						• EASYPLASMA™ Control Set	225601

(1) cf Dedicated instructions for use

## CEPHEN™ LS

Determination of aPTT.

This reagent offers a good sensitivity to the presence of LA.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• CEPHEN™ LS Liquid aPTT Lupus sensitive Ready to use	CE-IVD	CK521K	6 x 1 mL	-	-	• LA Control Plasma	SC081K
		CK522K	6 x 2.5 mL			• LA Control Plasma Weak	SC082K
						• LA Control Plasma High	SC083K
						• BIOPHEN™ Normal Control Plasma	223201
						• BIOPHEN™ Abnormal Control Plasma	223301
						• EASYPLASMA™ Control Set	225601

## FIBRINOGEN<sup>(1)</sup>

Elevated fibrinogen concentrations are observed in inflammation and have also been considered as a risk factor for cardiovascular disease and thrombosis.

Hypofibrinogenemia can be present in patients with fibrinogen deficiency or dysfunction (abnormal protein), and is also associated with severe liver diseases, or excessive consumption (Disseminated Intravascular Coagulation (DIC)).

Numerous variants of fibrinogen have been described, and are associated to asymptomatic cases or hypofibrinogenemia, with clinical manifestations of bleeding, or thrombosis (resulting from an impaired fibrinolysis).

### FIBRIPHEN™

Measurement of the fibrinogen concentration in plasma using the von Clauss method.

This reagent is available with the lyophilized presentation, or the ready to use liquid format.

REAGENT				CALIBRATORS		CONTROLS			
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.		
• FIBRIPHEN™ LRT Liquid and Ready to use	CE-IVD	CK585K	6 x 5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201		
				• EASYPLASMA™ Calibrator	226601	• BIOPHEN™ Abnormal Control Plasma	223301		
• FIBRIPHEN™	CE-IVD	CK571K	6 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201		
						CK572K	6 x 2 mL	• BIOPHEN™ Abnormal Control Plasma	223301
						CK575K	8 x 5 mL	• EASYPLASMA™ Calibrator	226601
						• EASYPLASMA™ Control Set	225601		

(1) cf Dedicated instructions for use

## LIAPHEN™ Fibrinogen

Determination of Fibrinogen antigen (Fib:Ag) in human citrated plasma or in purified medium, using a latex turbidimetric assay.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• LIAPHEN™ Fibrinogen Liquid and Ready to use	CE-IVD	120102	4 x 5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301



• Research •

## ZYMUTEST™ Fibrinogen

Measurement of human Fibrinogen in plasma, with an Elisa method.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Fibrinogen	RUO	RK024A	96 tests

## THROMBIN TIME (TT)<sup>(1)</sup>

TT is a screening test to assess abnormalities of fibrinogen and to detect thrombin inhibitors. It can be useful for the exploration of Disseminated Intravascular Coagulation (DIC) and liver diseases. A prolonged TT can result from the presence of antithrombin activity induced by therapy (e.g. Heparin, Bivalirudin, Argatroban, Dabigatran), the presence of high concentrations of Fibrin/Fibrinogen degradation products or qualitative (dysfibrinogenemia) or quantitative abnormalities of Fibrinogen (deficiency, DIC, fibrinolysis, hepatic disorders including cirrhosis). TT is normal in presence of a Factor XIII deficiency.

## HEMOCLLOT™ Thrombin Time

Determination of TT in human citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• HEMOCLLOT™ Thrombin Time LRT Liquid and Ready to use	CE-IVD	CK012K	6 x 5 mL	-	-	• BIOPHEN™ Normal Control Plasma • EASYPLASMA™ Control Set	223201 225601
• HEMOCLLOT™ Thrombin Time (T.T.)	CE-IVD	CK011K CK011L	6 x 2 mL 6 x 8 mL	-	-	• BIOPHEN™ Normal Control Plasma • EASYPLASMA™ Control Set	223201 225601

(1) cf Dedicated instructions for use



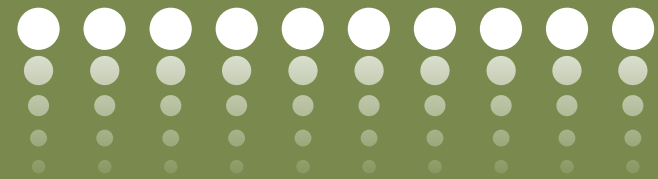
	Product Name	RS	Description	Ref.	Presentation	THROMBIN TIME			
						PT	aPTT	FIBRINOGEN	
CALIBRATORS	EASYPLASMA™ Calibrator	CE-IVD	Normal Human Plasma for the calibration of several coagulation factors (PT%, Fibrinogen); it may also be used as normal control plasma (PT, aPTT, TT)	226601	6 x 1 mL	●	●	●	●
	BIOPHEN™ Plasma Calibrator	CE-IVD 510(K)	Normal Human Plasma for the calibration of AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, α2-AP, vWF: Ag	222101	12 x 1 mL			●	
	PT Calibrator Set	CE-IVD	Five certified plasmas for PT/INR and PT% calibration and/or for verification of local ISI test system	SC084K	CAL1: 2 x 1 mL CAL2: 2 x 1 mL CAL3: 2 x 1 mL CAL4: 2 x 1 mL CAL5: 2 x 1 mL	●			
CONTROLS	EASYPLASMA™ Control Set	CE-IVD	Routine quality control plasmas for PT/INR/%, aPTT, Fibrinogen (Fbg) and Thrombin Time (TT) C1 Normal control plasma: Normal citrated human plasma, lyophilized. C2 Abnormal control plasma: Abnormal citrated human plasma, lyophilized	225601	C1: 6 x 1 mL C2: 6 x 1 mL	●	●	●	●
	BIOPHEN™ Normal Control Plasma	CE-IVD 510(K)	Normal quality control plasma for AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, aPCr (%FVL), lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag, α2-AP and Thrombin Time	223201	12 x 1 mL	●	●	●	●
	BIOPHEN™ Abnormal Control Plasma	CE-IVD 510(K)	Abnormal quality control plasma for AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag and α2-AP	223301	12 x 1 mL	●	●	●	
	LA Control Plasma	CE-IVD	Quality control plasmas, weak and high positive, for Lupus Anticoagulant	SC081K	C1: 6 x 0.5 mL C2: 6 x 0.5 mL		●		
	LA Control Plasma Weak	CE-IVD	Quality control plasmas, weak positive, for Lupus Anticoagulant	SC082K	C1: 6 x 0.5 mL		●		
	LA Control Plasma High	CE-IVD	Quality control plasmas, high positive, for Lupus Anticoagulant	SC083K	C2: 6 x 0.5 mL		●		





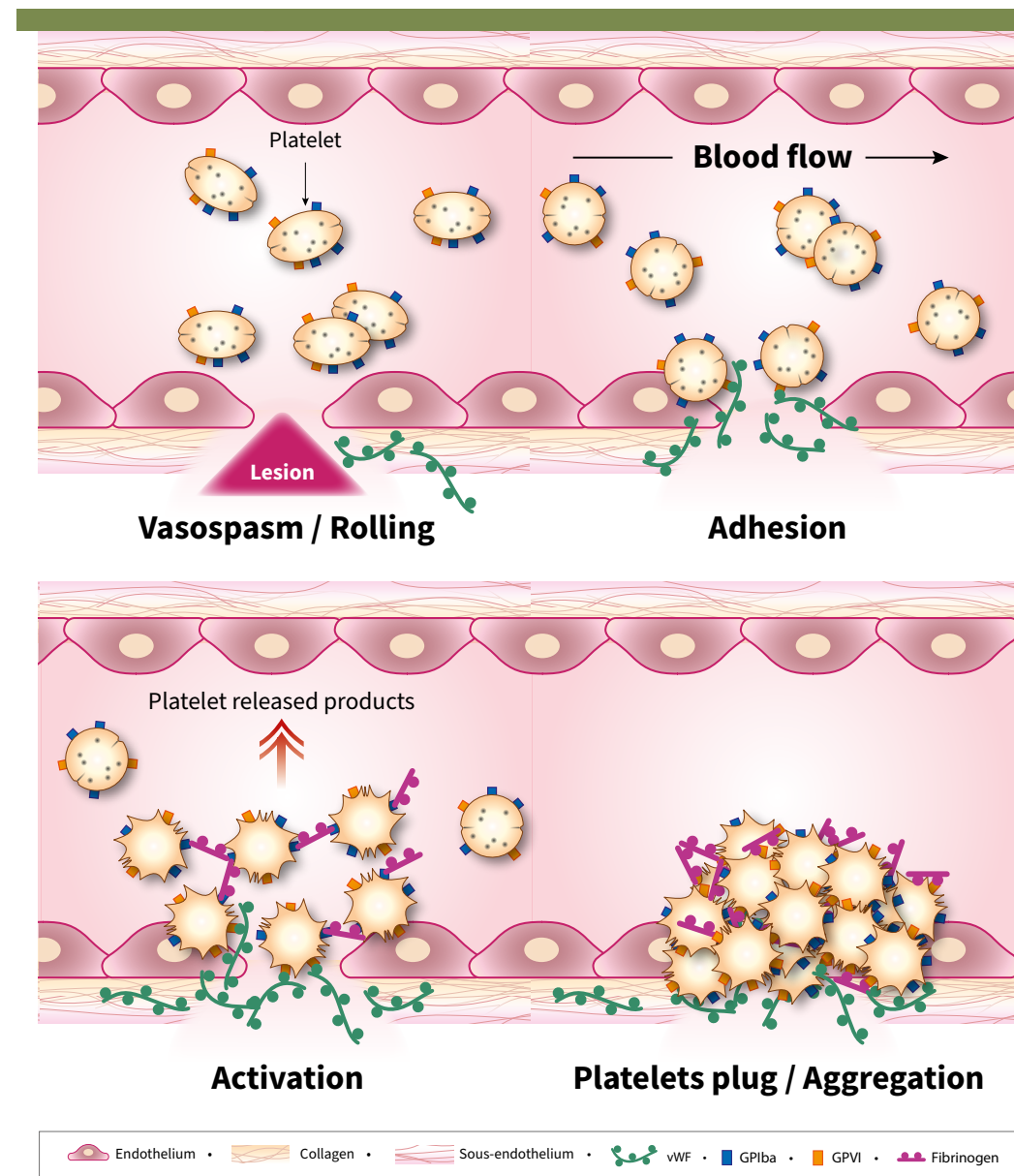


# PRIMARY HEMOSTASIS



## PLATELETS' ROLE

In the event of a vascular breach, blood platelets contribute to maintain the vessels' integrity by ensuring primary hemostasis, before being involved for coagulation. Exploring platelet functions is therefore highly useful for diagnosis of platelets anomalies and monitoring anti-aggregant treatments.



## PLATELET AGGREGATION

### ADP

Screening for thrombocytopathy, whether systemic or acquired.  
Biological monitoring of anti-platelet therapy.

REAGENT				AVAILABLE ON		
Product Name	RS	Ref.	Presentation	Aggregometer	Sysmex analyzers	
					CS Series except CS 1600	CN series
• ADP	CE-IVD	AG001K	3 x 0.1 µmol	●	●	●

### Arachidonic Acid

Screening for thrombocytopathy, whether systemic or acquired.  
Biological monitoring of anti-platelet therapy.

REAGENT				AVAILABLE ON		
Product Name	RS	Ref.	Presentation	Aggregometer	Sysmex analyzers	
					CS Series except CS 1600	CN series
• Arachidonic Acid	CE-IVD	AG003K	3 x 7.5 µmol	●	●	●

### Epinephrine

Screening for thrombocytopathy, whether systemic or acquired.  
Biological monitoring of anti-platelet therapy.

REAGENT				AVAILABLE ON		
Product Name	RS	Ref.	Presentation	Aggregometer	Sysmex analyzers	
					CS Series except CS 1600	CN series
• Epinephrine	CE-IVD	AG002K	3 x 0.5 µmol	●	●	●

### Collagen

Detection of constitutional thrombocytopathy or acquired thrombocytopathy.  
Biological monitoring of anti-platelet therapy.

REAGENT				AVAILABLE ON		
Product Name	RS	Ref.	Presentation	Aggregometer	Sysmex analyzers	
					CS Series except CS 1600	CN series
• Collagen	CE-IVD	AG005K	R1: 3 x 0.5 mg R2: 3 x 12 mL	●	●	●

## Ristocetin

For Ristocetin-Induced Platelet Aggregation (RIPA) tests. To detect von Willebrand disease, more specifically to highlight an increased affinity of von Willebrand Factor (vWF) for GPIIb $\alpha$  in type 2B and to identify Bernard-Soulier syndrome.

REAGENT				AVAILABLE ON		
Product Name	RS	Ref.	Presentation	Aggregometer	Sysmex analyzers	
					CS Series except CS 1600	CN series
• Ristocetin	CE-IVD	AG004K	3 x 7.5 mg	●	●	●

## OTHER RELATED ASSAYS

### Lyophilized Platelets

Platelets for Ristocetin cofactor activity assay (vWF:RCO).

REAGENT			
Product Name	RS	Ref.	Presentation
• Lyophilized Platelets	CE-IVD	AG006K on-demand	R1: 3 x 5 mL R2: 3 x 5 mL

### LIAPHEN™ vWF: Ag

Determination of von Willebrand Factor Antigen (vWF: Ag), in human citrated plasma with a Latex turbidimetric assay.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• LIAPHEN™ vWF:Ag Liquid and Ready to use	CE-IVD	120206	R1: 4 x 5 mL R2: 4 x 6 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301

### ZYMUTEST™ vWF

Determination of von Willebrand Factor (vWF) in human plasma with an Elisa method.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ vWF	CE-IVD	RK030A	96 tests

### ZYMUTEST™ vWF:CBA

Determination of human von Willebrand Factor (vWF) Collagen Binding Activity (CBA) in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ vWF:CBA	CE-IVD	RK038A	96 tests



## • Research •

### vWF Deficient Plasma

For any study or research protocol where a source of human vWF deficient plasma is required. This plasma is also FVIII deficient.

#### REAGENT

Product Name	RS	Ref.	Presentation
• vWF Deficient Plasma	RUO	DP150K	6 X 1 mL



## • Research •

### ZYMUTEST™ PF4

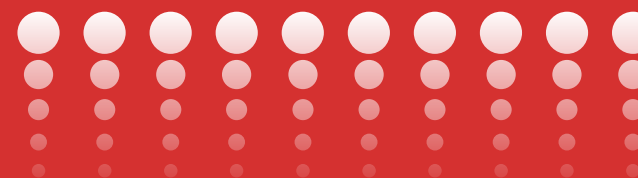
Measurement of human Platelet Factor 4 (PF4) by Elisa in platelet depleted plasma.

#### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ PF4	RUO	RK006A	96 tests



# BLEEDING DISORDERS





Factors assay portfolio:

		Intrinsic Pathway				Extrinsic Pathway		Common Pathway			
		Factor XII	Factor XI	Factor IX	Factor VIII:C	Factor VII	Factor VII-X	Factor X	Pro-thrombin	Factor V	Factor XIII
Clotting Assay	Deficient Plasma	DP080A - DP080K	DP070A - DP070K	DP050A - DP050K	DP040A - DP040K	DP030A - DP030K		DP060A - DP060K	DP010A - DP010K	DP020A - DP020K	DP200K
	In combination with	CK511K CK512K CK515K - CK515L	CK511K CK512K CK515K - CK515L	CK511K CK512K CK515K - CK515L	CK511K CK512K CK515K - CK515L	CK581 CK582 CK583 CK584K - CK584L CK586K - CK586L		CK581 CK582 CK583 CK584K - CK584L CK586K - CK586L	CK581 CK582 CK583 CK584K - CK584L CK586K - CK586L	CK581 CK582 CK583 CK584K - CK584L CK586K - CK586L	
	HEMOCLOT™						CK051K - CK051L				
	In combination with						CK581 CK582 CK583 CK584K - CK584L CK586K - CK586L				
Chromogenic Assay	BIOPHEN™			221801 221802 221806	227102 221402 221406	221304		221705			227005**
Elisa Assay	ZYMATEST™			RK032A	RK039A* on-demand	RK036A		RK033A		RK009A on-demand	RK034A on-demand

\* Inhibitor assay  
\*\* Need a specific wavelength



## HEMOPHILIA A <sup>(1)</sup>

A Factor VIII (FVIII) (or antihemophilic Factor A) deficiency or dysfunction leads to hemophilia A, which is an hereditary or congenital hemorrhagic disease.

Elevated concentrations of FVIII are observed in inflammatory or hepatic diseases and may be suggestive of an increased risk of venous thrombosis.

The FVIII concentration is increased during pregnancy.

### BIOPHEN™ FVIII Variant

Determination of Factor VIII (FVIII) activity in human citrated plasma or FVIII concentrates. Design with FX from bovine origin thus in intensive to Emicizumab.

REAGENT				CALIBRATOR		CONTROLS		
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.	
• BIOPHEN™ FVIII Variant	CE-IVD	227102	R1: 2 x 2.5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201	
			R2: 2 x 2.5 mL				• BIOPHEN™ Abnormal Control Plasma	223301
			R3: 2 x 2.5 mL					
			R4: 4 x 20 mL					

### BIOPHEN™ FVIII:C

Determination of Factor VIII activity (FVIII:C) in citrated human plasma or therapeutic concentrates.

REAGENT				CALIBRATOR		CONTROLS		
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.	
• BIOPHEN™ FVIII:C	CE-IVD	221402	R1: 2 x 2.5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201	
			R2: 2 x 2.5 mL				• BIOPHEN™ Abnormal Control Plasma	223301
			R3: 2 x 2.5 mL					
			R4: 4 x 25 mL					
			221406					R1: 2 x 6 mL
								R2: 2 x 6 mL
		R3: 2 x 6 mL						
		R4: 4 x 25 mL						

### Factor VIII:C Deficient Plasma

Used in combination with the CEPHEN™ (ref. CK511K – CK512K – CK515K – CK515L) to measure Factor VIII:C clotting activity in human citrated plasma, in the presence of cephalin, activator (aPTT reagent) and calcium.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• Factor VIII:C Deficient Plasma	CE-IVD	DP040A	1 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
		DP040K	6 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301

(1) cf Dedicated instructions for use

## DIAGNOSTIC OF INHIBITORS

### ZYMUTEST™ Anti-VIII MonoStrip IgG

Measurement of auto and allo-antibodies to FVIII, of the IgG isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-VIII MonoStrip IgG	CE-IVD	RK039A on-demand	32 tests

## HEMOPHILIA B <sup>(1)</sup>

A Factor IX (FIX) (or antihemophilic Factor B) deficiency or dysfunction leads to the hemophilia B disease, an hereditary or congenital coagulation disorder. FIX levels are reduced in patients receiving anti-vitamin K treatment, or in diseases such as liver disorders, cirrhosis or DIC. High FIX concentrations may be suggestive of an increased risk of venous thrombosis.

### BIOPHEN™ FIX

Determination of FIX activity in citrated human plasma or therapeutic concentrates.

REAGENT				CALIBRATOR		CONTROLS		
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.	
• BIOPHEN™ FIX	CE-IVD	221801	R1: 2 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201	
			R2: 2 x 1 mL				• BIOPHEN™ Abnormal Control Plasma	223301
			R3: 2 x 1 mL					
			R4: 2 x 15 mL					
		221802	R1: 2 x 2.5 mL					
			R2: 2 x 2.5 mL					
			R3: 2 x 2.5 mL					
			R4: 2 x 25 mL					
		221806	R1: 2 x 6 mL					
			R2: 2 x 6 mL					
			R3: 2 x 6 mL					
			R4: 4 x 25 mL					

### Factor IX Deficient Plasma

Used in combination with CEPHEN™ (ref. CK511K – CK512K – CK515K – CK515L) to measure FIX clotting activity in human citrated plasma, in the presence of cephalin, activator (aPTT reagent) and calcium.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• Factor IX Deficient Plasma	CE-IVD	DP050A	1 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
		DP050K	6 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301

(1) cf Dedicated instructions for use

### ZYMUTEST™ Factor IX

Measurement of FIX in human plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Factor IX	RUO	RK032A	96 tests

### VON WILLEBRAND DISEASE (VWD) <sup>(3)</sup>

Willebrand's disease is the most common bleeding disorder. It concerns a group of various types of von Willebrand disease. vWF functional or quantitative deficiency allows characterizing von Willebrand disease, which can be classed into 3 types:

- Type 1: vWD is characterized by a partial quantitative deficit of vWF (most frequently).
- Type 2: vWD is characterized by an abnormal vWF adhesion activity. It is divided into 4 subtypes: 2A, 2B, 2M and 2N, depending on the multimers functional abnormality.
- Type 3: vWD is characterized by a severe quantitative vWF deficiency.

vWF deficiencies can be associated with various other pathologies, thus constituting an acquired von Willebrand disease. When vascular endothelium is affected, the vWF concentration can be increased in relation to inflammatory processes.

### LIAPHEN™ vWF:Ag

Measurement of von Willebrand Factor Antigen (vWF: Ag), in human citrated plasma, with a latex turbidimetric assay.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• LIAPHEN™ vWF:Ag Liquid and Ready to use	CE-IVD	120206	R1: 4 x 5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 4 x 6 mL			• BIOPHEN™ Abnormal Control Plasma	223301

### ZYMUTEST™ vWF

Measurement of von Willebrand Factor (vWF) in human plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ vWF	CE-IVD	RK030A	96 tests

### ZYMUTEST™ vWF:CBA

Measurement of human von Willebrand Factor (vWF) Collagen Binding Activity (CBA) in human activated plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ vWF:CBA	CE-IVD	RK038A	96 tests

(3) [www.hemophilia.org](http://www.hemophilia.org)

### vWF Deficient Plasma

For any study or research protocol where a source of human vWF deficient plasma is required.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• vWF Deficient Plasma	RUO	DP150K	6 x 1 mL

### OTHER BLEEDING DISORDERS

#### FACTOR XII (FXII) <sup>(1,3)</sup>

Most affected individuals with FXII deficiency are asymptomatic and have rarely a mild tendency to bleed. However, they can show an impaired fibrinolysis, which can expose them to thrombosis.

Since bleeding time is usually normal, diagnosis is characterized by a prolonged activated partial thromboplastin time (aPTT) test. A specific FXII assay helps to confirm the diagnosis.

#### Factor XII Deficient Plasma

Used in combination with CEPHEN™ (ref. CK511K – CK512K – CK515K – CK515L) to measure FXII clotting activity in human citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• Factor XII Deficient Plasma	CE-IVD	DP080A	1 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
		DP080K	6 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301

#### FACTOR XI (FXI) <sup>(2)</sup>

FXI deficiency is a very rare disease. It is an inherited genetic disorder, affecting both women and men. Bleeding has a variable expression in the affected kindreds, it is not always dependent on the residual FXI concentration.

#### Factor XI Deficient Plasma

Used in combination with CEPHEN™ (ref. CK511K – CK512K – CK515K – CK515L) to measure FXI clotting activity in human citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• Factor XI Deficient Plasma	CE-IVD	DP070A	1 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
		DP070K	6 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301

(1) cf Dedicated instructions for use - (2) [www.afh.asso.fr](http://www.afh.asso.fr) - (3) [www.hemophilia.org](http://www.hemophilia.org)

## FACTOR VII (FVII)<sup>(3)</sup>

Autosomal recessive inheritance.

FVII can be deficient in presence of vitamin K deficiency (hepatic diseases, primary biliary cirrhosis, deficiency in new-borns, antibiotherapy, ...), vitamin K antagonists (dicoumarol therapy, ...), isolated deficiencies of FVII or accelerated clotting factor consumption (DIC).

### Factor VII Deficient Plasma

Used in combination with PT-Phen™ (ref. CK581 - CK582 - CK583 - CK584K - CK584L - CK586K - CK586L) to measure FVII clotting activity in human citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• Factor VII Deficient Plasma	CE-IVD	DP030A	1 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
		DP030K	6 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301



• Research •

### BIOPHEN™ FVII

Determination of FVII chromogenic activity in purified medium or citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ FVII	RUO	221304	R1: 2 x 4 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 2 x 2 mL			• BIOPHEN™ Abnormal Control Plasma	223301
			R3: 2 x 4 mL				
			R4: 4 x 25 mL				



• Research •

### ZYMUTEST™ Factor VII

Measurement of FVII antigen in human plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Factor VII	RUO	RK036A	96 tests

### FACTOR VII+X (FVII+FX)

### HEMOCLOT™ VII+X

Used in combination with PT-Phen™ (ref. CK581 - CK582 - CK583 - CK584K - CK584L - CK586K - CK586L) to measure FVII+FX clotting activity in human citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• HEMOCLOT™ VII+X	CE-IVD	CK051K	6 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
		CK051L	20 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301

## FACTOR X (FX)<sup>(1,2,3)</sup>

• Autosomal recessive inheritance.

• FX deficiency is extremely rare.

• People with mild FX deficiency experience easy bruising, nose or mouth bleeds, and bleeding after trauma or surgery. Symptoms for patients with severe FX deficiency include excessive umbilical cord bleeding, joint bleeds, intramuscular bleeds, and a high risk of intracranial hemorrhage in the first weeks of life.

### Factor X Deficient Plasma

Used in combination with PT-Phen™ (ref. CK581 - CK582 - CK583 - CK584K - CK584L - CK586K - CK586L) to measure FX clotting activity in human citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• Factor X Deficient Plasma	CE-IVD	DP060A	1 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
		DP060K	6 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301



• Research •

### BIOPHEN™ Factor X

Determination of FX chromogenic activity in citrated human plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Factor X	RUO	221705	R1: 4 x 2.5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 4 x 2.5 mL			• BIOPHEN™ Abnormal Control Plasma	223301
			R3: 4 x 5 mL				



• Research •

### ZYMUTEST™ Factor X

Measurement of human FX antigen in human plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Factor X	RUO	RK033A	96 tests

(1) cf Dedicated instructions for use - (2) [www.afh.asso.fr](http://www.afh.asso.fr) - (3) [www.hemophilia.org](http://www.hemophilia.org)





## FACTOR II (FII) / PROTHROMBIN <sup>(1,2,3)</sup>

- Autosomal recessive inheritance.
- Prothrombin deficiency is a rare hereditary coagulation disorder.
- Symptoms include excessive umbilical cord bleeding, easy bruising, frequent nosebleeds and hemorrhaging after surgery or trauma. Women with FII deficiency experience menorrhagia, heavy menstrual bleeding, and postpartum hemorrhage after childbirth.
- Dysprothrombinemia results from a protein abnormality, which affects prothrombin clotting activity.
- Hypoprothrombinemia occurs when prothrombin concentration is decreased.

### Factor II Deficient Plasma

Used in combination with PT-Phen™ (ref. CK581 - CK582 - CK583 - CK584K - CK584L - CK586K - CK586L) to measure Factor II (FII or Prothrombin) clotting activity in human citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• Prothrombin Deficient Plasma	CE-IVD	DP010A	1 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
		DP010K	6 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301

## FACTOR V (FV) <sup>(1)</sup>

- Autosomal recessive inheritance.
- FV is deficient in presence of congenital or acquired FV deficiencies, hepatic disorders or accelerated clotting factor consumption (DIC).
- High levels of FV are risk factors for venous thrombosis.

### Factor V Deficient Plasma

Used in combination with PT-Phen™ (ref. CK581 - CK582 - CK583 - CK584K - CK584L - CK586K - CK586L) to measure FV or Proaccelerin activity in human citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• Factor V Deficient Plasma	CE-IVD	DP020A	1 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
		DP020K	6 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301



### ZYMUTEST™ Factor V

Measurement of human FV antigen in plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Factor V	RUO	RK009A on-demand	96 tests

(1) cf Dedicated instructions for use - (2) [www.afh.asso.fr](http://www.afh.asso.fr) - (3) [www.hemophilia.org](http://www.hemophilia.org)

## FACTOR XIII (FXIII) <sup>(2)</sup>

- Autosomal recessive inheritance.
- Umbilical cord bleeding is common in FXIII deficiency.
- Some patients sustain a spontaneous intracranial hemorrhage, a brain bleed, which is the leading cause of mortality. Other symptoms of FXIII deficiency include bruising, nose and mouth bleeds, muscle bleeds and delayed bleeding after surgery.
- Women can experience menorrhagia, long, heavy menstrual periods, and repeat miscarriages.
- Men with FXIII deficiency may show signs of infertility.
- Acquired FXIII deficiency can be observed in presence of autoantibodies.

### BIOPHEN™ Factor XIII

- Determination of FXIII activity in human citrated plasma.
- Reagent and material required: automatic instrument for chromogenic assays with a wavelength at 340 nm.

REAGENT			
Product Name	RS	Ref.	Presentation
• BIOPHEN™ Factor XIII	CE-IVD	227005	R1: 3 x 4 mL
			R2: 3 x 5 mL



### Factor XIII Deficient Plasma

For any study or research protocol where a source of human FXIII deficient plasma is required.

REAGENT			
Product Name	RS	Ref.	Presentation
• Factor XIII Deficient Plasma	RUO	DP200K	6 x 1 mL



### ZYMUTEST™ Factor XIII-A

Measurement of FXIII (subunit A) in human plasma, by Elisa.

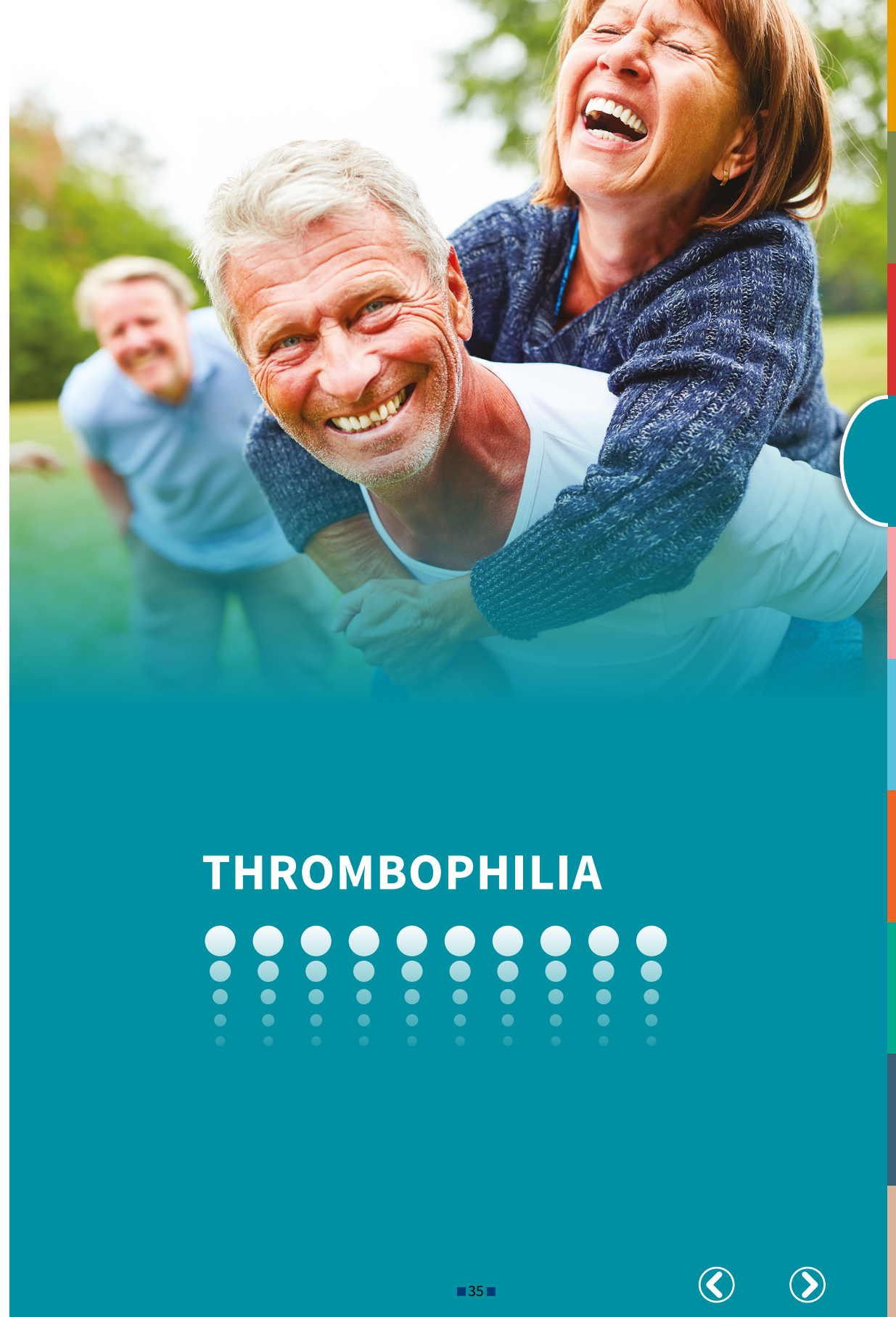
COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Factor XIII-A	RUO	RK034A on demand	96 tests

(2) [www.hemophilia.org](http://www.hemophilia.org)

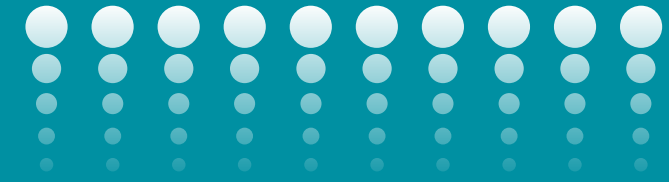


FVIII, FIX, vWF, FXII, FXI, FVII, FVII-X, FX, FII, FV

	Product Name	RS	Description	Ref.	Presentation	
CALIBRATOR	<b>BIOPHEN™ Plasma Calibrator</b>	CE-IVD 510(K)	Normal Human Plasma for the calibration of AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, α2-AP, vWF: Ag.	222101	12 x 1 mL	●
CONTROLS	<b>BIOPHEN™ Normal Control Plasma</b>	CE-IVD 510(K)	Normal quality control plasma for AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, aPCr (%FVL), lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag, α2-AP and Thrombin Time.	223201	12 x 1 mL	●
	<b>BIOPHEN™ Abnormal Control Plasma</b>	CE-IVD 510(K)	Abnormal quality control plasma for AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag and α2-AP.	223301	12 x 1 mL	●



# THROMBOPHILIA



- GLOBAL & ROUTINE TESTS
- PRIMARY HEMOSTASIS
- BLEEDING DISORDERS
- THROMBOPHILIA
- MONITORING ANTICOAGULANT
- FIBRINOLYSIS
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## ANTITHROMBIN (AT)<sup>(1)</sup>

Spontaneous thromboembolic diseases are observed in presence of congenital or acquired deficiencies of antithrombin. These deficiencies are classified in 4 different groups:

- Type I: Decreased AT concentration and decreased AT activity; this is the most frequent case.
- Type II RS (Reactive Site): Normal AT concentration and decreased biological activity; a protein abnormality is present at the active site.
- Type II HBS (Heparin Binding Site): Normal AT concentration, normal AT activity in the absence of heparin, but decreased in its presence.
- Type II (Pleiotropic): Decreased AT concentration and activity; nonfunctional protein and at a lowered level.

### BIOPHEN™ AT anti-(h)-Xa LRT

Determination of AT activity in human citrated plasma, using an anti-Xa chromogenic method (Human Xa).

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ AT anti-(h)-Xa LRT Liquid and Ready to use	CE-IVD	221123	R1: 3 x 3 mL R2: 3 x 3 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201
		221127	R1: 4 x 7.5 mL R2: 4 x 7.5 mL				223301

### BIOPHEN™ AT LRT

Determination of the heparin cofactor activity of AT in human citrated plasma, using an anti-Xa chromogenic method (Bovine Xa).

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ AT LRT Liquid and Ready to use	CE-IVD	221111	R1: 4 x 11 mL R2: 4 x 4 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201
			223301				

### BIOPHEN™ Antithrombin

Determination of AT activity in human citrated plasma, using an anti-Xa chromogenic method (Human Xa).

REAGENT				CALIBRATOR		CONTROLS		
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.	
• BIOPHEN™ Antithrombin	CE-IVD 510(k)	221102	R1: 2 x 2.5 mL R2: 2 x 2.5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201	
			221105				R1: 4 x 5 mL R2: 4 x 5 mL	223301
			221105				R3: 4 x 10 mL	223301

(1) cf Dedicated instructions for use



## BIOPHEN™ AT (Anti-IIa)

Determination of AT activity, in presence of an excess of heparin, in human citrated plasma or purified milieue, using an anti-IIa chromogenic method (Bovine IIa).

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ AT (Anti-IIa)	CE-IVD	221122	R1: 2 x 2.5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 2 x 2.5 mL			• BIOPHEN™ Abnormal Control Plasma	223301
			R3: 2 x 2.5 mL				

## LIAPHEN™ AT

Determination of Antithrombin antigen (AT:Ag) in human citrated plasma using a latex turbidimetric assay.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• LIAPHEN™ AT Liquid and Ready to use	CE-IVD	120002	R1: 2 x 2 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 2 x 10 mL			• BIOPHEN™ Abnormal Control Plasma	223301
		120008	R1: 2 x 1.5 mL				
			R2: 2 x 5 mL				

## PROTEIN C (PC) <sup>(1)</sup>

Assay of coagulation PC in plasma helps for the detection of congenital or acquired PC deficiencies.

Acquired deficiencies are observed in hepatic diseases, during VKA therapy or in Disseminated Intravascular Coagulation (DIC), among other contexts.

Congenital deficiencies can be quantitative (Type I) or qualitative (Type II) and are associated with recurrent venous thromboses.

Congenital or acquired PC deficiency is a risk factor for venous thrombosis.

## HEMOCLOT™ Protein C

Determination of PC in human citrated plasma with a clotting method.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• HEMOCLOT™ Protein C	CE-IVD	CK031K	R1: 3 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 3 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301
		CK032K	R1: 3 x 2 mL				
			R2: 3 x 2 mL				

(1) cf Dedicated instructions for use

## BIOPHEN™ Protein C LRT

Determination of PC activity in human citrated plasma with a chromogenic assay, in liquid format.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Protein C LRT Liquid and Ready to use	CE-IVD	221211	R1: 3 x 3 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 3 x 3 mL			• BIOPHEN™ Abnormal Control Plasma	223301

## BIOPHEN™ Protein C 5

Determination of PC activity in human citrated plasma with a chromogenic assay.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Protein C 5	CE-IVD 510(k)	221205	R1: 4 x 5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 4 x 5 mL			• BIOPHEN™ Abnormal Control Plasma	223301

## ZYMUTEST™ Protein C

Determination of human PC antigen in human plasma by Elisa.

REAGENT			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Protein C	CE-IVD	RK027A	96 tests

## LIAPHEN™ Protein C

Determination of Protein C antigen in human citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• LIAPHEN™ Protein C	CE-IVD	120003	R1: 4 x 5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 4 x 2.3 mL			• BIOPHEN™ Abnormal Control Plasma	223301



• Research •

## Protein C Deficient Plasma

Lyophilized, human citrated plasma, deficient for PC, for any protocol or research study where a source of human PC deficient plasma is required.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• Protein C Deficient Plasma	RUO	DP100K	6 x 1 mL	-	-	-	-



## PROTEIN S (PS) <sup>(1)</sup>

Congenital or acquired PS deficiencies are associated with an increased risk of venous thromboembolism.

In the early stages of inflammatory diseases, free PS concentration is decreased because of an elevation of C4b-BP. PS may be decreased in various contexts such as dicoumarol or L-asparaginase therapy, in hepatic disorders, nephrotic syndrome, during pregnancy, related to oral contraceptives intake or oestrogen therapy, viral infections, DIC. Free PS may also be decreased in new-borns. PS is slightly lower in females than in males.

Inherited PS deficiencies are classified into three types:

- Type I: decreased total and free PS levels (quantitative defects).
- Type II: decreased PS activity but normal antigenic levels (rare qualitative defects).
- Type III: normal levels of total PS but decreased free PS (free form distribution defect).

### LIAPHEN™ Free Protein S

Determination of free PS Antigen (free PS:Ag) in human citrated plasma with a latex turbidimetric assay.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• LIAPHEN™ Free Protein S Liquid and Ready to use	CE-IVD	120004	R1: 4 x 3 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 4 x 4.4 mL			• BIOPHEN™ Abnormal Control Plasma	223301

### HEMOCLOT™ Protein S

Determination of PS activity in citrated human plasma with a clotting method.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• HEMOCLOT™ Protein S	CE-IVD	CK041K	R1: 3 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 3 x 1 mL			• BIOPHEN™ Abnormal Control Plasma	223301
		CK042K	R1: 3 x 2 mL			• BIOPHEN™ Normal Control Plasma	223201
			R2: 3 x 2 mL				

### ZYMUTEST™ Free Protein S (II)

Determination of Free PS (the activated Protein C (aPC) cofactor) in human plasma by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Free Protein S (II)	CE-IVD	RK015B on-demand	96 tests

### ZYMUTEST™ Total Protein S

Measurement of human Total PS in plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Total Protein S	CE-IVD	RK021A	96 tests

(1) cf Dedicated instructions for use



Research

### Protein S Deficient Plasma

Lyophilized, human citrated plasma, deficient for PS, for any protocol or research study where a source of human PS deficient plasma is required.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• Protein S Deficient Plasma	RUO	DP110K	6 x 1 mL	-	-	-	-

## FACTOR V LEIDEN <sup>(1)</sup>

Factor V Leiden (FV-L) mutation is the most common hereditary thrombophilia risk factor. Patients carrying FV-L mutation have an increased risk of venous thrombosis.

This genetic anomaly can be evidenced with clotting assays, performed in presence or absence of APC.

### HEMOCLOT™ Quanti. VL

Quantitative determination of FV-L, by measuring its resistance to the inactivation by APC, in the presence of PS, in human citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• HEMOCLOT™ Quanti. VL	CE-IVD 510(k)	CK065K	R1: 3 x 2 mL	• BIOPHEN™ V-L Plasma Calibrator	222401	• BIOPHEN™ Normal Control Plasma	223201
			R2: 3 x 1 mL			• BIOPHEN™ V-L Control Plasma	223405

## PROTEIN Z (PZ)



Research

### ZYMUTEST™ Protein Z

Measurement of human PZ in plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Protein Z	RUO	RK031A	96 tests

(1) cf Dedicated instructions for use



## LUPUS ANTICOAGULANT (LA) <sup>(1)</sup>

LA are associated with numerous clinical states including e.g. lupus, autoimmune diseases, thrombosis, foetal loss and must usually be confirmed from multiple assays.

### CEPHEN™

#### CEPHEN™

Activated Partial Thromboplastin Time (aPTT) with low sensitivity to the presence of LA.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• CEPHEN™ Liquid aPTT Ready to use	CE-IVD	CK511K	6 x 1 mL	-	-	• LA Control Plasma	SC081K
		CK512K	6 x 2.5 mL	-	-	• LA Control Plasma Weak	SC082K
		CK515K	8 x 5 mL	-	-	• LA Control Plasma High	SC083K
		CK515L	12 x 5 mL	-	-	• BIOPHEN™ Normal Control Plasma	223201
						• BIOPHEN™ Abnormal Control Plasma	223301
						• EASYPLASMA™ Control Set	225601

#### CEPHEN™ LS

Activated Partial Thromboplastin Time (aPTT) with high LA sensitivity, to confirm its presence.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• CEPHEN™ LS Liquid aPTT Lupus sensitive Ready to use	CE-IVD	CK521K	6 x 1 mL	-	-	• LA Control Plasma	SC081K
		CK522K	6 x 2.5 mL	-	-	• LA Control Plasma Weak	SC082K
						• LA Control Plasma High	SC083K
						• BIOPHEN™ Normal Control Plasma	223201
						• BIOPHEN™ Abnormal Control Plasma	223301
						• EASYPLASMA™ Control Set	225601

### HEMOCLOT™

#### HEMOCLOT™ LA-S

Diluted Russell's Viper Venom Test (dRVVT) to screen for the presence of LA.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• HEMOCLOT™ LA-S	CE-IVD	CK090K	6 x 1 mL	-	-	• LA Control Plasma	SC081K
		CK094K	12 x 2 mL	-	-	• LA Control Plasma Weak	SC082K
						• LA Control Plasma High	SC083K
						• BIOPHEN™ Normal Control Plasma	223201

### HEMOCLOT™ LA-C

Diluted Russell's Viper Venom Test (dRVVT) with high Phospholipid content to confirm for the presence of LA.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• HEMOCLOT™ LA-C	CE-IVD	CK091K	6 x 1 mL	-	-	• LA Control Plasma	SC081K
						• LA Control Plasma Weak	SC082K
						• LA Control Plasma High	SC083K
						• BIOPHEN™ Normal Control Plasma	223201

#### BIOPHEN™ NormalPlasma

Source of lyophilized normal human plasma, which should be qualified by the laboratory for its specific application.

REAGENT			
Product Name	RS	Ref.	Presentation
• BIOPHEN™ NormalPlasma 2	CE-IVD	223602	10 x 2 mL
• BIOPHEN™ NormalPlasma 5		223605	8 x 5 mL

### Anti-Cardiolipin / Anti-Phospholipid Antibodies

Assay of anti-cardiolipin/anti-phospholipid antibodies causing the anti-phospholipid syndrome (APS), and able to provoke recurrent miscarriages, unexplained thrombosis. Assays intended to investigate any clinical situation where anti-Cardiolipin/anti-phospholipid antibodies can be present.

#### ZYMUTEST™ ACA-APA - IgG - Isotype

Measurement of anti-cardiolipin / anti-phospholipid antibodies of the IgG isotype, in human plasma or serum, or in any biological fluid, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ ACA-APA - IgG - Isotype	CE-IVD	RK029A on-demand	96 tests

#### Anti-β2GPI Autoantibodies

Assay of autoantibodies to β2GPI of the IgG isotype, in case of anti-phospholipid syndrome, recurrent unexplained miscarriages, unexplained lupus anticoagulant, without or with thrombosis, any clinical situation where the assay of anti-β2GPI autoantibodies is required.

#### ZYMUTEST™ ANTI β2-GLYCOPROTEIN I - IgG - Isotype

Measurement of autoantibodies to β2GPI of the IgG isotype, in human plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ ANTI β2-GLYCO- PROTEIN I - IgG - Isotype	CE-IVD	RK014A on-demand	96 tests

(1) cf Dedicated instructions for use



## OTHER AUTOANTIBODIES



• Research •

### ZYMUTEST™ Anti-Annexin V, IgG

Measurement of autoantibodies to Annexin V of the IgG isotype, in human plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-Annexin V, IgG	RUO	RK005A on-demand	96 tests



• Research •

### ZYMUTEST™ Anti-Annexin V, IgM

Measurement of autoantibodies to Annexin V of the IgM isotype, in human plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-Annexin V, IgM	RUO	RK005B on-demand	96 tests



• Research •

### ZYMUTEST™ Anti-PROTEIN S IgG-Isotype

Measurement of autoantibodies to PS of the IgG isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-PROTEIN S IgG- Isotype	RUO	RK020A on-demand	96 tests



• Research •

### ZYMUTEST™ Anti-PROTEIN S IgM-Isotype

Measurement of autoantibodies to PS of the IgM isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-PROTEIN S IgM- Isotype	RUO	RK020B on-demand	96 tests



• Research •

### ZYMUTEST™ Anti-PROTEIN Z IgG-Isotype

Measurement of autoantibodies to Protein Z of the IgG isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-PROTEIN Z IgG- Isotype	RUO	RK025A on-demand	96 tests



• Research •

### ZYMUTEST™ Anti-PROTEIN Z IgM-Isotype

Measurement of autoantibodies to Protein Z of the IgM isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-PROTEIN Z IgM- Isotype	RUO	RK025B on-demand	96 tests



• Research •

### ZYMUTEST™ Anti-Prothrombin IgG

Measurement of autoantibodies to Prothrombin, of the IgG isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-Prothrombin IgG	RUO	RK007A on-demand	96 tests



## PHOSPHOLIPID BINDING PROTEINS



• Research •

### ZYMUTEST™ β2GPI

Immuno-assay for measuring human Beta 2 Glycoprotein I (β2GPI) in plasma, by Elisa.

#### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ β2GPI	RUO	RK022A on-demand	96 tests



• Research •

### ZYMUTEST™ Annexin V

Measurement of human Annexin V in plasma, by Elisa.

#### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Annexin V	RUO	RK004A on-demand	96 tests

## BLOOD ACTIVATION BIOMARKERS



• Research •

### ZYMUTEST™ DDimer

Measurement of the Fibrin Degradation Products (DDimer) in plasma, by Elisa.

#### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ DDimer	RUO	RK023A on-demand	96 tests



• Research •

### ZYMUTEST™ FPA

Determination of human FPA, tested on bentonite adsorbed human plasma, using a Competitive Enzyme Linked Immuno Assay (CELIA). Fibrinogen, when present in the specimen, must be removed (i.e., bentonite adsorption of human plasma), as it cross-reacts with antibodies to FPA.

#### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ FPA	RUO	RK016B	96 tests



• Research •

### ZYMUTEST™ CRP

High sensitive measurement of human CRP in plasma, by Elisa.

#### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ CRP	RUO	RK010A on-demand	96 tests



• Research •

### ZYMUPHEN™ MP ACTIVITY

Measurement of microparticles' procoagulant activity in human plasma.

#### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUPHEN™ MP ACTIVITY	RUO	521096 on-demand	96 tests



• Research •

### ZYMUPHEN™ MP-TF

Determination of the procoagulant activity of microparticles exposing Tissue Factor (MP-TF), in human plasma and in purified milieu.

#### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUPHEN™ MP-TF	RUO	521196 on-demand	96 tests



• Research •

### ZYMUTEST™ Tissue Factor (full length)

Determination of Full-Length Tissue Factor (FL-TF) (1-263) on plasma and purified milieu.

#### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Tissue Factor (full length)	RUO	RK035A on-demand	96 tests







## Research

### ZYMUTEST™ Total Tissue Factor

Determination of Tissue Factor (TF) on plasma and purified milieu. This kit does not recognize alternatively spliced Tissue Factor (asTF).

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Total Tissue Factor	RUO	RK042A on-demand	96 tests

## ACTIVATED FACTORS



## Research

### Factor XIa (FXIa)

#### BIOPHEN™ Factor XIa

Measurement of activated Factor XI (FXIa) activity, through FIX activation and Factor Xa generation.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Factor XIa	RUO	220412	R1A: 2 x 3 mL	-	-	• BIOPHEN™ FXIa Control Set	224801
			R1B: 2 x 3 mL				
			R2: 2 x 3 mL				
			R3: 2 x 3 mL				
			R4: 2 x 25 mL				
Cal: 2 x 2 mL							



## Research

### Factor IXa (FIXa)

#### BIOPHEN™ Factor IXa

Determination of FIXa activity, in purified medium.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Factor IXa (ACT. FIX)	RUO	221812	R1: 2 x 2.5 mL	-	-	• BIOPHEN™ FIXa Control Set	224601 on-demand
			R2: 2 x 2.5 mL				
			R3: 2 x 2.5 mL				
			R4: 2 x 25 mL				
			Cal: 2 x 1 mL				

### Factor VIIa (FVIIa)

#### HEMOCLOT™ Factor VIIa

Determination of activated Factor VII (FVIIa) activity, in purified medium or citrated plasma.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• HEMOCLOT™ Factor VIIa	CE-IVD	CK092K	R1: 3 x 2 mL	• BIOPHEN™ Calibrator Factor VIIa	226301	• BIOPHEN™ FVIIa Control Set	224901 on-demand
			R2: 3 x 2 mL				
			R3: 3 x 20 mL				



## Research

#### BIOPHEN™ Factor VIIa

Determination of activated Factor VII (FVIIa) activity, in purified milieu.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Factor VIIa	RUO	221312 on-demand	R1: 2 x 4 mL R2: 2 x 2 mL R3: 2 x 4 mL R4: 2 x 25 mL	-	-	-	-



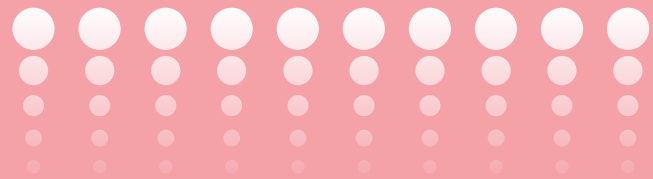
Product Name	RS	Description	Ref.	Presentation																	
					ANTI-THROMBIN	PROTEIN C	PROTEIN S	LUPUS ANTICOAGULANT FACTOR V LEIDEN	FXa	FXIa	FVIIa										
<b>CALIBRATORS</b> <b>BIOPHEN™ Plasma Calibrator</b>	CE-IVD 510(K)	Normal Human Plasma for the calibration of AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, α2-AP, vWF: Ag	222101	12 x 1 mL																	
	CE-IVD 510(K)	For the calibration of FV-L assay	222401	CAL1: 3 x 0.5 mL																	
				CAL2: 3 x 0.5 mL																	
CE-IVD	For the calibration of FVIIa activity measurements	226301	6 x 2 mL																		

Product Name	RS	Description	Ref.	Presentation																		
					ANTI-THROMBIN	PROTEIN C	PROTEIN S	LUPUS ANTICOAGULANT FACTOR V LEIDEN	FXa	FXIa	FVIIa											
<b>CONTROLS</b>	CE-IVD 510(K)	Normal quality control plasma for AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, aPCr (%FVL), lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag, α2-AP and Thrombin Time	223201	12 x 1 mL																		
	CE-IVD 510(K)	Abnormal quality control plasma for AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag and α2-AP	223301	12 x 1 mL																		
	CE-IVD	Quality control plasmas, weak and high positive, for Lupus Anticoagulant	SC081K	C1: 6 x 0.5 mL C2: 6 x 0.5 mL																		
	CE-IVD	Quality control plasmas, weak positive, for Lupus Anticoagulant.	SC082K	C1: 6 x 0.5 mL																		
	CE-IVD	Quality control plasmas, high positive, for Lupus Anticoagulant.	SC083K	C2: 6 x 0.5 mL																		
	CE-IVD 510(K)	Quality control of FV-L	223405	12 x 0.5 mL																		
	CE-IVD	Quality control of FVIIa activity measurements.	224901 on-demand	C1: 3 x 1 mL C2: 3 x 1 mL																		
	RUO	Quality control of FXIa activity measurements	224801	C1: 3 x 1 mL C2: 3 x 1 mL																		
	RUO	Quality control of FIXa activity measurements	224601 on-demand	C1: 6 x 1 mL C2: 6 x 1 mL																		
	CE-IVD	Routine quality control plasmas for PT/INR/%, aPTT, Fibrinogen (Fbg) and Thrombin Time (TT) C1 Normal control plasma: Normal citrated human plasma, lyophilized. C2 Abnormal control plasma: Abnormal citrated human plasma, lyophilized	225601	C1: 6 x 1 mL																		
C2: 6 x 1 mL																						





# MONITORING ANTICOAGULANT



Anticoagulants are widely used to prevent and treat thromboembolic disorders. The major groups are Anti-aggregants, Vitamin K antagonists, Polysaccharide anticoagulants (like heparins) and Direct Oral Anticoagulants (DOACs), targeted to thrombin or Factor Xa. The major risks are bleeding (excess of drug), or recurrent thrombosis (insufficient dosage). Direct Oral Anticoagulants (DOACs) are becoming more and more used. In some situations, such as overdosage, bleeding, urgent surgery or non-compliance with therapeutic protocol, measurement of their anticoagulant activity in plasma is essential. Dedicated assays, calibrated with a like to like drug in plasma, are proposed for these applications. Patient follow-up is based on the evaluation of the response to anticoagulant therapy and the early detection of relapses.

### Assay portfolio for anticoagulants

RS	REAGENT	DRUG	HIT	Isotype	CALIBRATORS												
					Heparin induced Thrombocytopenia												
					UFH	UFH - LMWH	Fondaparinux	Rivaroxaban	Apixaban	Edoxaban	Danaparoid	Argatroban	Bivalirudin	Dabigatran			
CE-IND	BIOPHEN™ Heparin LRT 221011 - 221013 - 221015				●	●	●	●	●	●	●						
	BIOPHEN™ DixaI 221030							●	●	●							
	HEMOCLOT™ Thrombin Inhibitors CK002K - CK002L												●	●	●		
	BIOPHEN™ DTI 220202													●	●		
	ZYMUTEST™ HIA IgM RK040B - on-demand			●													
	ZYMUTEST™ HIA IgA RK040C - on-demand			●													
	ZYMUTEST™ HIA IgG, IgA, IgM RK040E - on-demand			●													
RUO	BIOPHEN™ Heparin (AT+) 221007				●*	●*	●*										
	BIOPHEN™ Anti-Xa (2 stages Heparin Assay) 221005				●*	●*											
	BIOPHEN™ Anti-IIa (2 stages Heparin Assay) 220005				●*												
CE-IND 510 (k)	BIOPHEN™ Heparin 221003 - 221006				●	●	●				●						
	ZYMUTEST™ HIA IgG RK040A			●													
	ZYMUTEST™ HIA IgGAM RK040D			●													
	ZYMUTEST™ HIA Mono Strip, IgG RK041A			●													
ZYMUTEST™ HIA Mono Strip, IgGAM RK041D			●														

\*RUO kit



Assay portfolio for anticoagulants

RS	REAGENT	CONTROLS										DILUTION BUFFER
		UFH	UFH - LMWH	Fondaparinux	Rivaroxaban	Apixaban	Edoxaban	Danaparoid	Argatroban	Bivalirudin	Dabigatran	
		Anti-Xa					Anti-IIa					
CE-IVD	BIOPHEN™ Heparin LRT 221011 - 221013 - 221015	●	●	●	●	●	●	●				●
	BIOPHEN™ DiXaI 221030				●	●	●				●	
	HEMOCLOT™ Thrombin Inhibitors CK002K - CK002L							●	●	●		
	BIOPHEN™ DTI 220202								●	●		
	ZYMUTEST™ HIA IgM RK040B - on-demand											
	ZYMUTEST™ HIA IgA RK040C - on-demand											
	ZYMUTEST™ HIA IgG, IgA, IgM RK040E - on-demand											
	BIOPHEN™ Heparin (AT+) 221007	223101*	223001* 223701*	●*								
	BIOPHEN™ Anti-Xa (2 stages Heparin Assay) 221005	223101*	223001* 223701*									
	BIOPHEN™ Anti-IIa (2 stages Heparin Assay) 220005	223101*										
CE-IVD 510 (K)	BIOPHEN™ Heparin 221003 - 221006	●	●	●			●					
	ZYMUTEST™ HIA IgG RK040A											
	ZYMUTEST™ HIA IgGAM RK040D											
	ZYMUTEST™ HIA Mono Strip, IgG RK041A											
ZYMUTEST™ HIA Mono Strip, IgGAM RK041D												

\*RUO kit  
\*\*Special dilution buffer reducing heparin Interferences for anti-Xa chromogenic assays

ANTI-XA CHROMOGENIC ASSAYS

BIOPHEN™ Heparin LRT

One stage, kinetics anti-Xa method for the measurement of heparin (UFH, LMWH), its analogs (Arixtra®/Fondaparinux and Orgaran®/Sodium Danaparoid), or direct anti-FXa drugs in human citrated plasma. This method is appropriate for the direct Factor Xa (FXa) inhibitors: Apixaban, Rivaroxaban, and Edoxaban.

REAGENT				CALIBRATORS		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Heparin LRT Liquid and Ready to use	CE-IVD	221011	R1: 4 x 7.5 mL	<ul style="list-style-type: none"> <li>• BIOPHEN™ UFH Calibrator</li> <li>• BIOPHEN™ Heparin Calibrator</li> <li>• BIOPHEN™ Orgaran® Calibrator</li> <li>• BIOPHEN™ Arixtra® Calibrator</li> <li>• BIOPHEN™ Rivaroxaban Plasma Calibrator</li> <li>• BIOPHEN™ Rivaroxaban Calibrator Low</li> <li>• BIOPHEN™ Apixaban Calibrator Low</li> <li>• BIOPHEN™ Apixaban Calibrator</li> <li>• BIOPHEN™ Edoxaban Calibrator Low</li> <li>• BIOPHEN™ Edoxaban Calibrator</li> </ul>	222301	• BIOPHEN™ UFH Control Plasma	223101
			R2: 4 x 7.5 mL			222001	• BIOPHEN™ UFH Control C1
		221013	R1: 3 x 3 mL		222201	• BIOPHEN™ UFH Control C2	223901
			R2: 3 x 3 mL		222501	• BIOPHEN™ LMWH Control Low	223701
		221015	R1: 4 x 5 mL		222701	• BIOPHEN™ LMWH Control Low CI	224301
					226001	• BIOPHEN™ LMWH Control Low CII	224401
			R2: 4 x 5 mL		226101	• BIOPHEN™ LMWH Control Plasma	223001
					226201	• BIOPHEN™ LMWH Control C3	223801
		226401	226501		• BIOPHEN™ LMWH Control C4	224201	
					• BIOPHEN™ Orgaran® Control	223501	
• BIOPHEN™ Arixtra® Control Plasma	224001						
• BIOPHEN™ Rivaroxaban Control Low	225101						
• BIOPHEN™ Rivaroxaban Control Plasma	224501						
• BIOPHEN™ Apixaban Control Low	225201						
• BIOPHEN™ Apixaban Control	225301						
• BIOPHEN™ Edoxaban Control Low	225401						
• BIOPHEN™ Edoxaban Control	225501						



## BIOPHEN™ DiXal

Two-stage, chromogenic anti-Xa method for the measurement of direct Factor Xa inhibitors (DiXals), such as Rivaroxaban, Apixaban or Edoxaban, in citrated human plasma. This method is not suitable for indirect inhibitors such as heparins or Fondaparinux.

REAGENT				CALIBRATORS		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ DiXal	CE-IVD	221030	R1: 3 x 2.5 mL	• BIOPHEN™ Rivaroxaban Plasma Calibrator	222701	• BIOPHEN™ Rivaroxaban Control Low	225101
			R2: 3 x 2.5 mL	• BIOPHEN™ Rivaroxaban Calibrator Low	226001	• BIOPHEN™ Rivaroxaban Control Plasma	224501
			R3: 4 x 20 mL	• BIOPHEN™ Apixaban Calibrator Low	226101	• BIOPHEN™ Apixaban Control Low	225201
				• BIOPHEN™ Apixaban Calibrator	226201	• BIOPHEN™ Apixaban Control	225301
				• BIOPHEN™ Edoxaban Calibrator Low	226401	• BIOPHEN™ Edoxaban Control Low	225401
				• BIOPHEN™ Edoxaban Calibrator	226501	• BIOPHEN™ Edoxaban Control	225501



• Research •

## BIOPHEN™ HEPARIN (AT+)

Kinetics assay for measuring the concentration of heparin, and heparin-like anticoagulants, in human citrated plasma or in any other biological fluid, using an anti-Xa chromogenic method, with the addition of Antithrombin (AT), when endogenous AT concentration is insufficient for measuring heparin.

REAGENT				CALIBRATORS		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ HEPARIN (AT+)	RUO	221007	R1: 2 x 7.5 mL	• BIOPHEN™ UFH Calibrator	222301	• BIOPHEN™ UFH Control	223101
			R2: 2 x 7.5 mL	• BIOPHEN™ Heparin Calibrator	222001	• BIOPHEN™ LMWH Control Plasma	223001
			R3: 2 x 2.5 mL	• BIOPHEN™ Arixtra® Calibrator	222501	• BIOPHEN™ LMWH Control Low	223701



• Research •

## BIOPHEN™ ANTI-Xa (2 Stages Heparin Assay)

Two stages chromogenic anti-Xa method for measuring the activity of heparins (UFH or LMWH), in presence of a constant amount of AT, in compliance with Pharmacopeias. This method can be used for testing heparin in human citrated plasma, or in purified solutions.

REAGENT				CALIBRATORS		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ ANTI-Xa (2 Stages Heparin Assay)	RUO	221005	R1: 2 x 1 mL	• BIOPHEN™ UFH Calibrator	222301	• BIOPHEN™ UFH Control	223101
			R2: 2 x 1 mL			• BIOPHEN™ LMWH Control Plasma	223001
			R3: 2 x 1 mL			• BIOPHEN™ Heparin Calibrator	222001



• Research •

## BIOPHEN™ ANTI-IIa (2 Stages Heparin Assay)

Two stages chromogenic anti-IIa assay for measuring the activity of heparins (UFH or LMWH), in presence of a constant amount of AT, in compliance with Pharmacopeias. This method can be used for testing heparin in human citrated plasma, or in purified solutions.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ ANTI-IIa (2 Stages Heparin Assay)	RUO	220005	R1: 2 x 1 mL	• BIOPHEN™ UFH Calibrator	222301	• BIOPHEN™ UFH Control	223101
			R2: 2 x 1 mL				
			R3: 2 x 1 mL				



• Research •

## BIOPHEN™ HEPARIN Anti-IIa (kinetics)

One stage, kinetics anti-IIa method for measuring the concentration of heparin, and heparin-like anticoagulants. This method is proposed for testing heparin in buffer, or purified systems. Not suitable for testing plasma.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ HEPARIN Anti-IIa (kinetics)	RUO	221020	R1: 2 x 5 mL	-	-	-	-
			R2: 2 x 10 mL				
			R3: 2 x 10 mL				
			R4: 2 x 20 mL				

## BIOPHEN™ Heparin: lyophilized reagents

Determination of heparin and heparin like anticoagulants. Using an anti-Xa method.

REAGENT				CALIBRATORS		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Heparin	CE-IVD 510(k)	221003	R1: 3 x 3 mL	• BIOPHEN™ UFH Calibrator	222301	• BIOPHEN™ UFH Control Plasma	223101
			R2: 3 x 3 mL			• BIOPHEN™ UFH Control C1	224101
						• BIOPHEN™ UFH Control C2	223901
		221006	R1: 4 x 6 mL			• BIOPHEN™ LMWH Control Low	223701
						• BIOPHEN™ Heparin Calibrator	222001
						• BIOPHEN™ Orgaran® Calibrator	222201
			R2: 4 x 6 mL	• BIOPHEN™ LMWH Control Low CII	222501	• BIOPHEN™ LMWH Control Low CII	224401
				• BIOPHEN™ LMWH Control Plasma		• BIOPHEN™ LMWH Control Plasma	223001
				• BIOPHEN™ LMWH Control C3		• BIOPHEN™ LMWH Control C3	223801
				• BIOPHEN™ LMWH Control C4		• BIOPHEN™ LMWH Control C4	224201



## Tris-NaCl-EDTA buffer, pH 7.85

Special dilution buffer for anti-Xa chromogenic assays, especially using BIOPHEN™ DiXal kit (221030) or BIOPHEN™ Heparin LRT kits (221011/221013/221015).

Special dilution buffer reducing heparin Interferences for anti-Xa chromogenic assays

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris-NaCl-EDTA buffer, pH 7.85	CE-IVD	AR032A on-demand	1 x 20 mL
		AR032K	4 x 20 mL

## DIRECT ANTI-IIA ASSAYS

### HEMOCLOT™ Thrombin Inhibitors

Anti-IIa clotting method for the measurement of Dabigatran and other Direct Thrombin Inhibitors (DTIs), on human citrated plasma. This method is also appropriate for testing Argatroban or Bivalirudin in plasma.

REAGENT				CALIBRATORS		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• HEMOCLOT™ Thrombin Inhibitors	CE-IVD	CK002K	R1: 3 x 1 mL	• BIOPHEN™ Dabigatran Calibrator Low	222901	• BIOPHEN™ Dabigatran Control Low	225001
			R2: 3 x 1 mL				
		CK002L	R1: 3 x 2.5 mL	• Argatroban Plasma Calibrator	SC030K	• Argatroban Control Plasma	SC035K
			R2: 3 x 2.5 mL	• BIOPHEN™ Bivalirudin Calibrator	226701	• BIOPHEN™ Bivalirudin Control	225701

### BIOPHEN™ DTI

Anti-IIa chromogenic method for the determination of Direct Thrombin (FIIa) Inhibitors (DTI) such as Dabigatran and Bivalirudin, in citrated human plasma.

REAGENT				CALIBRATORS		CONTROLS					
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.				
• BIOPHEN™ DTI	CE-IVD	220202	R1: 2 x 2.5 mL	• BIOPHEN™ Dabigatran Calibrator Low	222901	• BIOPHEN™ Dabigatran Control Low	225001				
			R2: 2 x 2.5 mL					• BIOPHEN™ Dabigatran Plasma Calibrator	222801	• BIOPHEN™ Dabigatran Control Plasma	224701
			R3: 2 x 25 mL					• BIOPHEN™ Bivalirudin Calibrator	226701	• BIOPHEN™ Bivalirudin Control	225701

## HEPARIN INDUCED THROMBOCYTOPENIA

Measurement of heparin dependent antibodies.

### ZYMUTEST™ HIA IgG

Detection of heparin-dependent antibodies (anti heparin PF4 complexes) of the IgG isotype, responsible of heparin induced thrombocytopenia (HIT) in human plasma or serum.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ HIA IgG	CE-IVD 510(k)	RK040A	96 tests

### ZYMUTEST™ HIA IgM

Detection of heparin-dependent antibodies (anti heparin PF4 complexes) of the IgM isotype, responsible of heparin induced thrombocytopenia (HIT) in human plasma or serum.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ HIA IgM	CE-IVD	RK040B on-demand	96 tests

### ZYMUTEST™ HIA IgA

Detection of heparin-dependent antibodies of the IgA isotype (anti heparin PF4 complexes), responsible of heparin induced thrombocytopenia (HIT) in human plasma or serum.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ HIA IgA	CE-IVD	RK040C on-demand	96 tests

### ZYMUTEST™ HIA IgGAM

Detection and qualitative screening assay of heparin-dependent antibodies (anti heparin PF4 complexes), responsible of heparin induced thrombocytopenia (HIT) whatever the isotype is: IgG, IgA and IgM, in human plasma or serum.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ HIA IgGAM	CE-IVD 510(k)	RK040D	96 tests



## ZYMUTEST™ HIA IgG, IgA, IgM

Specific isotyping assay.

Screening assay for the detection and the specific assay of heparin-dependent antibodies of IgG, IgA, IgM isotypes, responsible of heparin induced thrombocytopenia (HIT) in human plasma or serum.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ HIA IgG, IgA, IgM	CE-IVD	RK040E on-demand	32 tests

## ZYMUTEST™ HIA MonoStrip IgG

Detection and assay of heparin-dependent antibodies of the IgG isotype (anti heparin PF4 complexes), in human plasma or serum.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ HIA MonoStrip IgG	CE-IVD 510(k)	RK041A	32 tests

## ZYMUTEST™ HIA MonoStrip IgGAM

Detection and screening assay of heparin-dependent antibodies (anti heparin PF4 complexes), responsible of heparin induced thrombocytopenia (HIT) whatever the isotype is: IgG, IgA and IgM, in human plasma or serum.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ HIA MonoStrip IgGAM	CE-IVD 510(k)	RK041D	32 tests





Product Name	RS	Description	Ref.	Presentation	Approximate Content	ANTICOAGULANTS																			
						UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN										
<b>BIOPHEN™ UFH Calibrator</b>	CE-IVD 510(K)	UFH calibrator plasma set	222301	CAL1: 4 x 1 mL	0 IU/mL																				
				CAL2: 4 x 1 mL	0.35 IU/mL																				
				CAL3: 4 x 1 mL	0.70 IU/mL	●																			
				CAL4: 4 x 1 mL	1.05 IU/mL																				
				CAL5: 4 x 1 mL	1.40 IU/mL																				
<b>BIOPHEN™ Heparin Calibrator</b>	CE-IVD 510(K)	LMWH calibrator plasma set	222001	CAL1: 4 x 1 mL	0 IU/mL																				
				CAL2: 4 x 1 mL	0.40 IU/mL																				
				CAL3: 4 x 1 mL	0.80 IU/mL	●	●																		
				CAL4: 4 x 1 mL	1.20 IU/mL																				
				CAL5: 4 x 1 mL	1.60 IU/mL																				
<b>BIOPHEN™ Arixtra® Calibrator</b>	CE-IVD	Arixtra® calibrator plasma set	222501	CAL1: 3 x 1 mL	0 µg/mL																				
				CAL2: 3 x 1 mL	0.50 µg/mL																				
				CAL3: 3 x 1 mL	1 µg/mL																				
				CAL4: 3 x 1 mL	1.50 µg/mL																				
<b>BIOPHEN™ Riva-roxaban Plasma Calibrator</b>	CE-IVD	Riva-roxaban calibrator plasma set, standard range	222701	CAL1: 4 x 1 mL	50 ng/mL																				
				CAL2: 4 x 1 mL	250 ng/mL																				
				CAL3: 4 x 1 mL	500 ng/mL																				
<b>BIOPHEN™ Riva-roxaban Calibrator Low</b>	CE-IVD	Riva-roxaban calibrator plasma set, low range	226001	CAL1: 4 x 1 mL	0 ng/mL																				
				CALII: 4 x 1 mL	50 ng/mL																				
				CALIII: 4 x 1 mL	100 ng/mL																				
<b>BIOPHEN™ Apixaban Calibrator</b>	CE-IVD	Apixaban calibrator plasma set, standard range	226201	CAL1: 4 x 1 mL	50 ng/mL																				
				CAL2: 4 x 1 mL	300 ng/mL																				
				CAL3: 4 x 1 mL	600 ng/mL																				
<b>BIOPHEN™ Apixaban Calibrator Low</b>	CE-IVD	Apixaban calibrator plasma set, low range	226101	CAL1: 4 x 1 mL	0 ng/mL																				
				CALII: 4 x 1 mL	50 ng/mL																				
				CALIII: 4 x 1 mL	100 ng/mL																				

Product Name	RS	Description	Ref.	Presentation	Approximate Content	ANTICOAGULANTS																			
						UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN										
<b>BIOPHEN™ Edoxaban Calibrator</b>	CE-IVD	Edoxaban calibrator plasma set, standard range	226501	CAL1: 4 x 1 mL	0 ng/mL																				
				CAL2: 4 x 1 mL	250 ng/mL																				
				CAL3: 4 x 1 mL	500 ng/mL																				
<b>BIOPHEN™ Edoxaban Calibrator Low</b>	CE-IVD	Edoxaban calibrator plasma set, low range	226401	CALI: 4 x 1 mL	0 ng/mL																				
				CALII: 4 x 1 mL	50 ng/mL																				
				CALIII: 4 x 1 mL	100 ng/mL																				
<b>BIOPHEN™ Orgaran® Calibrator</b>	CE-IVD	Orgaran® calibrator plasma set	222201	CAL1: 4 x 1 mL	0 U/mL																				
				CAL2: 4 x 1 mL	0.40 U/mL																				
				CAL3: 4 x 1 mL	0.80 U/mL																				
				CAL4: 4 x 1 mL	1.20 U/mL																				
				CAL5: 4 x 1 mL	1.60 U/mL																				
<b>Argatroban Plasma Calibrator</b>	CE-IVD	Argatroban calibrator plasma set	SC030K	CAL1: 4 x 1 mL	0 µg/mL																				
				CAL2: 4 x 1 mL	0.50 µg/mL																				
				CAL3: 4 x 1 mL	1 µg/mL																				
				CAL4: 4 x 1 mL	1.50 µg/mL																				
				CAL5: 4 x 1 mL	2 µg/mL																				
<b>BIOPHEN™ Bivalirudin Calibrator</b>	CE-IVD	Bivalirudin calibrator plasma set	226701	CAL1: 2 x 1 mL	0 µg/mL																				
				CAL2: 2 x 1 mL	1 µg/mL																				
				CAL3: 2 x 1 mL	2 µg/mL																				
				CAL4: 2 x 1 mL	3.50 µg/mL																				
<b>BIOPHEN™ Dabigatran Plasma Calibrator</b>	CE-IVD	Dabigatran calibrator plasma set, standard range	222801	CAL1: 4 x 1 mL	50 ng/mL																				
				CAL2: 4 x 1 mL	250 ng/mL																				
				CAL3: 4 x 1 mL	500 ng/mL																				
<b>BIOPHEN™ Dabigatran Calibrator Low</b>	CE-IVD	Dabigatran calibrator plasma set, low range	222901	CAL1: 4 x 1 mL	0 ng/mL																				
				CALII: 4 x 1 mL	50 ng/mL																				
				CALIII: 4 x 1 mL	100 ng/mL																				



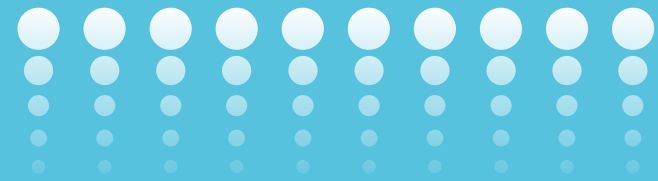
Product Name	RS	Description	Ref.	Presentation	Approximate Content	ANTICOAGULANTS														
						UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN					
<b>BIOPHEN™ UFH Control</b>	CE-IVD 510(K)	UFH quality control plasma set	223101	C1: 6 x 1 mL	0.20 IU/mL															
				C2: 6 x 1 mL	0.50 IU/mL		●													
			224101	C1: 12 x 1 mL	0.20 IU/mL		●													
			223901	C2: 12 x 1 mL	0.50 IU/mL		●													
<b>BIOPHEN™ LMWH Control Plasma</b>	CE-IVD 510(K)	LMWH quality control plasma set	223001	C3: 6 x 1 mL	0.80 IU/mL															
				C4: 6 x 1 mL	1.20 IU/mL		●													
			223801	C3: 12 x 1 mL	0.80 IU/mL		●													
			224201	C4: 12 x 1 mL	1.20 IU/mL		●													
<b>BIOPHEN™ LMWH Control Low</b>	CE-IVD 510(K)	LMWH quality control plasma set, low range	223701	C1: 6 x 1 mL	0.25 IU/mL															
				C1I: 6 x 1 mL	0.50 IU/mL		●													
			224301	C1: 12 x 1 mL	0.25 IU/mL		●													
			224401	C1I: 12 x 1 mL	0.50 IU/mL		●													
<b>BIOPHEN™ Arixtra® Control Plasma</b>	CE-IVD	Arixtra® quality control plasma set	224001	C1: 6 x 1 mL	0.40 µg/mL															
				C2: 6 x 1 mL	1.20 µg/mL		●													
<b>BIOPHEN™ Rivaroxaban Control Plasma</b>	CE-IVD	Rivaroxaban quality control plasma set, standard range	224501	C1: 6 x 1 mL	100 ng/mL															
				C2: 6 x 1 mL	300 ng/mL		●													
<b>BIOPHEN™ Rivaroxaban Control Low</b>	CE-IVD	Rivaroxaban quality control plasma set, low range	225101	C1: 6 x 1 mL	25 ng/mL															
				C1I: 6 x 1 mL	75 ng/mL		●													
<b>BIOPHEN™ Apixaban Control</b>	CE-IVD	Apixaban quality control plasma set, standard range	225301	C1: 6 x 1 mL	200 ng/mL															
				C2: 6 x 1 mL	400 ng/mL		●													

Product Name	RS	Description	Ref.	Presentation	Approximate Content	ANTICOAGULANTS													
						UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN				
<b>BIOPHEN™ Apixaban Control Low</b>	CE-IVD	Apixaban quality control plasma set, low range	225201	C1: 6 x 1 mL	25 ng/mL														
				C1I: 6 x 1 mL	75 ng/mL														
<b>BIOPHEN™ Edoxaban Control</b>	CE-IVD	Edoxaban quality control plasma set, standard range	225501	C1: 6 x 1 mL	150 ng/mL														
				C2: 6 x 1 mL	300 ng/mL														
<b>BIOPHEN™ Edoxaban Control Low</b>	CE-IVD	Edoxaban quality control plasma set, low range	225401	C1: 6 x 1 mL	25 ng/mL														
				C1I: 6 x 1 mL	75 ng/mL														
<b>BIOPHEN™ Orgaran® Control</b>	CE-IVD	Orgaran® quality control plasma set	223501	C1: 6 x 1 mL	0.50 U/mL														
				C2: 6 x 1 mL	1 U/mL														
<b>Argatroban Control Plasma</b>	CE-IVD	Argatroban quality control plasma set	SC035K	C1: 6 x 1 mL	0.65 µg/mL														
				C2: 6 x 1 mL	1.25 µg/mL														
<b>BIOPHEN™ Bivalirudin Control</b>	CE-IVD	Bivalirudin quality control plasma set	225701	C1: 3 x 1 mL	1.50 µg/mL														
				C2: 3 x 1 mL	4 µg/mL														
<b>BIOPHEN™ Dabigatran Control Plasma</b>	CE-IVD	Dabigatran quality control plasma set, standard range	224701	C1: 6 x 1 mL	100 ng/mL														
				C2: 6 x 1 mL	300 ng/mL														
<b>BIOPHEN™ Dabigatran Control Low</b>	CE-IVD	Dabigatran quality control plasma set, low range	225001	C1: 6 x 1 mL	25 ng/mL														
				C1I: 6 x 1 mL	75 ng/mL														

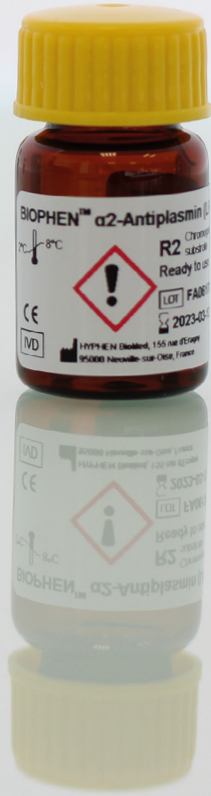




# FIBRINOLYSIS



- GLOBAL & ROUTINE TESTS
- PRIMARY HEMOSTASIS
- BLEEDING DISORDERS
- THROMBOPHILIA
- MONITORING ANTICOAGULANT
- FIBRINOLYSIS**
- CALIBRATORS & CONTROLS
- RESEARCH
- AUXILIARY REAGENTS
- INDEX



## EXPLORE PLASMINOGEN ACTIVITY

Measurement of plasminogen activity may be for detecting congenital or acquired Plasminogen deficiencies.

### BIOPHEN™ Plasminogen (LRT)

Determination of Plasminogen Activity in human plasma, in liquid format.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Plasminogen (LRT) Liquid and Ready to use	CE-IVD	221511	R1: 3 x 3 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 3 x 3 mL			• BIOPHEN™ Abnormal Control Plasma	223301

## EXPLORE PLASMINOGEN ACTIVATOR INHIBITORS

### ANTIPLASMIN: α2-ANTIPLASMIN <sup>(1)</sup>

Assaying α2-AP activity may be useful in case of α2-AP deficiency or during fibrinolytic therapy.

### BIOPHEN™ α2-Antiplasmin (LRT)

Determination of α2-Antiplasmin (α2-AP) activity, in human citrated plasma, in liquid format.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ α2-Antiplasmin (LRT) Liquid and Ready to use	CE-IVD	220502	R1: 3 x 3 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 3 x 3 mL			• BIOPHEN™ Abnormal Control Plasma	223301

## PLASMINOGEN ACTIVATOR INHIBITOR-1: PAI-1



• Research •

### ZYMUTEST™ PAI-1 Activity

Measurement of the activity of human Tissue-Plasminogen Activator Inhibitor, type I (PAI-1), in plasma, by Bio-Immuno-Assay.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ PAI-1 Activity	RUO	RK019A	96 tests

(1) cf Dedicated instructions for use

## ZYMUTEST™ PAI-1 Antigen

Measurement of human Tissue- Plasminogen Activator Inhibitor, type I (PAI-1) in plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ PAI-1 Antigen	CE-IVD	RK012A	96 tests

## THROMBIN ACTIVATABLE FIBRINOLYSIS INHIBITOR: TAFI



• Research •

### ZYMUTEST™ (Total) TAFI :Ag

Measurement of human Total TAFI (Thrombin Activatable Fibrinolysis Inhibitor) antigen forms in plasma. Zymogen, as well as inactive forms are measured, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ (Total) TAFI :Ag	RUO	RK008A on-demand	96 tests



• Research •

### ZYMUTEST™ (Activatable) TAFI

Measurement of human Total TAFI (Thrombin Activatable Fibrinolysis Inhibitor) zymogen and fully activatable (or CPU), in plasma. Inactive forms of TAFI are measured, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ (Activatable) TAFI	RUO	RK037A on-demand	96 tests



## EXPLORE PLASMINOGEN ACTIVATORS

### Tissue plasminogen activator tPA



• Research •

#### ZYMUPHEN™ tPA Activity

Measurement of tPA activity in human acidified citrated plasma, using a Bio-Immuno-Assay.

##### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUPHEN™ tPA Activity	RUO	521296 on-demand	96 tests

#### ZYMUTEST™ tPA Antigen

This kit allows measuring homogeneously human tPA in plasma, by Elisa. The assay measures tPA, whether its presentation is, free and active or complexed with its inhibitors. It can be used to measure tPA:Ag in biological fluids only if an appropriate standard is used.

##### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ tPA Antigen	CE-IVD	RK011A	96 tests

PLASMINOGEN ACTIVATOR INHIBITORS  
PLASMINOGEN ACTIVITY

	Product Name	RS	Description	Ref.	Presentation		
<b>CALIBRATOR</b>	<b>BIOPHEN™ Plasma Calibrator</b>	CE-IVD 510(K)	Normal Human Plasma for the calibration of AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, α2-AP, vWF: Ag	222101	12 x 1 mL	●	●
<b>CONTROLS</b>	<b>BIOPHEN™ Normal Control Plasma</b>	CE-IVD 510(k)	Normal quality control plasma for AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, aPCr (%FVL), lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag, α2-AP and Thrombin Time	223201	12 x 1 mL	●	●
	<b>BIOPHEN™ Abnormal Control Plasma</b>	CE-IVD 510(K)	Abnormal quality control plasma for AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag and α2-AP	223301	12 x 1 mL	●	●



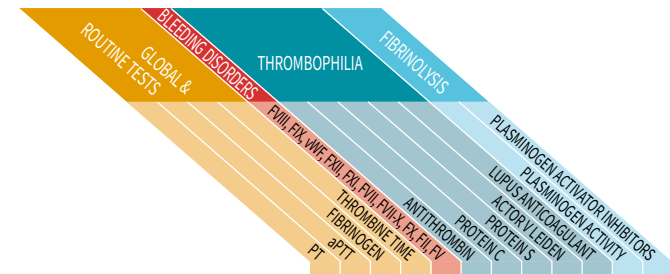


# CALIBRATORS & CONTROLS





## MULTI CALIBRATORS & CONTROLS



	Product Name	RS	Description	Ref.	Presentation	PT	aPTT	FIBRINOGEN	THROMBIN TIME	FVII, FIX, vWF, FVIII, FX, FVII-X, FXI, FXII	ANTI-THROMBIN	PROTEIN C	PLASMINOGEN ACTIVITY	LUPUS ANTICOAGULANT ACTIVITY	PLASMINOGEN ACTIVITY INHIBITORS	
CALIBRATORS	<b>EASYPLASMA™ Calibrator</b>	CE-IVD	Normal Human Plasma for the calibration of several coagulation factors (PT%, Fibrinogen); it may also be used as normal control plasma (PT, aPTT, TT)	226601	6 x 1 mL	●	●	●	●						●	
	<b>BIOPHEN™ Plasma Calibrator</b>	CE-IVD 510(k)	Normal Human Plasma for the calibration of AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, α2-AP, vWF: Ag	222101	12 x 1 mL			●		●	●	●	●	●	●	●
CONTROLS	<b>EASYPLASMA™ Control Set</b>	CE-IVD	Routine quality control plasmas for PT/INR/%, aPTT, Fibrinogen (Fbg) and Thrombin Time (TT) C1 Normal control plasma: Normal citrated human plasma, lyophilized. C2 Abnormal control plasma: Abnormal citrated human plasma, lyophilized	225601	C1: 6 x 1 mL C2: 6 x 1 mL	●	●	●	●						●	
	<b>BIOPHEN™ Normal Control Plasma</b>	CE-IVD 510(k)	Normal quality control plasma for AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, aPcr (%FVL), lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag, α2-AP and Thrombin Time	223201	12 x 1 mL	●	●	●	●	●	●	●	●	●	●	●
	<b>BIOPHEN™ Abnormal Control Plasma</b>	CE-IVD 510(k)	Abnormal quality control plasma for AT, PC, PS, Free PS, FVII-X, Plasminogen, FII, FV, FVII, FVIII:C, FIX, FX, FXI, FXII, FXIII, Fibrinogen, lupus anticoagulant, PT/INR/%, aPTT, vWF: Ag and α2-AP	223301	12 x 1 mL	●	●	●	●	●	●	●	●	●	●	●





**SPECIFICS  
CALIBRATORS & CONTROLS**

Product Name	RS	Description	Ref.	Presentation	Approximative Content	THROMBOPHILIA																	
						ROUTINE TESTS	GLOBAL & ROUTINE TESTS	ACTIVATED PROTEIN C RESISTANCE	LUPUS ANTICOAGULANT	FXa	FXa	FVIIa	OTHER	FVIIa	FXa	FXa							
<b>CALIBRATORS</b> PT Calibrator Set	CE-IVD	Five certified plasmas for PT/INR and PT% calibration and/or for verification of local ISI test system	SC084K	CAL1: 2 x 1 mL	INR 1.00																		
				CAL2: 2 x 1 mL	INR 2.00																		
				CAL3: 2 x 1 mL	INR 3.00																		
				CAL4: 2 x 1 mL	INR 4.00																		
				CAL5: 2 x 1 mL	INR 5.00																		
<b>BIOPHEN™ V-L Plasma Calibrator</b>	CE-IVD 510(k)	For the calibration of FV-L assay	222401	CAL1: 3 x 0.5 mL	10 %																		
				CAL2: 3 x 0.5 mL	25 %																		
				CAL3: 3 x 0.5 mL	50 %																		
<b>BIOPHEN™ Calibrator Factor VIIa</b>	CE-IVD	For the calibration of FVIIa activity measurements	226301	6 x 2 mL	400 mIU/mL																		

<b>CONTROLS</b>	LA Control Plasma	CE-IVD	Quality control plasmas, weak and high positive, of Lupus Anticoagulant	SC081K	C1: 6 x 0.5 mL	Weak														
					C2: 6 x 0.5 mL	High														
	LA Control Plasma Weak	CE-IVD	Quality control plasmas, weak positive, of Lupus Anticoagulant	SC082K	C1: 6 x 0.5 mL	Weak														
	LA Control Plasma High	CE-IVD	Quality control plasmas, high positive, of Lupus Anticoagulant	SC083K	C2: 6 x 0.5 mL	High														
	<b>BIOPHEN™ V-L Control Plasma</b>	CE-IVD 510(k)	Quality control of FV-L (Plasma presenting APC resistance)	223405	12 x 0.5 mL	40 % FV-L														
<b>BIOPHEN™ FVIIa Control Set</b>	CE-IVD	Quality control of FVIIa activity measurements	224901 on-demand	C1: 3 x 1 mL	75.00 mIU/mL															
				C2: 3 x 1 mL	250.00 mIU/mL															

**SPECIFICS  
CALIBRATORS & CONTROLS**

Product Name	RS	Description	Ref.	Presentation	Approximative Content	THROMBOPHILIA														
						ROUTINE TESTS	GLOBAL & ROUTINE TESTS	ACTIVATED PROTEIN C RESISTANCE	LUPUS ANTICOAGULANT	FXa	FXa	FVIIa	OTHER	FVIIa	FXa	FXa				
<b>BIOPHEN™ FXIa Control Set</b>	RUO	Quality control of FXIa activity measurements	224801	C1: 3 x 1 mL	10.00 mIU/mL															
				C2: 3 x 1 mL	30.00 mIU/mL															
<b>BIOPHEN™ FIXa Control Set</b>	RUO	Quality control of FIXa activity measurements	224601 on-demand	C1: 6 x 1 mL	6.00 mIU/mL															
				C2: 6 x 1 mL	12.00 mIU/mL															
<b>High Positive DDimer Control Plasma</b>	RUO	High Positive DDimer Control Plasma	SC101K	6 x 1 mL	2.00 µg/mL															
<b>Negative DDimer Control Plasma</b>	RUO	Negative DDimer Control Plasma	SC102K	6 x 1 mL	< 0.50 µg/mL															
<b>DDimer Control Plasma Low</b>	RUO	DDimer Control Plasma Low	SC103K	6 x 1 mL	0.80 µg/mL															



**ANTICOAGULANTS  
CALIBRATORS**



Product Name	RS	Description	Ref.	Presentation	Approximate Content	UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN		
<b>BIOPHEN™ UFH Calibrator</b>	CE-IVD 510(K)	UFH calibrator plasma set	222301	CAL1: 4 x 1 mL	0 IU/mL												
				CAL2: 4 x 1 mL	0.35 IU/mL												
				CAL3: 4 x 1 mL	0.70 IU/mL	●											
				CAL4: 4 x 1 mL	1.05 IU/mL												
				CAL5: 4 x 1 mL	1.40 IU/mL												
<b>BIOPHEN™ Heparin Calibrator</b>	CE-IVD 510(K)	LMWH calibrator plasma set	222001	CAL1: 4 x 1 mL	0 IU/mL												
				CAL2: 4 x 1 mL	0.40 IU/mL												
				CAL3: 4 x 1 mL	0.80 IU/mL	●	●										
				CAL4: 4 x 1 mL	1.20 IU/mL												
				CAL5: 4 x 1 mL	1.60 IU/mL												
<b>BIOPHEN™ Arixtra® Calibrator</b>	CE-IVD	Arixtra® calibrator plasma set	222501	CAL1: 3 x 1 mL	0 µg/mL												
				CAL2: 3 x 1 mL	0.50 µg/mL												
				CAL3: 3 x 1 mL	1 µg/mL												
				CAL4: 3 x 1 mL	1.50 µg/mL												
<b>BIOPHEN™ Riva- roxaban Plasma Calibrator</b>	CE-IVD	Riva- roxaban calibrator plasma set, standard range	222701	CAL1: 4 x 1 mL	50 ng/mL												
				CAL2: 4 x 1 mL	250 ng/mL												
				CAL3: 4 x 1 mL	500 ng/mL												
<b>BIOPHEN™ Riva- roxaban Calibrator Low</b>	CE-IVD	Riva- roxaban calibrator plasma set, low range	226001	CALI: 4 x 1 mL	0 ng/mL												
				CALII: 4 x 1 mL	50 ng/mL												
				CALIII: 4 x 1 mL	100 ng/mL												
<b>BIOPHEN™ Apixaban Calibrator</b>	CE-IVD	Apixaban calibrator plasma set, standard range	226201	CAL1: 4 x 1 mL	50 ng/mL												
				CAL2: 4 x 1 mL	300 ng/mL												
				CAL3: 4 x 1 mL	600 ng/mL												
<b>BIOPHEN™ Apixaban Calibrator Low</b>	CE-IVD	Apixaban calibrator plasma set, low range	226101	CALI: 4 x 1 mL	0 ng/mL												
				CALII: 4 x 1 mL	50 ng/mL												
				CALIII: 4 x 1 mL	100 ng/mL												

**ANTICOAGULANTS  
CALIBRATORS**



Product Name	RS	Description	Ref.	Presentation	Approximate Content	UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN
<b>BIOPHEN™ Edoxaban Calibrator</b>	CE-IVD	Edoxaban calibrator plasma set, standard range	226501	CAL1: 4 x 1 mL	0 ng/mL										
				CAL2: 4 x 1 mL	250 ng/mL										
				CAL3: 4 x 1 mL	500 ng/mL										
<b>BIOPHEN™ Edoxaban Calibrator Low</b>	CE-IVD	Edoxaban calibrator plasma set, low range	226401	CALI: 4 x 1 mL	0 ng/mL										
				CALII: 4 x 1 mL	50 ng/mL										
				CALIII: 4 x 1 mL	100 ng/mL										
<b>BIOPHEN™ Orgaran® Calibrator</b>	CE-IVD	Orgaran® calibrator plasma set	222201	CAL1: 4 x 1 mL	0 U/mL										
				CAL2: 4 x 1 mL	0.40 U/mL										
				CAL3: 4 x 1 mL	0.80 U/mL										
				CAL4: 4 x 1 mL	1.20 U/mL										
				CAL5: 4 x 1 mL	1.60 U/mL										
<b>Argatroban Plasma Calibrator</b>	CE-IVD	Argatroban calibrator plasma set	SC030K	CAL1: 4 x 1 mL	0 µg/mL										
				CAL2: 4 x 1 mL	0.50 µg/mL										
				CAL3: 4 x 1 mL	1 µg/mL										
				CAL4: 4 x 1 mL	1.50 µg/mL										
				CAL5: 4 x 1 mL	2 µg/mL										
<b>BIOPHEN™ Bivalirudin Calibrator</b>	CE-IVD	Bivalirudin calibrator plasma set	226701	CAL1: 2 x 1 mL	0 µg/mL										
				CAL2: 2 x 1 mL	1 µg/mL										
				CAL3: 2 x 1 mL	2 µg/mL										
				CAL4: 2 x 1 mL	3.50 µg/mL										
				CAL5: 2 x 1 mL	5 µg/mL										
<b>BIOPHEN™ Dabigatran Plasma Calibrator</b>	CE-IVD	Dabigatran calibrator plasma set, standard range	222801	CAL1: 4 x 1 mL	0 ng/mL										
				CAL2: 4 x 1 mL	250 ng/mL										
				CAL3: 4 x 1 mL	500 ng/mL										
<b>BIOPHEN™ Dabigatran Calibrator Low</b>	CE-IVD	Dabigatran calibrator plasma set, low range	222901	CALI: 4 x 1 mL	0 ng/mL										
				CALII: 4 x 1 mL	50 ng/mL										
				CALIII: 4 x 1 mL	100 ng/mL										



**ANTICOAGULANTS  
CONTROLS**



Product Name	RS	Description	Ref.	Presentation	Approximative Content	UFH	LMWH	Rivaroxaban	Apixaban	Edoxaban	Danaparoid	Argatroban	Bivalirudin	Dabigatran
<b>BIOPHEN™ UFH Control Plasma</b>	CE-IVD 510(K)	UFH quality control plasma set	223101	C1: 6 x 1 mL	0.20 IU/mL	●								
				C2: 6 x 1 mL	0.50 IU/mL									
			224101	C1: 12 x 1 mL	0.20 IU/mL	●								
			223901	C2: 12 x 1 mL	0.50 IU/mL	●								
<b>BIOPHEN™ LMWH Control Plasma</b>	CE-IVD 510(K)	LMWH quality control plasma set	223001	C3: 6 x 1 mL	0.80 IU/mL		●							
				C4: 6 x 1 mL	1.20 IU/mL									
			223801	C3: 12 x 1 mL	0.80 IU/mL	●								
			224201	C4: 12 x 1 mL	1.20 IU/mL	●								
<b>BIOPHEN™ LMWH Control Low</b>	CE-IVD 510(K)	LMWH quality control plasma set, low range	223701	C1: 6 x 1 mL	0.25 IU/mL	●								
				C1: 6 x 1 mL	0.50 IU/mL									
			224301	C1: 12 x 1 mL	0.25 IU/mL	●								
			224401	C1: 12 x 1 mL	0.50 IU/mL	●								
<b>BIOPHEN™ Arixtra® Control Plasma</b>	CE-IVD	Arixtra® quality control plasma set	224001	C1: 6 x 1 mL	0.40 µg/mL			●						
				C2: 6 x 1 mL	1.20 µg/mL									
<b>BIOPHEN™ Rivaroxaban Control Plasma</b>	CE-IVD	Rivaroxaban quality control plasma set, standard range	224501	C1: 6 x 1 mL	100 ng/mL				●					
				C2: 6 x 1 mL	300 ng/mL									
<b>BIOPHEN™ Rivaroxaban Control Low</b>	CE-IVD	Rivaroxaban quality control plasma set, low range	225101	C1: 6 x 1 mL	25 ng/mL					●				
				C1: 6 x 1 mL	75 ng/mL									
<b>BIOPHEN™ Apixaban Control</b>	CE-IVD	Apixaban quality control plasma set, standard range	225301	C1: 6 x 1 mL	200 ng/mL						●			
				C2: 6 x 1 mL	400 ng/mL									

**ANTICOAGULANTS  
CONTROLS**



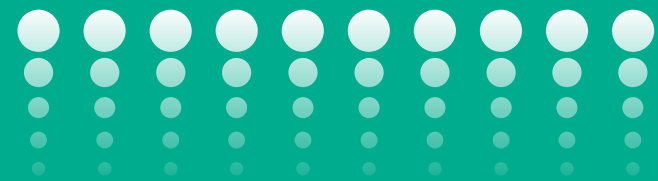
Product Name	RS	Description	Ref.	Presentation	Approximative Content	UFH	LMWH	Rivaroxaban	Apixaban	Edoxaban	Danaparoid	Argatroban	Bivalirudin	Dabigatran
<b>BIOPHEN™ Apixaban Control Low</b>	CE-IVD	Apixaban quality control plasma set, low range	225201	C1: 6 x 1 mL	25 ng/mL					●				
				C1: 6 x 1 mL	75 ng/mL									
<b>BIOPHEN™ Edoxaban Control</b>	CE-IVD	Edoxaban quality control plasma set, standard range	225501	C1: 6 x 1 mL	150 ng/mL						●			
				C2: 6 x 1 mL	300 ng/mL									
<b>BIOPHEN™ Edoxaban Control Low</b>	CE-IVD	Edoxaban quality control plasma set, low range	225401	C1: 6 x 1 mL	25 ng/mL						●			
				C1: 6 x 1 mL	75 ng/mL									
<b>BIOPHEN™ Orgaran® Control</b>	CE-IVD	Orgaran® quality control plasma set	223501	C1: 6 x 1 mL	0.50 U/mL							●		
				C2: 6 x 1 mL	1 U/mL									
<b>Argatroban Control Plasma</b>	CE-IVD	Argatroban quality control plasma set	SC035K	C1: 6 x 1 mL	0.65 µg/mL								●	
				C2: 6 x 1 mL	1.25 µg/mL									
<b>BIOPHEN™ Bivalirudin Control</b>	CE-IVD	Bivalirudin quality control plasma set	225701	C1: 3 x 1 mL	1.50 µg/mL									●
				C2: 3 x 1 mL	4 µg/mL									
<b>BIOPHEN™ Dabigatran Control Plasma</b>	CE-IVD	Dabigatran quality control plasma set, standard range	224701	C1: 6 x 1 mL	100 ng/mL									●
				C2: 6 x 1 mL	300 ng/mL									
<b>BIOPHEN™ Dabigatran Control Low</b>	CE-IVD	Dabigatran quality control plasma set, low range	225001	C1: 6 x 1 mL	25 ng/mL									●
				C1: 6 x 1 mL	75 ng/mL									





- GLOBAL & ROUTINE TESTS
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## RESEARCH



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All products on this section are for Research Use Only (RUO) and should not be used for patient diagnosis or treatment.  
The results obtained should be for research purposes only.



• RESEARCH PRODUCT •

## PURIFIED HUMAN PROTEINS AND ENZYMES

### Human Activated Protein C

Purified Human Enzymes used in APC Resistance assays and all research studies and protocols where a source of highly purified APC is necessary.

REAGENT			
Product Name	RS	Ref.	Presentation
• Human Activated Protein C	RUO	EZ004C on-demand	1 x 100 µg

### Anti-Thrombin (AT)

Purified Human Proteins for all research studies and protocols where a source of highly purified human AT is necessary.

REAGENT			
Product Name	RS	Ref.	Presentation
• Anti-Thrombin (AT)	RUO	PP004B	1 x 10 IU <sup>*(a)</sup>
		PP004L	10 x 10 IU <sup>*(a)</sup>
		PP004D	1 x 25 IU <sup>*(a)</sup>
		PP004M	10 x 25 IU <sup>*(a)</sup>
		PP004C	1 x 10 mg

<sup>\*(a)</sup>: 1 NIH is equivalent to 1 International Unit (IU) ("A reunification of the US ("NIH") and International Unit into a single standard for Thrombin", Longstaff et al, Thromb Haemost 2005, 93:261-6)

### Plasminogen

Purified Human Proteins for all research studies and protocols where a source of highly purified plasminogen is necessary.

REAGENT			
Product Name	RS	Ref.	Presentation
• Plasminogen	RUO	PP005B	1 x 1.5 mg

### Human Platelet Factor 4 (PF4)

Purified Human Proteins for all research studies and protocols where a source of highly purified PF4 is necessary.

REAGENT			
Product Name	RS	Ref.	Presentation
• Human platelet factor 4 (PF4)	RUO	PP003A	1 x 100 µg



## Prekallikrein Pool

Purified Human Proteins for all research studies and protocols where a source of Prekallikrein pool is necessary.

REAGENT			
Product Name	RS	Ref.	Presentation
• Prekallikrein Pool	RUO	PP501K	6 x 2 mL

## Human Prothrombin

Purified Human Proteins for all research studies and protocols where a source of highly purified Prothrombin is necessary.

REAGENT			
Product Name	RS	Ref.	Presentation
• Human Prothrombin	RUO	PP006B	1 x 1 mg

## Human Thrombin

Purified Human Enzymes for all research studies and protocols where a source of highly purified human Thrombin is necessary.

REAGENT			
Product Name	RS	Ref.	Presentation
• Human Thrombin	RUO	EZ006O	1 x 10 NIH <sup>*(a)</sup>
		EZ006K	6 x 10 NIH <sup>*(a)</sup>
		EZ006A	1 x 100 NIH <sup>*(a)</sup>
		EZ006L	10 x 100 NIH <sup>*(a)</sup>
		EZ006B	1 x 1000 NIH <sup>*(a)</sup>

<sup>\*(a)</sup>: 1 NIH is equivalent to 1 International Unit (IU) ("A reunification of the US ("NIH") and International Unit into a single standard for Thrombin", Longstaff et al, *Thromb Haemost* 2005, 93:261-6)

## PURIFIED RECOMBINANT HUMAN PROTEINS

### Recombinant Hirudin

Thrombin inhibitor, which can be used in any *in vitro* laboratory research application where an efficient inhibition of Thrombin is required.

REAGENT			
Product Name	RS	Ref.	Presentation
• Recombinant Hirudin	RUO	RE120A	1 x 16,000 ATU
		RE120B	1 x 160,000 ATU

## PURIFIED BOVINE PROTEINS & ENZYMES

### Purified bovine Factor Xa

Purified bovine enzyme used in all research studies and protocols where a source of highly purified bovine Factor Xa (FXa) is necessary or in studies on Heparin and Low Molecular Weight Heparin.

REAGENT			
Product Name	RS	Ref.	Presentation
• Purified bovine Factor Xa	RUO	BE101D	1 x 30 µg
		BE101L	10 x 30 µg

### Bovine Thrombin

Purified bovine enzyme used in all research studies and protocols where a source of highly purified bovine Thrombin is necessary.

REAGENT			
Product Name	RS	Ref.	Presentation
• Bovine Thrombin	RUO	BE102A	1 x 21 NIH <sup>*(a)</sup>
		BE102K	6 x 21 NIH <sup>*(a)</sup>
		BE102C	1 x 1000 NIH <sup>*(a)</sup>

<sup>\*(a)</sup>: 1 NIH is equivalent to 1 International Unit (IU) ("A reunification of the US ("NIH") and International Unit into a single standard for Thrombin", Longstaff et al, *Thromb Haemost* 2005, 93:261-6)

## OTHER ENZYMES

### Protac®

Purified Protein C activator.

REAGENT			
Product Name	RS	Ref.	Presentation
• Protac®	RUO	EZ011B on-demand	1 x 5 units



## CHROMOGENIC SUBSTRATES

All research studies and protocols where a source of chromogenic substrate is required.

REAGENT				
Product Name	RS	Ref.	Presentation	Peptide sequence
• <b>BIOPHEN™ CS-01(38)</b> Thrombin Chromogenic Substrate	RUO	229001	1 x 25 mg	H-D-Phe-Pip-Arg-pNa, 2HCl
	RUO	229001C	12 x 25 mg	
• <b>BIOPHEN™ CS-01(81)</b> Thrombin Chromogenic Substrate	RUO	229005 on-demand	1 x 25 mg	Tos-Gly-Pro-Arg-pNa. AcOH
• <b>BIOPHEN™ CS-11(32)</b> Factor Xa Chromogenic Substrate	RUO	229011	1 x 25 mg	Suc-Ile-Glu (γ Pip)Gly-Arg-pNa, HCl
• <b>BIOPHEN™ CS-11(65)</b> Factor Xa Chromogenic Substrate	RUO	229014	1 x 25 mg	D-Arg-Gly-Arg-pNa, 2HCl
	RUO	229014C	12 x 25 mg	
• <b>BIOPHEN™ CS-11(22)</b> Factor Xa Chromogenic Substrate	RUO	229015 on-demand	1 x 25 mg	Mixture (50%-50%) of Bz-Ile-Glu (γOCH <sub>3</sub> )-Gly-Arg-pNa (form 1) and Bz-Ile-Glu (γOH)Gly-Arg-pNa (form 2)
• <b>BIOPHEN™ CS-21(66)</b> Activated Protein C Chromogenic substrate	RUO	229021	1 x 25 mg	p-Glu-Pro-Arg-pNa. HCl
• <b>BIOPHEN™ CS-31(02)</b> Kallikrein Chromogenic substrate	RUO	229031	1 x 25 mg	D-PrO-Phe-Arg-pNa, 2HCl
• <b>BIOPHEN™ CS-41(03)</b> Plasmin and Plasminogen-SK Chromogenic substrate	RUO	229041 on-demand	1 x 25 mg	PyroGlu-Phe-Lys-pNa-HCl
• <b>BIOPHEN™ CS-61(44)</b> Urokinase Chromogenic Substrate	RUO	229061	1 x 25 mg	pyro-Glu-Gly-Arg-pNa.HCl
• <b>BIOPHEN™ CS-05(88)</b> tPA and broad spectrum Chromogenic substrate	RUO	229091	1 x 25 mg	H-D-Ile-Pro-Arg-pNa-2HCl



## RESEARCH KITS

### GLOBAL & ROUTINE TESTS

#### FIBRINOGEN

##### ZYMUTEST™ Fibrinogen

Measurement of human Fibrinogen in plasma, with an Elisa method.

##### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• <b>ZYMUTEST™ Fibrinogen</b>	RUO	RK024A	96 tests

### PRIMARY HEMOSTASIS

#### OTHER RELATED ASSAYS

##### vWF Deficient Plasma

For any study or research protocol where a source of human vWF deficient plasma is required. This plasma is also FVIII deficient.

##### REAGENT

Product Name	RS	Ref.	Presentation
• <b>vWF Deficient Plasma</b>	RUO	DP150K	6 x 1 mL

##### ZYMUTEST™ PF4

Measurement of human Platelet Factor 4 (PF4) by Elisa in platelet depleted plasma.

##### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• <b>ZYMUTEST™ PF4</b>	RUO	RK006A	96 tests

### BLEEDING DISORDERS

#### HEMOPHILIA B

##### ZYMUTEST™ Factor IX

Measurement of FIX in human plasma, or in any biological medium where FIX is present, by Elisa.

##### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• <b>ZYMUTEST™ Factor IX</b>	RUO	RK032A	96 tests



## VON WILLEBRAND DISEASE (VWD)

### vWF Deficient Plasma

For any study or research protocol where a source of human vWF deficient plasma is required.

REAGENT			
Product Name	RS	Ref.	Presentation
• vWF Deficient Plasma	RUO	DP150K	6 x 1 mL

## OTHER BLEEDING DISORDERS

### BIOPHEN™ FVII

Determination of FVII chromogenic activity in purified medium or citrated plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ FVII	RUO	221304	R1: 2 x 4 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 2 x 2 mL			• BIOPHEN™ Abnormal Control Plasma	223301
			R3: 2 x 4 mL				
			R4: 4 x 25 mL				

### ZYMUTEST™ Factor VII

Measurement of FVII antigen in human plasma, by Elisa

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Factor VII	RUO	RK036A	96 tests

### BIOPHEN™ Factor X

Determination of FX chromogenic activity in citrated human plasma.

REAGENT				CALIBRATOR		CONTROLS	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Factor X	RUO	221705	R1: 4 x 2.5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma	223201
			R2: 4 x 2.5 mL			• BIOPHEN™ Abnormal Control Plasma	223301
			R3: 4 x 5 mL				

### ZYMUTEST™ Factor X

Measurement of human FX antigen in human plasma, by Elisa

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Factor X	RUO	RK033A	96 tests

### ZYMUTEST™ Factor V

Measurement of human FV antigen in plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Factor V	RUO	RK009A on-demand	96 tests

### Factor XIII Deficient Plasma

For any study or research protocol where a source of human FXIII deficient plasma is required.

REAGENT			
Product Name	RS	Ref.	Presentation
• Factor XIII Deficient Plasma	RUO	DP200K	6 x 1 mL

### ZYMUTEST™ Factor XIII-A

Measurement of FXIII (subunit A) in human plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Factor XIII-A	RUO	RK034A on-demand	96 tests

## THROMBOPHILIA

### PROTEIN C (PC)

#### Protein C Deficient Plasma

Lyophilized, human citrated plasma, deficient for PC, for any protocol or research study where a source of human PC deficient plasma is required.

REAGENT			
Product Name	RS	Ref.	Presentation
• Protein C Deficient Plasma	RUO	DP100K	6 x 1 mL

### PROTEIN S (PS)

#### Protein S Deficient Plasma

Lyophilized, human citrated plasma, deficient for PS, for any protocol or research study where a source of human PS deficient plasma is required.

REAGENT			
Product Name	RS	Ref.	Presentation
• Protein S Deficient Plasma	RUO	DP110K	6 x 1 mL





## PROTEIN Z (PZ)

### ZYMUTEST™ Protein Z

Measurement of human PZ in plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Protein Z	RUO	RK031A	96 tests

## OTHER AUTOANTIBODIES

### ZYMUTEST™ Anti-Annexin V, IgG

Measurement of autoantibodies to Annexin V of the IgG isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-Annexin V, IgG	RUO	RK005A on-demand	96 tests

### ZYMUTEST™ Anti-Annexin V, IgM

Measurement of autoantibodies to Annexin V of the IgM isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-Annexin V, IgM	RUO	RK005B on-demand	96 tests

### ZYMUTEST™ Anti-PROTEIN S IgG-Isotype

Measurement of autoantibodies to PS of the IgG isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-PROTEIN S IgG-Isotype	RUO	RK020A on-demand	96 tests

### ZYMUTEST™ Anti-PROTEIN S IgM-Isotype

Measurement of autoantibodies to PS of the IgM isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-PROTEIN S IgM-Isotype	RUO	RK020B on-demand	96 tests

### ZYMUTEST™ Anti-PROTEIN Z IgG-Isotype

Measurement of autoantibodies to Protein Z of the IgG isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-PROTEIN Z IgG-Isotype	RUO	RK025A on-demand	96 tests

### ZYMUTEST™ Anti-PROTEIN Z IgM-Isotype

Measurement of autoantibodies to Protein Z of the IgM isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-PROTEIN Z IgM-Isotype	RUO	RK025B on-demand	96 tests

### ZYMUTEST™ Anti-Prothrombin IgG

Measurement of autoantibodies to Prothrombin, of the IgG isotype, in human plasma.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Anti-Prothrombin IgG	RUO	RK007A on-demand	96 tests

## PHOSPHOLIPID BINDING PROTEINS

### ZYMUTEST™ β2GPI

Immuno-assay for measuring human Beta 2 Glycoprotein I (β2GPI) in plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ β2GPI	RUO	RK022A on-demand	96 tests

### ZYMUTEST™ Annexin V

Measurement of human Annexin V in plasma, or in any fluid where Annexin V can be present, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Annexin V	RUO	RK004A on-demand	96 tests

## BLOOD ACTIVATION BIOMARKERS

### ZYMUTEST™ DDimer

Measurement of the Fibrin Degradation Products (DDimer) in plasma, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ DDimer	RUO	RK023A on-demand	96 tests



## ZYMUTEST™ FPA

Determination of human FPA, for use on bentonite adsorbed human plasma, using a Competitive Enzyme Linked Immuno Assay (CELIA). Fibrinogen, when present in the specimen, must be removed (i.e. bentonite adsorption of human plasma), as it cross-reacts with antibodies to FPA.

### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ FPA	RUO	RK016B	96 tests

## ZYMUTEST™ CRP

High sensitive measurement of human CRP in plasma, serum, by Elisa.

### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ CRP	RUO	RK010A on-demand	96 tests

## ZYMUPHEN™ MP ACTIVITY

Measurement of microparticles' procoagulant activity in human plasma.

### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUPHEN™ MP ACTIVITY	RUO	521096 on-demand	96 tests

## ZYMUPHEN™ MP-TF

Determination of the procoagulant activity of microparticles exposing Tissue Factor (MP-TF), in human plasma and in purified milieu.

### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUPHEN™ MP-TF	RUO	521196 on-demand	96 tests

## ZYMUTEST™ Tissue Factor (full length)

Determination of Full-Length Tissue Factor (FL-TF) (1-263) on plasma and purified milieu.

### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Tissue Factor (full length)	RUO	RK035A on-demand	96 tests

## ZYMUTEST™ Total Tissue Factor

Determination of Tissue Factor (TF) on plasma and purified milieu. This kit does not recognize alternatively spliced Tissue Factor (asTF).

### COMPLETE SOLUTION

Product Name	RS	Ref.	Presentation
• ZYMUTEST™ Total Tissue Factor	RUO	RK042A on-demand	96 tests

## ACTIVATED FACTORS

### Factor XIa (FXIa)

#### BIOPHEN™ Factor XIa

Measurement of activated Factor XI (FXIa) activity, through FIX activation and Factor Xa generation.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Factor XIa	RUO	220412	R1A: 2 x 3 mL	-	-	• BIOPHEN™ FXIa Control Set	224801
			R1B: 2 x 3 mL				
			R2: 2 x 3 mL				
			R3: 2 x 3 mL				
			R4: 2 x 25 mL				
CAL: 2 x 2 mL							

### Factor IXa (FIXa)

#### BIOPHEN™ Factor IXa

Determination of FIXa activity, in purified medium.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Factor IXa	RUO	221812	R1: 2 x 2.5 mL	-	-	• BIOPHEN™ FIXa Control Set	224601 on-demand
			R2: 2 x 2.5 mL				
			R3: 2 x 2.5 mL				
			R4: 2 x 25 mL				
			CAL: 2 x 1 mL				

### Factor VIIa (FVIIa)

#### BIOPHEN™ Factor VIIa

Determination of activated Factor VII (FVIIa) activity, in purified milieu.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Factor VIIa	RUO	221312 on-demand	R1: 2 x 4 mL	-	-	-	-
			R2: 2 x 2 mL				
			R3: 2 x 4 mL				
			R4: 2 x 25 mL				



## MONITORING ANTICOAGULANT

### BIOPHEN™ HEPARIN (AT+)

Kinetics assay for measuring the concentration of heparin, and heparin-like anticoagulants, in human citrated plasma or in any other biological fluid, using an anti-Xa chromogenic method, with the addition of Antithrombin (AT), when endogenous AT concentration is insufficient for measuring heparin.

REAGENT				CALIBRATORS		CONTROLS					
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.				
• BIOPHEN™ HEPARIN (AT+)	RUO	221007	R1: 2 x 7.5 mL	• BIOPHEN™ UFH Calibrator	222301	• BIOPHEN™ UFH Control Plasma	223101				
			R2: 2 x 7.5 mL					• BIOPHEN™ Heparin Calibrator	222001	• BIOPHEN™ LMWH Control Plasma	223001
			R3: 2 x 2.5 mL					• BIOPHEN™ Arixtra® Calibrator	222501	• BIOPHEN™ LMWH Control Low	223701
						• BIOPHEN™ Arixtra® Control Plasma	224001				

### BIOPHEN™ ANTI-Xa (2 Stages Heparin Assay)

Two stages chromogenic anti-Xa method for measuring the activity of heparins (UFH or LMWH), in presence of a constant amount of AT, in compliance with Pharmacopeias. This method can be used for testing heparin in human citrated plasma, or in purified solutions.

REAGENT				CALIBRATORS		CONTROLS					
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.				
• BIOPHEN™ ANTI-Xa (2 Stages Heparin Assay)	RUO	221005	R1: 2 x 1 mL	• BIOPHEN™ UFH Calibrator	222301	• BIOPHEN™ UFH Control Plasma	223101				
			R2: 2 x 1 mL					• BIOPHEN™ Heparin Calibrator	222001	• BIOPHEN™ LMWH Control Plasma	223001
			R3: 2 x 1 mL							• BIOPHEN™ LMWH Control Low	223701

### BIOPHEN™ ANTI-IIa (2 Stages Heparin Assay)

Two stages chromogenic anti-IIa assay for measuring the activity of heparins (UFH or LMWH), in presence of a constant amount of AT, in compliance with Pharmacopeias. This method can be used for testing heparin in human citrated plasma, or in purified solutions.

REAGENT				CALIBRATOR		CONTROL				
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.			
• BIOPHEN™ ANTI-IIa (2 Stages Heparin Assay)	RUO	220005	R1: 2 x 1 mL	• BIOPHEN™ UFH Calibrator	222301	• BIOPHEN™ UFH Control Plasma	223101			
			R2: 2 x 1 mL							
			R3: 2 x 1 mL							

### BIOPHEN™ HEPARIN ANTI-IIa (kinetics)

One stage, kinetics anti-IIa method for measuring the concentration of heparin, and heparin-like anticoagulants. This method is proposed for testing heparin in buffer, or purified systems. Not suitable for testing plasma.

REAGENT				CALIBRATOR		CONTROL	
Product Name	RS	Ref.	Presentation	Product Name	Ref.	Product Name	Ref.
• BIOPHEN™ Heparin ANTI-IIa (kinetics)	RUO	221020	R1: 2 x 5 mL	-	-	-	-
			R2: 2 x 10 mL				
			R3: 2 x 10 mL				
			R4: 2 x 20 mL				

## FIBRINOLYSIS

### EXPLORE PLASMINOGEN ACTIVATOR INHIBITORS

#### PLASMINOGEN ACTIVATOR INHIBITOR-1: PAI-1

##### ZYMUTEST™ PAI-1 Activity

Measurement of the activity of human Tissue-Plasminogen Activator Inhibitor, type I (PAI-1), in plasma, by Bio-Immuno-Assay.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ PAI-1 Activity	RUO	RK019A	96 tests

#### THROMBIN ACTIVATABLE FIBRINOLYSIS INHIBITOR: TAFI

##### ZYMUTEST™ (Total) TAFI:Ag

Measurement of human Total TAFI (Thrombin Activatable Fibrinolysis Inhibitor) antigen forms in plasma. Zymogen, as well as inactive forms are measured, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ (Total) TAFI:Ag	RUO	RK008A on-demand	96 tests

##### ZYMUTEST™ (Activatable) TAFI

Measurement of human TAFI (Thrombin Activatable Fibrinolysis Inhibitor) zymogen and fully activatable (or CPU), in plasma. Inactive forms of TAFI are measured, by Elisa.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUTEST™ (Activatable) TAFI	RUO	RK037A on-demand	96 tests

### EXPLORE PLASMINOGEN ACTIVATORS

#### Tissue plasminogen activator tPA

##### ZYMUPHEN™ tPA Activity

Measurement of tPA activity in human acidified citrated plasma, using a Bio-Immuno-Assay.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• ZYMUPHEN™ tPA Activity	RUO	521296 on-demand	96 tests



## AUXILIARY REAGENTS

### BUFFERS & SOLUTIONS FOR CLOTTING OR CHROMOGENIC ASSAYS

#### Tris-NaCl buffer

Dilution buffer for coagulation assays, or for any application where Tris Buffer Saline (TBS) is needed.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris-NaCl buffer Ready to use	RUO	AR004K	3 x 50 mL

#### Tris-NaCl buffer – pH 7.40

Dilution buffer for biological tests.

Can be used as buffer recommended by the US and European Pharmacopoeia for the assay of Heparin anti-IIa and anti-Xa activity verified and validated in combination with BIOPHEN™ ANTI-IIa (2 Stages Heparin Assay) (220005) and BIOPHEN™ ANTI-Xa (2 Stages Heparin Assay) (221005) kits.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris-NaCl buffer - pH 7.40 Ready to use	RUO	AR028K	4 x 20 mL

#### Tris-NaCl buffer, with Albumin – pH 7.40

Dilution buffer for biological tests, recommended mainly for diluting purified proteins and enzymes (Albumine prevents adsorption of purified proteins on recipient walls).

Can be used as “buffer A” recommended by the European Pharmacopoeia for Heparin anti-IIa assay.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris-NaCl buffer, with Albumin - pH 7.40 Ready to use	RUO	AR005A	1 x 50 mL
		AR005K	3 x 50 mL
		AR005L	4 x 20 mL

#### Phosphate NaCl (PBS) buffer

REAGENT			
Product Name	RS	Ref.	Presentation
• Phosphate NaCl (PBS) buffer Ready to use	RUO	AR006K on-demand	3 x 50 mL

#### Tris buffer

Buffer for chromogenic assays.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris buffer Ready to use	RUO	AR008K on-demand	3 x 50 mL

#### Tris NaCl EDTA PEG buffer (10 x conc.)

Buffer for chromogenic assays.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris NaCl EDTA PEG buffer, 10 x concentrated	RUO	AR015A	1 x 10 mL

#### Tris NaCl EDTA PEG buffer – pH 8.40

Dilution buffer for biological tests.

Can be used as buffer recommended by the US and EU Pharmacopoeia for the assay of heparin anti-IIa and anti-Xa activity verified and validated in combination with BIOPHEN™ ANTI-IIa (2 Stages Heparin Assay) (220005) and BIOPHEN™ ANTI-Xa (2 Stages Heparin Assay) (221005) kits.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris NaCl EDTA PEG buffer - pH 8.40 Ready to use	RUO	AR030K	4 x 20 mL

#### Tris NaCl EDTA BSA buffer – pH 8.40

Dilution buffer for biological tests.

Can be used as buffer recommended by the US and EU Pharmacopoeia for the assay of heparin.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris NaCl EDTA BSA buffer - pH 8.40 Ready to use	RUO	AR031K	4 x 25 mL

#### Tris EDTA NaCl – pH 8.40

Dilution buffer for biological tests.

Can be used as buffer recommended by the US and EU Pharmacopoeia for the assay of heparin anti-IIa and anti-Xa activity verified and validated in combination with BIOPHEN™ ANTI-IIa (2 Stages Heparin Assay) (220005) and BIOPHEN™ ANTI-Xa (2 Stages Heparin Assay) (221005) kits.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris EDTA NaCl - pH 8.40 Ready to use	RUO	AR029K	4 x 20 mL

#### Tris EDTA buffer (10 x conc.) – pH 8.40

Buffer for chromogenic assays.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris EDTA buffer, 10 x concentrated - pH 8.40	RUO	AR015B	1 x 20 mL



## Prothrombin Activator Diluent

Prothrombin Activator Diluent for the assay of Prothrombin activity using chromogenic assays (such as the Prothrombin activation by ecarin).

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Prothrombin Activator Diluent</b> Ready to use	RUO	AR022A	1 x 20 mL

## AT-Tris buffer Anti-Xa

Dilution buffer for the measurement of the Progressive Antithrombin activity (Anti-Xa) in plasma, with an Anti-Xa method, using a variant protocol with BIOPHEN™ AT (Anti-Xa) kit (221102/221105), performed in the absence of Heparin.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>AT-Tris buffer Anti-Xa</b> Ready to use	RUO	AR103A	1 x 10 mL

## AT-Tris buffer Anti-IIa

Dilution buffer for the measurement of Progressive Antithrombin activity (Anti-IIa) in plasma, using an Anti-IIa method, and a variant protocol of BIOPHEN™ AT (Anti-IIa), performed in the absence of Heparin.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>AT-Tris buffer Anti-IIa</b> Ready to use	RUO	AR104A on-demand	1 x 10 mL

## BUFFERS AND SOLUTIONS FOR ELISA

### ELISA dilution buffer, with albumin

Dilution buffer for enzyme immunoassays.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Elisa dilution buffer, with albumin</b> Ready to use	RUO	AR010A	1 x 50 mL

### FPA anticoagulant solution

Special anticoagulant solution (ACS) for the assay of FPA.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>FPA anticoagulant solution</b> Ready to use	RUO	AR013A	1 x 20 mL

## Wash solution for Elisa

For enzyme immunoassays.

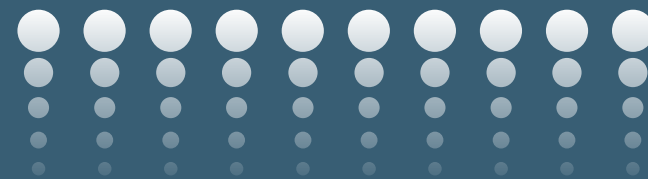
REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Wash solution for Elisa</b>	RUO	AR011K	3 x 50 mL



Product Name	RS	Description	Ref.	Presentation	Approximative Content	THROMBOPHILIA			
						FXa	FIXa	OTHER	
<b>CONTROLS</b>	BIOPHEN™ FXIa Control Set	RUO	Quality control of FXIa activity measurements	224801	C1: 3 x 1 mL	10.00 mIU/mL	●		
					C2: 3 x 1 mL	30.00 mIU/mL			
	BIOPHEN™ FIXa Control Set	RUO	Quality control of FIXa activity measurements	224601 on-demand	C1: 6 x 1 mL	6.00 mIU/mL		●	
					C2: 6 x 1 mL	12.00 mIU/mL			
	High Positive DDimer Control Plasma	RUO	High Positive DDimer Control Plasma	SC101K	6 x 1 mL	2.00 µg/mL			
Negative DDimer Control Plasma	RUO	Negative DDimer Control Plasma	SC102K	6 x 1 mL	0.50 µg/mL			●	
DDimer Control Plasma Low	RUO	DDimer Control Plasma Low	SC103K	6 x 1 mL	0.80 µg/mL				



## AUXILIARY REAGENTS



**Imidazole buffer**

Dilution buffer for coagulation assays.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Imidazole buffer</b> Ready to use	CE-IVD	AR021B	1 x 15 mL <sup>(b)</sup>
		AR021M	3 x 15 mL <sup>(b)</sup>
		AR021K	3 x 25 mL
		AR021N	12 x 15 mL <sup>(b)</sup>
		AR021L	12 x 25 mL

(b): to be used preferably on Sysmex analyzers

**Calcium Chloride 0.025M (M/40)**

Calcium Chloride solution for coagulation assays, such as the Activated Partial Thromboplastin Time (aPTT) or for the assays of factors of the intrinsic coagulation pathway.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Calcium Chloride 0.025M (M/40)</b> Ready to use	CE-IVD	AR001B	3 x 15 mL <sup>(b)</sup>
		AR001L	12 x 15 mL <sup>(b)</sup>
		AR001K	12 x 25 mL

(b): to be used preferably on Sysmex analyzers

**Special Tris-BSA buffer**

Special dilution buffer for FVIII:C, FIX and FIXa.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Special Tris-BSA buffer</b>	CE-IVD	AR026A	3 x 25 mL
		AR026K	12 x 25 mL

**Tris NaCl EDTA buffer - pH 7.85**

Special dilution buffer for anti-Xa chromogenic assays, especially using BIOPHEN™ DiXal kit (221030) or BIOPHEN™ Heparin LRT kits (221011/221013/221015).

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Tris NaCl EDTA buffer - pH 7.85</b> Ready to use	CE-IVD	AR032 on-demand	1 x 20 mL
		AR032K	4 x 20 mL





## Research

### Tris-NaCl buffer

Dilution buffer for coagulation assays, or for any application where Tris Buffer Saline (TBS) is needed.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Tris-NaCl buffer</b> Ready to use	RUO	AR004K	3 x 50 mL



## Research

### Tris-NaCl buffer - pH 7.40

Dilution buffer for biological tests.

Can be used as buffer recommended by the US and EU Pharmacopoeia for the assay of heparin anti-IIa and anti-Xa activity verified and validated in combination with BIOPHEN™ ANTI-IIa (2 Stages Heparin Assay) (220005) and BIOPHEN™ ANTI-Xa (2 Stages Heparin Assay) (221005) kits.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Tris-NaCl buffer - pH 7.40</b> Ready to use	RUO	AR028K	4 x 20 mL



## Research

### Tris-NaCl buffer, with Albumin - pH 7.40

Dilution buffer for biological tests, recommended mainly for diluting purified proteins and enzymes (Albumine prevents adsorption of purified proteins on recipient walls).

Can be used as “buffer A” recommended by the European Pharmacopoeia for Heparin anti-IIa assay.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Tris-NaCl buffer, with Albumin - pH 7.40</b> Ready to use	RUO	AR005A	1 x 50 mL
		AR005K	3 x 50 mL
		AR005L	4 x 20 mL



## Research

### Phosphate NaCl (PBS) buffer

Phosphate Buffer Saline (PBS).

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Phosphate NaCl (PBS) buffer</b> Ready to use	RUO	AR006K on-demand	3 x 50 mL



## Research

### Tris buffer

Buffer for chromogenic assays.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Tris buffer - pH 8.40</b> Ready to use	RUO	AR008K on-demand	3 x 50 mL



## Research

### Tris NaCl EDTA PEG buffer (10 x conc.)

Buffer for chromogenic assays.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Tris NaCl EDTA PEG buffer (10 x conc.)</b>	RUO	AR015A	1 x 10 mL



## Research

### Tris NaCl EDTA PEG buffer - pH 8.40

Dilution buffer for biological tests.

Can be used as buffer recommended by the US and EU Pharmacopoeia for the assay of heparin anti-IIa and anti-Xa activity verified and validated in combination with BIOPHEN™ ANTI-IIa (2 Stages Heparin Assay) (220005) and BIOPHEN™ ANTI-Xa (2 Stages Heparin Assay) (221005) kits.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Tris NaCl EDTA PEG buffer - pH 8.40</b> Ready to use	RUO	AR030K	4 x 20 mL



## Research

### Tris NaCl EDTA BSA buffer - pH 8.40

Dilution buffer for biological tests.

Can be used as buffer recommended by the US and EU Pharmacopoeia for the assay of heparin.

REAGENT			
Product Name	RS	Ref.	Presentation
• <b>Tris NaCl EDTA BSA buffer - pH 8.40</b> Ready to use	RUO	AR031K	4 x 25 mL







## • Research •

### Tris EDTA NaCl - pH 8.40

Dilution buffer for biological tests.

Can be used as buffer recommended by the US and EU Pharmacopoeia for the assay of heparin anti-IIa and anti-Xa activity verified and validated in combination with BIOPHEN™ ANTI-IIa (2 Stages Heparin Assay) (220005) and BIOPHEN™ ANTI-Xa (2 Stages Heparin Assay) (221005) kits.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris EDTA NaCl - pH 8.40 Ready to use	RUO	AR029K	4 x 20 mL



## • Research •

### Tris EDTA buffer (10 x conc.)- pH 8.40

Buffer for chromogenic assays.

REAGENT			
Product Name	RS	Ref.	Presentation
• Tris EDTA buffer 10 x concentrated - pH 8.40	RUO	AR015B	1 x 20 mL



## • Research •

### Prothrombin Activator Diluent

Prothrombin Activator Diluent for the assay of Prothrombin activity using chromogenic assays (such as the Prothrombin activation by ecarin).

REAGENT			
Product Name	RS	Ref.	Presentation
• Prothrombin Activator Diluent Ready to use	RUO	AR022A	1 x 20 mL



## • Research •

### AT-Tris buffer Anti-Xa

Dilution buffer for the measurement of the Progressive Antithrombin activity (Anti-Xa) in plasma, with an Anti-Xa method, using a variant protocol with BIOPHEN™ AT (Anti-Xa) kit (221102/221105), performed in the absence of Heparin.

REAGENT			
Product Name	RS	Ref.	Presentation
• AT-Tris buffer Anti-Xa Ready to use	RUO	AR103A	1 x 10 mL



## • Research •

### AT-Tris buffer Anti-IIa

Dilution buffer for the measurement of Progressive Antithrombin activity (Anti-IIa) in plasma, using an Anti-IIa method, and a variant protocol of BIOPHEN™ AT (Anti-IIa), performed in the absence of Heparin.

REAGENT			
Product Name	RS	Ref.	Presentation
• AT-Tris buffer Anti-IIa Ready to use	RUO	AR104A on-demand	1 x 10 mL

## BUFFERS AND SOLUTIONS FOR ELISA



## • Research •

### Elisa dilution buffer, with albumin

Dilution buffer for enzyme immunoassays.

REAGENT			
Product Name	RS	Ref.	Presentation
• Elisa dilution buffer, with albumin Ready to use	RUO	AR010A	1 x 50 mL



## • Research •

### FPA anticoagulant solution

Special anticoagulant solution (ACS) for the assay of FPA.

REAGENT			
Product Name	RS	Ref.	Presentation
• FPA anticoagulant solution Ready to use	RUO	AR013A	1 x 20 mL



## • Research •

### Wash solution for Elisa

For enzyme immunoassays.

REAGENT			
Product Name	RS	Ref.	Presentation
• Wash solution for Elisa Ready to use	RUO	AR011K	3 x 50 mL



## OTHER SOLUTIONS

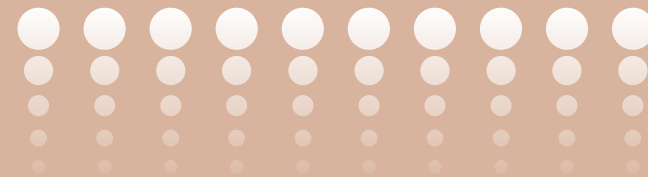
### BIOPHEN™ NormalPlasma

Pool of normal human plasma.

REAGENT			
Product Name	RS	Ref.	Presentation
• BIOPHEN™ NormalPlasma 2	CE-IVD	223602	10 x 2 mL
• BIOPHEN™ NormalPlasma 5		223605	8 x 5 mL



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In vitro diagnostic medical device.

Read carefully the instructions in the system user manual and on the labeling and/or instructions for use of the reagent.

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