PRODUCT CATALOG

Last update March 2022

HYPHEN BioMed
A Sysmex Group Company

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 remain 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 **R**esearch **U**se **O**nly. 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 series.

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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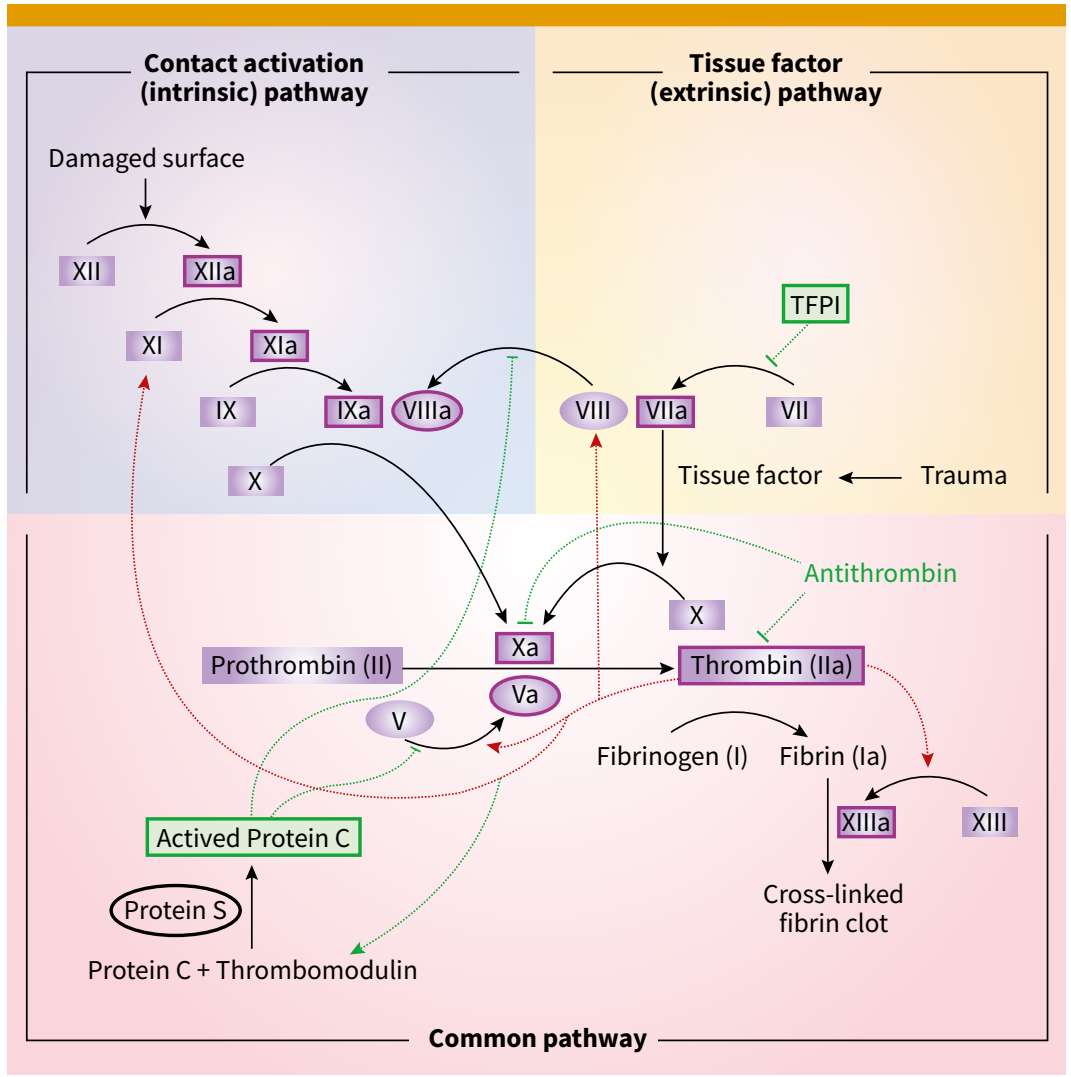
GLOBAL & ROUTINE TESTS

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)[1]

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	• EASYPLASMA™ Control Set	225601
• **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)[1]

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	• EASYPLASMA™ Calibrator	226601	• 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 intructions 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
						• LA Control Plasma Weak	SC082K
						• LA Control Plasma High	SC083K
		CK522K	6 x 2.5 mL			• BIOPHEN™ Normal Control Plasma	223201
						• BIOPHEN™ Abnormal Control Plasma	223301
						• EASYPLASMA™ Control Set	225601

FIBRINOGEN[1]

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
						• BIOPHEN™ Abnormal Control Plasma	223301
				• EASYPLASMA™ Calibrator	226601	• EASYPLASMA™ Control Set	225601
• **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 intructions for use

LIAPHEN™ Fibrinogen

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

REAGENT			
Product Name	RS	Ref.	Presentation
• **LIAPHEN™ Fibrinogen** Liquid and Ready to use	CE-IVD	120102	4 x 5 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ Plasma Calibrator	222101

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma	223201
• BIOPHEN™ Abnormal Control Plasma	223301

• Research •

ZYMUTEST™ Fibrinogen

Measurement of human Fibrinogen in plasma, or in any fluid where Fibrinogen can be present, with an Elisa method.

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

THROMBIN TIME (TT)(1)

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.

HEMOCLOT™ Thrombin Time

Determination of TT in human citrated plasma.

REAGENT			
Product Name	RS	Ref.	Presentation
• **HEMOCLOT™ Thrombin Time LRT** Liquid and Ready to use	CE-IVD	CK012K	6 x 5 mL
• **HEMOCLOT™ Thrombin Time (T.T.)**	CE-IVD	CK011K	6 x 2 mL
		CK011L	6 x 8 mL

CALIBRATOR	
Product Name	Ref.
• EASYPLASMA™ Calibrator	226601
-	-

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma • EASYPLASMA™ Control Set	223201 225601
• BIOPHEN™ Normal Control Plasma • EASYPLASMA™ Control Set	223201 225601

(1) cf Dedicated intructions for use

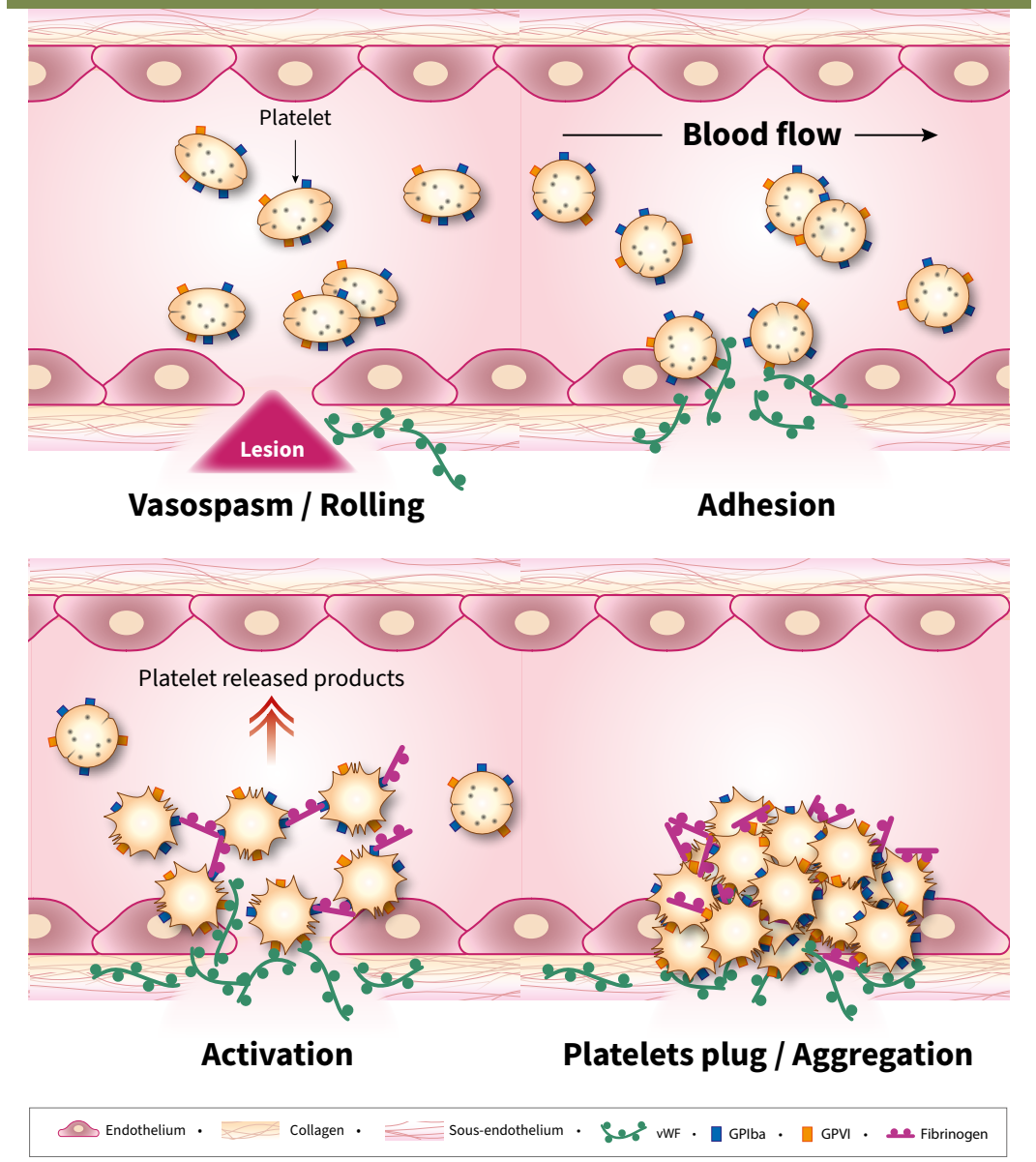
PT · aPTT · FIBRINOGEN · THROMBIN TIME

	Product Name	RS	Description	Ref.	Presentation	PT	aPTT	FIBRINOGEN	THROMBIN TIME
CALIBRATORS	**EASYPLASMA™ Calibrator**	CE-IVD	Routine calibrator plasmas for PT/INR/%, aPTT, Fibrinogen (Fbg) and Thrombin Time (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 and LA	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	C1: 2 x 1 mL C2: 2 x 1 mL C3: 2 x 1 mL C4: 2 x 1 mL C5: 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, of 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, of Lupus Anticoagulant	SC082K	C3: 6 x 0.5 mL		●		
	LA Control Plasma High	CE-IVD	Quality control plasmas, high positive, of Lupus Anticoagulant	SC083K	C4: 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*	Sysmex analyzers: CN series
• **ADP**	CE-IVD	AG001K	3 x 0.5 mL	●	●	●

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*	Sysmex analyzers: CN series
• **Arachidonic Acid**	CE-IVD	AG003K	3 x 0.5 mL	●	●	●

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*	Sysmex analyzers: CN series
• **Epinephrine**	CE-IVD	AG002K	3 x 0.5 mL	●	●	●

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*	Sysmex analyzers: CN series
• **Collagen**	CE-IVD	AG005K	R1: 3 x 0.5 mL 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 GPIb 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*	Sysmex analyzers: CN series
• **Ristocetin**	CE-IVD	AG004K	3 x 0.5 mL	●	●	●

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.

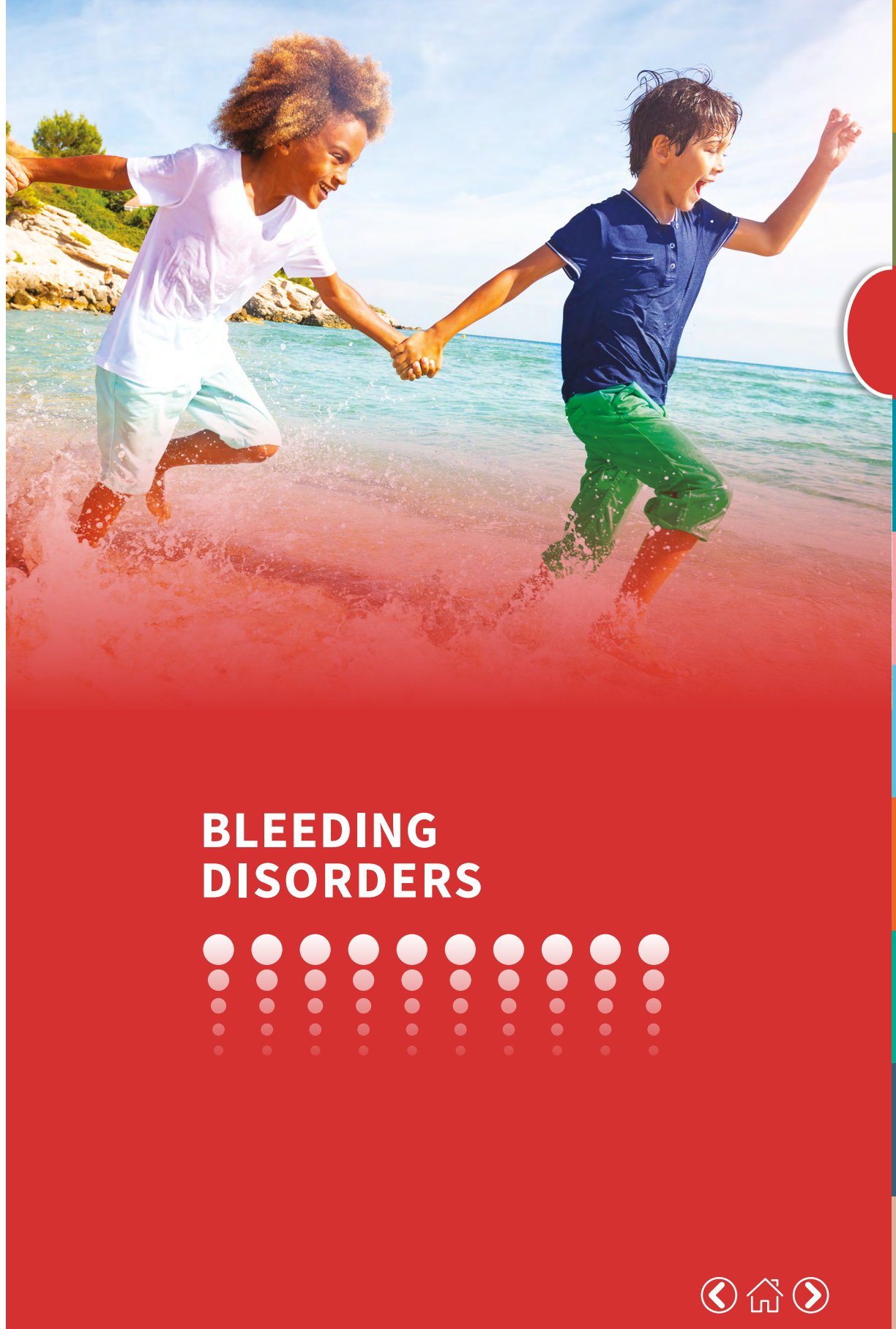
REAGENT			
Product Name	RS	Ref.	Presentation
• **vWF Deficient Plasma**	RUO	DP150K	6 X 1 mL

Research

ZYMUTEST™ PF4

Measurement of human Platelet Factor 4 (PF4) by Elisa in platelet depleted plasma, or in any fluid where PF4 must be measured.

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	DP0200A - DP0200K
	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	221402 221406	221304		221705			227005
Elisa Assay	ZYMUTEST™			RK032A	RK039A* on-demand	RK036A		RK033A		RK009A on-demand	RK034A on-demand

** Inhibitor assay*

HEMOPHILIA A [1]

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: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 R2: 2 x 2.5 mL R3: 2 x 2.5 mL R4: 4 x 25 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301
		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 • BIOPHEN™ Abnormal Control Plasma	223201 223301
		DP040K	6 x 1 mL				

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** 32 tests	CE-IVD	RK039A on-demand	Elisa Strips: 4 x 8 Sample Diluent-Anti-VIII: 2 x 12 mL Positive Control: 4 vials Negative Control: 4 vials Anti-IgG (Fcγ)-HRP immunoconjugate: 4 vials Conjugate Diluent: 1 x 10 mL Wash Solution: 2 x 12 mL 3,3', 5,5'-Tetramethylbenzidine: 1 x 10 mL 0.45 M Sulfuric acid: 1 x 3 mL

(1) cf Dedicated intructions for use

HEMOPHILIA B [1]

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 R2: 2 x 1 mL R3: 2 x 1 mL R4: 2 x 15 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301
		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 • BIOPHEN™ Abnormal Control Plasma	223201 223301
		DP050K	6 x 1 mL				

• Research •

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
• **ZYMUTEST™ Factor IX**	RUO	RK032A	96 tests

(1) cf Dedicated intructions for use

VON WILLEBRAND DISEASE (VWD) [3]

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			
Product Name	RS	Ref.	Presentation
• **LIAPHEN™ vWF:Ag** Liquid and Ready to use	CE-IVD	120206	R1: 4 x 5 mL R2: 4 x 6 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ Plasma Calibrator	222101

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma	223201
• 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

• Research •

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

(3) www.hemophilia.org

OTHER BLEEDING DISORDERS

FACTOR XII (FXII) [1,3]

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			
Product Name	RS	Ref.	Presentation
• **Factor XII Deficient Plasma**	CE-IVD	DP080A	1 x 1 mL
		DP080K	6 x 1 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ Plasma Calibrator	222101

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma	223201
• BIOPHEN™ Abnormal Control Plasma	223301

FACTOR XI (FXI) [2]

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			
Product Name	RS	Ref.	Presentation
• **Factor XI Deficient Plasma**	CE-IVD	DP070A	1 x 1 mL
		DP070K	6 x 1 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ Plasma Calibrator	222101

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma	223201
• BIOPHEN™ Abnormal Control Plasma	223301

FACTOR VII (FVII) [3]

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).

(1) cf Dedicated intructions for use - (2) www.afh.asso.fr - (3) www.hemophilia.org

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 R2: 2 x 2 mL R3: 2 x 4 mL R4: 4 x 25 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301

Research

ZYMUTEST™ Factor VII

Measurement of FVII antigen in human plasma, or in any biological medium where FVII can be present, 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) [1,2,3]

- 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 R2: 4 x 2.5 mL R3: 4 x 5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301

Research

ZYMUTEST™ Factor X

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

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

(1) cf Dedicated intructions for use - (2) www.afh.asso.fr - (3) www.hemophilia.org

FACTOR II (FII) / PROTHROMBIN [1,2,3]

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

REAGENT			
Product Name	RS	Ref.	Presentation
• **Prothrombin Deficient Plasma**	CE-IVD	DP010A	1 x 1 mL
		DP010K	6 x 1 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ Plasma Calibrator	222101

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma	223201
• BIOPHEN™ Abnormal Control Plasma	223301

FACTOR V (FV) [1]

- 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			
Product Name	RS	Ref.	Presentation
• **Factor V Deficient Plasma**	CE-IVD	DP020A	1 x 1 mL
		DP020K	6 x 1 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ Plasma Calibrator	222101

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma	223201
• BIOPHEN™ Abnormal Control Plasma	223301

• Research •

ZYMUTEST™ Factor V

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

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

(1) cf Dedicated intructions for use - (2) www.afh.asso.fr - (3) www.hemophilia.org

FACTOR XIII (FXIII) [2]

- 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

• Research •

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

• Research •

ZYMUTEST™ Factor XIII-A

Measurement of FXIII (subunit A) in human plasma, or in any biological medium where Factor XIII (FXIII) is present, by Elisa.

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

(2) www.hemophilia.org

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

	Product Name	RS	Description	Ref.	Presentation	
CALIBRATOR	**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 and LA.	222101	12 x 1 mL	●
CONTROLS	**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	●

THROMBOPHILIA

ANTITHROMBIN (AT) [1]

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 223301
		221127	R1: 4 x 7.5 mL R2: 4 x 7.5 mL				

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 R3: 2 x 5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301
		221105	R1: 4 x 5 mL R2: 4 x 5 mL R3: 4 x 10 mL				

(1) cf Dedicated intructions for use

BIOPHEN™ AT (Anti-IIa)

Determination of AT activity, in presence of an excess of heparin, in human citrated plasma or purified milieu, 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 R2: 2 x 2.5 mL R3: 2 x 25 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301

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 R2: 2 x 10 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301
		120008	R1: 2 x 1.5 mL R2: 2 x 5 mL				

PROTEIN C (PC) (1)

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

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

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 R2: 3 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301
		CK032K	R1: 3 x 2 mL R2: 3 x 2 mL				

(1) cf Dedicated intructions 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 R2: 3 x 3 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 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 R2: 4 x 5 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 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

• 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) [1]

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 œstrogen 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 R2: 4 x 4.4 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 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 R2: 3 x 1 mL	• BIOPHEN™ Plasma Calibrator	222101	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ Abnormal Control Plasma	223201 223301
		CK042K	R1: 3 x 2 mL 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, or in any fluid where Total PS can be present, by Elisa.

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

(1) cf Dedicated intructions 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 [1]

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 R2: 3 x 1 mL	• BIOPHEN™ V-L Plasma Calibrator	222401	• BIOPHEN™ Normal Control Plasma • BIOPHEN™ V-L Control Plasma	223201 223405

PROTEIN Z (PZ)

· Research ·

ZYMUTEST™ Protein Z

Measurement of human PZ in plasma, or in any fluid, by Elisa.

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

(1) cf Dedicated intructions for use

LUPUS ANTICOAGULANT (LA) [1]

LA are associated with numerous clinical states including e.g. lupus, autoimmune diseases, thrombosis, fœtal 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	• EASYPLASMA™ Calibrator	226601	• 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
						• LA Control Plasma Weak	SC082K
						• LA Control Plasma High	SC083K
		CK522K	6 x 2.5 mL			• BIOPHEN™ Normal Control Plasma	223201
						• BIOPHEN™ Abnormal Control Plasma	223301
						• EASYPLASMA™ Control Set	225601

HEMOCLOT™

HEMOCLOT™ LA-S

Simplified 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
						• LA Control Plasma Weak	SC082K
		CK094K	12 x 2 mL			• LA Control Plasma High	SC083K
						• BIOPHEN™ Normal Control Plasma	223201

(1) cf Dedicated intructions for use

HEMOCLOT™ LA-C

Simplified 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

Pool of normal human plasma.

REAGENT			
Product Name	RS	Ref.	Presentation
• **BIOPHEN™ Normal-Plasma**	CE-IVD	223602	10 x 2 mL
		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.

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

Anti-β2GP1 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 or serum or in any biological fluid, by Elisa.

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

· Research ·

ZYMUTEST™ Anti-Annexin V, IgG

Measurement of autoantibodies to Annexin V of the IgG isotype, in human plasma or serum or in any biological fluid where autoantibodies to Annexin V must be measured.

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 or serum or in any biological fluid where autoantibodies to Annexin V must be measured.

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 or in any biological fluid where autoantibodies to PS must be measured.

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 or in any biological fluid where autoantibodies to PS must be measured.

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 or in any biological fluid where autoantibodies to Protein Z must be measured.

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 or in any biological fluid where autoantibodies to Protein Z must be measured.

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 or in any biological fluid where autoantibodies to Prothrombin must be measured.

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 Glyocoprotein I (β2GPI) in plasma, or in any fluid where β2GPI can be present, 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, 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

• Research •

ZYMUTEST™ DDimer

Measurement of the Fibrin Degradation Products (DDimer) in plasma, or in any fluid where DDimer can be present, 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, or in any fluid where FPA can be present, 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, serum, or in any fluid where CRP can be present, 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, or in any biological fluid where FL-TF can be present.

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, or in any biological fluid where TF can be present. 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 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	-	-	• BIOPHEN™ FXIa Control Set	224801

· 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 R2: 2 x 2.5 mL R3: 2 x 2.5 mL R4: 2 x 25 mL Cal: 2 x 1 mL	-	-	• BIOPHEN™ FIXa Control Set	224601

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 R2: 3 x 2 mL R3: 3 x 20 mL	• BIOPHEN™ Calibrator Factor VIIa	226301	• BIOPHEN™ FVIIa Control Set	224901 on-demand

· 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	-	-	-	-

CALIBRATORS

Product Name	RS	Description	Ref.	Presentation	ANTITHROMBIN	PROTEIN C	PROTEIN S	LUPUS ANTICOAGULANT	FACTOR V LEIDEN	FXIa	FIXa	FVIIa
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 and LA	222101	12 x 1 mL	●	●	●		●			
BIOPHEN™ V-L Plasma Calibrator	CE-IVD 510(K)	For the calibration of FV-L assay	222401	C1: 3 x 0,5 mL C2: 3 x 0,5 mL C3: 3 x 0,5 mL				●				
BIOPHEN™ FVIIa Calibrator	CE-IVD	For the calibration of FVIIa activity measurements	226301	6 x 2 mL								●
EASYPLASMA™ Calibrator	CE-IVD	Routine calibrator plasmas for PT/INR/%, aPTT, Fibrinogen (Fbg) and Thrombin Time (TT)	226601	6 x 1 mL					●			

CONTROLS

Product Name	RS	Description	Ref.	Presentation	ANTITHROMBIN	PROTEIN C	PROTEIN S	LUPUS ANTICOAGULANT	FACTOR V LEIDEN	FXIa	FIXa	FVIIa
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, of 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, of Lupus Anticoagulant.	SC082K	C1: 6 x 0.5 mL					●			
LA Control Plasma High	CE-IVD	Quality control plasmas, high positive, of Lupus Anticoagulant.	SC083K	C2: 6 x 0.5 mL					●			
BIOPHEN™ V-L Control Plasma	CE-IVD 510(K)	Quality control of FV-L	223405	12 x 0.5 mL				●				
BIOPHEN™ FVIIa Control Set	CE-IVD	Quality control of FVIIa activity measurements.	224901 on-demand	C1: 3 x 1 mL C2: 3 x 1 mL								●
BIOPHEN™ FXIa Control Set	RUO	Quality control of FXIa activity measurements	224801	C1: 3 x 1 mL C2: 3 x 1 mL						●		
BIOPHEN™ FIXa Control Set	RUO	Quality control of FIXa activity measurements	224601	C1: 6 x 1 mL C2: 6 x 1 mL							●	
EASYPLASMA™ Control Set	CE-IVD	Routine quality control plasmasfor 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

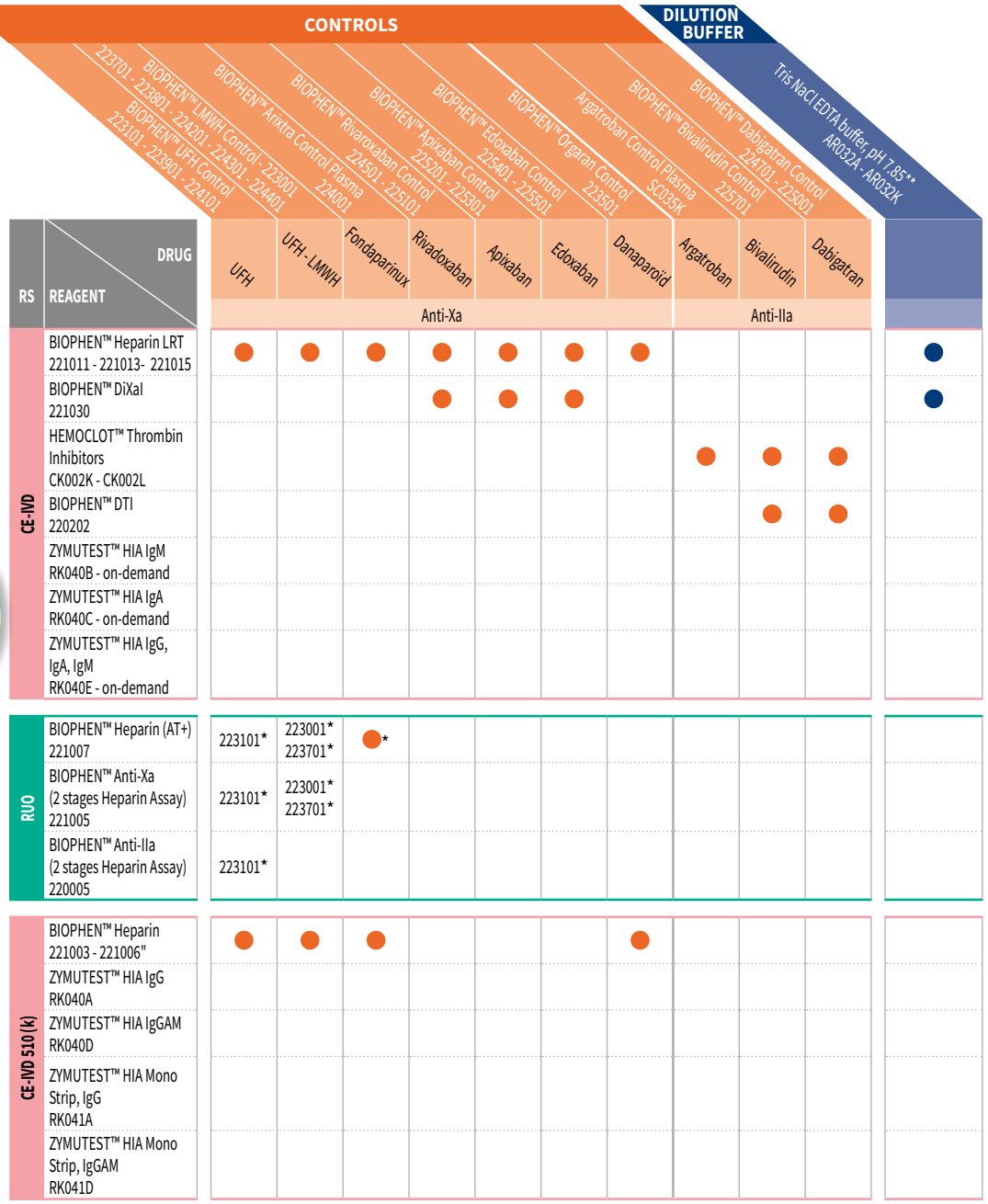
Anticoagulants are widely used to prevent and treat thromboembolic disorders.
The major groups are Anti-aggregants, Vitamin K antagonists, Polysaccharide anticoagulants (like heparins) and Direct Oral Anticoagulants (DOACs), targeted to thrombin or Factor Xa.
The major risks are bleeding (excess of drug), 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	UFH	UFH - LMWH	Fondaparinux	Rivaroxaban	Apixaban	Edoxaban	Danaparoid	Argatroban	Bivalirudin	Dabigatran
		Heparin induced Thrombocytopenia		Anti-Xa							Anti-IIa		
CE-IVD	BIOPHEN™ Heparin LRT 221011 - 221013- 221015			●	●	●	●	●	●	●			
CE-IVD	BIOPHEN™ DiXal 221030						●	●	●				
CE-IVD	HEMOCLOT™ Thrombin Inhibitors CK002K - CK002L										●	●	●
CE-IVD	BIOPHEN™ DTI 220202											●	●
CE-IVD	ZYMUTEST™ HIA IgM RK040B - on-demand		●										
CE-IVD	ZYMUTEST™ HIA IgA RK040C - on-demand		●										
CE-IVD	ZYMUTEST™ HIA IgG, IgA, IgM RK040E - on-demand		●										
RUO	BIOPHEN™ Heparin (AT+) 221007			●*	●*	●*							
RUO	BIOPHEN™ Anti-Xa (2 stages Heparin Assay) 221005			●*	●*								
RUO	BIOPHEN™ Anti-IIa (2 stages Heparin Assay) 220005			●*									
CE-IVD 510 (k)	BIOPHEN™ Heparin 221003 - 221006"			●	●	●				●			
CE-IVD 510 (k)	ZYMUTEST™ HIA IgG RK040A		●										
CE-IVD 510 (k)	ZYMUTEST™ HIA IgGAM RK040D	●											
CE-IVD 510 (k)	ZYMUTEST™ HIA Mono Strip, IgG RK041A		●										
CE-IVD 510 (k)	ZYMUTEST™ HIA Mono Strip, IgGAM RK041D	●											

*RUO kit

Assay portfolio for anticoagulants



*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 Danaparoïd), 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 R2: 4 x 7.5 mL	• BIOPHEN™ UFH Calibrator • BIOPHEN™ Heparin Calibrator • BIOPHEN™ Orgaran® Calibrator • BIOPHEN™ Arixtra® Calibrator • BIOPHEN™ Rivaroxaban Calibrator • BIOPHEN™ Apixaban Calibrator • BIOPHEN™ Edoxaban Calibrator	222301 222001 222201 222501 222701 226001 226101 226201 226401 226501	• BIOPHEN™ UFH Control • BIOPHEN™ LMWH Control • BIOPHEN™ Orgaran® Control • BIOPHEN™ Arixtra® Control Plasma • BIOPHEN™ Rivaroxaban Control • BIOPHEN™ Apixaban Control • BIOPHEN™ Edoxaban Control	223101 224101 223901 223701 224301 224401 223001 223801 224201 223501 224001 225101 224501 225201 225301 225401 225501
		221013	R3: 3 x 3 mL R4: 3 x 3 mL				
		221015	R1: 4 x 5 mL R2: 4 x 5 mL				

BIOPHEN™ DiXaI

Two-stage, chromogenic anti-Xa method for the measurement of direct Factor Xa inhibitors (DiXaIs), such as Rivaroxaban, Apixaban or Edoxaban, in citrated human plasma (or purified medium). 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™ DiXaI**	CE-IVD	221030	R1: 3 x 2.5 mL R2: 3 x 2.5 mL R3 : 4 x 20 mL	• BIOPHEN™ Rivaroxaban Calibrator • BIOPHEN™ Apixaban Calibrator • BIOPHEN™ Edoxaban Calibrator	222701 226001 226101 226201 226401 226501	• BIOPHEN™ Rivaroxaban Control • BIOPHEN™ Apixaban Control • BIOPHEN™ Edoxaban Control	224501 225101 225201 225301 225401 225501

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 R2: 2 x 7.5 mL R3: 2 x 2.5 mL	• BIOPHEN™ UFH Calibrator • BIOPHEN™ Heparin Calibrator • BIOPHEN™ Arixtra® Calibrator	222301 222001 222501	• BIOPHEN™ UFH Control • BIOPHEN™ LMWH Control • BIOPHEN™ Arixtra® Control Plasma	223101 223001 223701 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 R2: 2 x 1 mL R3: 2 x 1 mL	•BIOPHEN™ UFH Calibrator • BIOPHEN™ Heparin Calibrator	222301 222001	• BIOPHEN™ UFH Control • BIOPHEN™ LMWH Control	223101 223001 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 R2: 2 x 1 mL R3: 2 x 1 mL	•BIOPHEN™ UFH Calibrator	222301	• BIOPHEN™ UFH Control	223101

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 R3: 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 221006	R1: 3 x 3 mL R2: 3 x 3 mL R3: 4 x 6 mL R3: 4 x 6 mL	• BIOPHEN™ UFH Calibrator • BIOPHEN™ Heparin Calibrator • BIOPHEN™ Orgaran® Calibrator • BIOPHEN™ Arixtra® Calibrator	222301 222001 222201 222501	• BIOPHEN™ UFH Control • BIOPHEN™ LMWH Control • BIOPHEN™ Orgaran® Control • BIOPHEN™ Arixtra® Control Plasma	223101 224101 223901 223701 224301 224401 223001 223801 224201 223501 224001

Tris-NaCl-EDTA buffer, pH 7.85

Special dilution buffer for anti-Xa chromogenic assays, especially using BIOPHEN™ DiXaI 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	1 x 20 mL
		AR032K	4 x 20 mL

DIRECT ANTI-IIA ASSAYS

HEMOCLOT™ Thrombin Inhibitors

Anti-IIa 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			
Product Name	RS	Ref.	Presentation
• **HEMOCLOT™ Thrombin Inhibitors**	CE-IVD	CK002K	R1: 3 x 1 mL
			R2: 3 x 1 mL
		CK002L	R1: 3 x 2.5 mL
			R2: 3 x 2.5 mL

CALIBRATORS	
Product Name	Ref.
• BIOPHEN™ Dabigatran Calibrator	222901 222801
• BIOPHEN™ Plasma Calibrator	SC030K
• BIOPHEN™ Bivalirudin Calibrator	226701

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Dabigatran Control	225001 224701
• Argatroban Control Plasma	SC035K
• 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			
Product Name	RS	Ref.	Presentation
• **BIOPHEN™ DTI**	CE-IVD	220202	R1: 2 x 2.5 mL
			R2: 2 x 2.5 mL
			R3: 2 x 2.5 mL

CALIBRATORS	
Product Name	Ref.
• BIOPHEN™ Dabigatran Calibrator	222901 222801
• BIOPHEN™ Bivalirudin Calibrator	226701

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Dabigatran Control	225001 224701
• 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 or any other biological fluids where these antibodies must be detected.

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 or any other biological fluids where these antibodies must be detected.

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 or any other biological fluids where these antibodies must be detected.

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 or any other biological fluids where these antibodies must be detected.

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 or any other biological fluids where these antibodies must be detected.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• **ZYMUTEST™ HIA IgG, IgA, IgM** 32 tests	CE-IVD	RK040E on-demand	Micro Elisa plate: 12 x 8 HIA Sample Diluent: 2 x 50 mL HIA IgG Positive control: 1 vial HIA IgM Positive control: 1 vial HIA IgA Positive control: 1 vial Negative control: 3 vials Cell lysate lyophilised: 3 vials Anti-IgG (Fcγ)-HRP immunoconjugate: 1 vial Anti-IgM(μ)-HRP immunoconjugate: 1 vial Anti-IgA(α)-HRP immunoconjugate: 1 vial Conjugate Diluent: 1 x 25 mL Wash Solution: 1 x 50 mL Tetramethylbenzidine: 1 x 25 mL 0.45 M Sulfuric acid: 1 x 6 mL

ZYMUTEST™ HIA MonoStrip IgG

Detection and assay of heparin-dependent antibodies of the IgG isotype (anti heparin PF4 complexes), in human plasma or serum or any other biological fluids where these antibodies must be detected.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• **ZYMUTEST™ HIA MonoStrip IgG** 32 tests	CE-IVD 510(k)	RK041A	Micro Elisa plate: 4 x 8 HIA Sample Diluent: 2 x 12 mL HIA Positive control: 4 vials Negative control: 4 vials Cell lysate lyophilised: 4 vials Anti-IgG (Fcγ)-HRP immunoconjugate: 4 vials Conjugate Diluent: 1 x 10 mL Wash Solution: 2 x 12 mL Tetramethylbenzidine: 1 x 10 mL 0.45 M Sulfuric acid: 1 x 3 mL

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 or any other biological fluids where these antibodies must be detected.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• **ZYMUTEST™ HIA MonoStrip IgGAM** 32 tests	CE-IVD 510(k)	RK041D	Micro Elisa plate: 4 x 8 HIA Sample Diluent: 2 x 12 mL HIA Positive control: 4 vials Negative control: 4 vials Cell lysate lyophilised: 4 vials Anti-IgG (Fcγ)-IgM(μ)-IgA(α)-HRP immunoconjugate: 4 vials Conjugate Diluent: 1 x 10 mL Wash Solution: 2 x 12 mL Tetramethylbenzidine: 1 x 10 mL 0.45 M Sulfuric acid: 1 x 3 mL

	Product Name	RS	Description	Ref.	Presentation	Approximative Content	UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN
CALIBRATORS	**BIOPHEN™ UFH Calibrator**	CE-IVD 510(K)	UFH calibrator plasma set	222301	C1: 4 x 1 mL	0.00 IU/mL										
					C2: 4 x 1 mL	0.35 IU/mL										
					C3: 4 x 1 mL	0.70 IU/mL	●									
					C4: 4 x 1 mL	1.05 IU/mL										
					C5: 4 x 1 mL	1.40 IU/mL										
	BIOPHEN™ Heparin Calibrator	CE-IVD 510(K)	LMWH calibrator plasma set	222001	C1: 4 x 1 mL	0.00 IU/mL										
					C2: 4 x 1 mL	0.40 IU/mL										
					C3: 4 x 1 mL	0.80 IU/mL	●	●								
					C4: 4 x 1 mL	1.20 IU/mL										
					C5: 4 x 1 mL	1.60 IU/mL										
	BIOPHEN™ Arixtra® Calibrator	CE-IVD	Arixtra® calibrator plasma set	222501	C1: 3 x 1 mL	0.00 µg/mL										
					C2: 3 x 1 mL	0.50 µg/mL			●							
					C3: 3 x 1 mL	1.00 µg/mL										
					C4: 3 x 1 mL	1.50 µg/mL										
	BIOPHEN™ Riva-roxaban Plasma Calibrator	CE-IVD	Riva-roxaban calibrator plasma set, standard range	222701	C1: 4 x 1 mL	50.00 ng/mL										
					C2: 4 x 1 mL	250.00 ng/mL				●						
					C3: 4 x 1 mL	500.00 ng/mL										
	BIOPHEN™ Riva-roxaban Calibrator Low	CE-IVD	Riva-roxaban calibrator plasma set, low range	226001	CI: 4 x 1 mL	0.00 ng/mL										
					CII: 4 x 1 mL	50.00 ng/mL				●						
					CIII: 4 x 1 mL	100.00 ng/mL										
	BIOPHEN™ Apixaban Calibrator	CE-IVD	Apixaban calibrator plasma set, standard range	226201	C1: 4 x 1 mL	50.00 ng/mL										
					C2: 4 x 1 mL	300.00 ng/mL					●					
					C3: 4 x 1 mL	600.00 ng/mL										
	BIOPHEN™ Apixaban Calibrator Low	CE-IVD	Apixaban calibrator plasma set, low range	226101	CI: 4 x 1 mL	0.00 ng/mL										
					CII: 4 x 1 mL	50.00 ng/mL					●					
					CIII: 4 x 1 mL	100.00 ng/mL										

	Product Name	RS	Description	Ref.	Presentation	Approximative Content	UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN
CALIBRATORS	**BIOPHEN™ Edoxaban Calibrator**	CE-IVD	Edoxaban calibrator plasma set, standard range	226501	C1: 4 x 1 mL	0.00 ng/mL										
					C2: 4 x 1 mL	250.00 ng/mL							●			
					C3: 4 x 1 mL	500.00 ng/mL										
	BIOPHEN™ Edoxaban Calibrator Low	CE-IVD	Edoxaban calibrator plasma set, low range	226401	CI: 4 x 1 mL	0.00 ng/mL										
					CII: 4 x 1 mL	50.00 ng/mL							●			
					CIII: 4 x 1 mL	100.00 ng/mL										
	BIOPHEN™ Orgaran® Calibrator	CE-IVD	Orgaran® calibrator plasma set	222201	C1: 4 x 1 mL	0.00 U/mL										
					C2: 4 x 1 mL	0.40 U/mL										
					C3: 4 x 1 mL	0.80 U/mL									●	
					C4: 4 x 1 mL	1.20 U/mL										
					C5: 4 x 1 mL	1.60 U/mL										
	Argatroban Plasma Calibrator	CE-IVD	Argatroban calibrator plasma set	SC030K	C1: 4 x 1 mL	0.00 µg/mL										
					C2: 4 x 1 mL	0.50 µg/mL										
					C3: 4 x 1 mL	1.00 µg/mL								●		
					C4: 4 x 1 mL	1.50 µg/mL										
					C5: 4 x 1 mL	2.00 µg/mL										
	BIOPHEN™ Bivalirudin Calibrator	CE-IVD	Bivalirudin calibrator plasma set	226701	C1: 2 x 1 mL	0.00 µg/mL										
					C2: 2 x 1 mL	1.00 µg/mL										
					C3: 2 x 1 mL	2.00 µg/mL									●	
					C4: 2 x 1 mL	3.50 µg/mL										
					C5: 2 x 1 mL	5.00 µg/mL										
	BIOPHEN™ Dabigatran Plasma Calibrator	CE-IVD	Dabigatran calibrator plasma set, standard range	222801	C1: 4 x 1 mL	50.00 ng/mL										
					C2: 4 x 1 mL	250.00 ng/mL										●
					C3: 4 x 1 mL	500.00 ng/mL										
	BIOPHEN™ Dabigatran Calibrator Low	CE-IVD	Dabigatran calibrator plasma set, low range	222901	CI: 4 x 1 mL	0.00 ng/mL										
					CII: 4 x 1 mL	50.00 ng/mL										●
					CIII: 4 x 1 mL	100.00 ng/mL										

CONTROLS

Product Name	RS	Description	Ref.	Presentation	Approximative Content	UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN
BIOPHEN™ UFH Control	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	●									
BIOPHEN™ LMWH Control Plasma	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		●								
BIOPHEN™ LMWH Control Low	CE-IVD 510(K)	LMWH quality control plasma set, low range	223701	CI: 6 x 1 mL	0.25 IU/mL		●								
				CII: 6 x 1 mL	0.50 IU/mL										
			224301	CI: 12 x 1 mL	0.25 IU/mL		●								
			224401	CII: 12 x 1 mL	0.50 IU/mL		●								
BIOPHEN™ Arixtra® Control Plasma	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										
BIOPHEN™ Riva-roxaban Control Plasma	CE-IVD	Riva-roxaban quality control plasma set, standard range	224501	C1: 6 x 1 mL	100.00 ng/mL				●						
				C2: 6 x 1 mL	300.00 ng/mL										
BIOPHEN™ Riva-roxaban Control Low	CE-IVD	Riva-roxaban quality control plasma set, low range	225101	CI: 6 x 1 mL	25.00 ng/mL				●						
				CII: 6 x 1 mL	75.00 ng/mL										
BIOPHEN™ Apixaban Control	CE-IVD	Apixaban quality control plasma set, standard range	225301	C1: 6 x 1 mL	200.00 ng/mL					●					
				C2: 6 x 1 mL	400.00 ng/mL										

CONTROLS

Product Name	RS	Description	Ref.	Presentation	Approximative Content	UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN
BIOPHEN™ Apixaban Control Low	CE-IVD	Apixaban quality control plasma set, low range	225201	CI: 6 x 1 mL	25.00 ng/mL						●				
				CII: 6 x 1 mL	75.00 ng/mL										
BIOPHEN™ Edoxaban Control	CE-IVD	Edoxaban quality control plasma set, standard range	225501	C1: 6 x 1 mL	150.00 ng/mL							●			
				C2: 6 x 1 mL	300.00 ng/mL										
BIOPHEN™ Edoxaban Control Low	CE-IVD	Edoxaban quality control plasma set, low range	225401	CI: 6 x 1 mL	25.00 ng/mL							●			
				CII: 6 x 1 mL	75.00 ng/mL										
BIOPHEN™ Orgaran® Control	CE-IVD	Orgaran® quality control plasma set	223501	C1: 6 x 1 mL	0.50 U/mL								●		
				C2: 6 x 1 mL	1.00 U/mL										
Argatroban Control Plasma	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								●		
BIOPHEN™ Bivalirudin Control	CE-IVD	Bivalirudin quality control plasma set	225701	C1: 3 x 1 mL	1.50 µg/mL									●	
				C2: 3 x 1 mL	4.00 µg/mL										
BIOPHEN™ Dabigatran Control Plasma	CE-IVD	Dabigatran quality control plasma set, standard range	224701	C1: 6 x 1 mL	100.00 ng/mL										●
				C2: 6 x 1 mL	300.00 ng/mL										
BIOPHEN™ Dabigatran Control Low	CE-IVD	Dabigatran quality control plasma set, low range	225001	CI: 6 x 1 mL	25.00 ng/mL										●
				CII: 6 x 1 mL	75.00 ng/mL										

FIBRINOLYSIS

BIOPHEN™ α2-Antiplasmin
R1 Human Plasma
Ready to use
LOT FA061774
2023-03-17
IVD
BIOPHEN™ α2-Antiplasmin
R2
Ready to use
LOT FA061774
2023-03-17
IVD

EXPLORE PLASMINOGEN ACTIVITY

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

BIOPHEN™ Plasminogen (LRT)

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

REAGENT			
Product Name	RS	Ref.	Presentation
• **BIOPHEN™ Plasminogen (LRT)** Liquid and Ready to use	CE-IVD	221511	R1: 3 x 3 mL R2: 3 x 3 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ Plasma Calibrator	222101

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma	223201
• BIOPHEN™ Abnormal Control Plasma	223301

EXPLORE PLASMINOGEN ACTIVATOR INHIBITORS

ANTIPLASMIN: α2-ANTIPLASMIN [1]

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			
Product Name	RS	Ref.	Presentation
• **BIOPHEN™ α2-Antiplasmin (LRT)** Liquid and Ready to use	CE-IVD	220502	R1: 3 x 3 mL R2: 3 x 3 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ Plasma Calibrator	222101

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma	223201
• 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, or in any fluid where active PAI-1 can be present, by Bio-Immuno-Assay.

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

(1) cf Dedicated intructions for use

ZYMUTEST™ PAI-1 Antigen

Measurement of human Tissue- Plasminogen Activator Inhibitor, type I (PAI-1) in plasma, or in any fluid where PAI-1: Ag can be present, 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, or in any fluid where Total TAFI can be present. 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, or in any fluid where human TAFI zymogen can be present. Inactive forms of TAFI are measured, by Elisa.

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

Tissue plasminogen activator tPA

· Research ·

ZYMUPHEN™ tPA Activity

Measurement of tPA activity in human acidified citrated plasma or in purified milieu, 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 Tissue Plasminogen Activator (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.

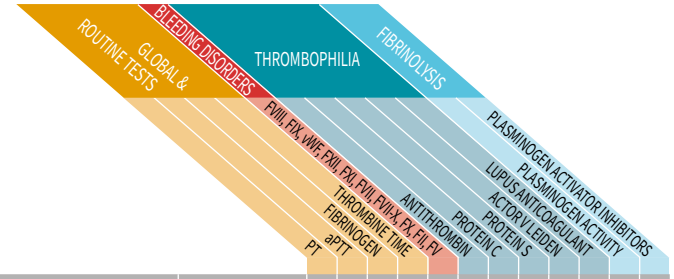
COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• **ZYMUTEST™ tPA Antigen**	CE-IVD	RK011A	96 tests

PLASMINOGEN ACTIVATOR INHIBITORS
PLASMINOGEN ACTIVITY

	Product Name	RS	Description	Ref.	Presentation		
CALIBRATOR	**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 and LA	222101	12 x 1 mL	●	●
CONTROLS	**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	●	●

CALIBRATORS & CONTROLS

MULTI CALIBRATORS & CONTROLS



	Product Name	RS	Description	Ref.	Presentation
CALIBRATORS	**EASYPLASMA™ Calibrator**	CE-IVD	Routine calibrator plasmas for PT/INR/%, aPTT, Fibrinogen (Fbg) and Thrombin Time (TT)	226601	6 x 1 mL
CALIBRATORS	**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 and LA	222101	12 x 1 mL
CONTROLS	**EASYPLASMA™ Control Set**	CE-IVD	Routine quality control plasmasfor 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
CONTROLS	**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
CONTROLS	**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

SPECIFICS
CALIBRATORS & CONTROLS

	Product Name	RS	Description	Ref.	Presentation	Approximative Content	PT	aPTT	ACTIVATED PROTEIN C RESISTANCE	LUPUS ANTICOAGULANT	FXIa	FIXa	FVIIa
CALIBRATORS	**PT Calibrator Set**	CE-IVD	Five certified plasmas for PT/ INR and PT% calibration and/or for verification of local ISI test system	SC084K	C1: 2 x 1 mL	INR 1.00							
					C2: 2 x 1 mL	INR 2.00							
					C3: 2 x 1 mL	INR 3.00	●						
					C4: 2 x 1 mL	INR 4.00							
					C5: 2 x 1 mL	INR 5.00							
	BIOPHEN™ V-L Plasma Calibrator	CE-IVD 510(k)	For the calibration of FV-L assay	222401	C1: 3 x 0.5 mL	10 %							
					C2: 3 x 0.5 mL	25 %				●			
					C3: 3 x 0.5 mL	50 %							
	BIOPHEN™ Calibrator Factor VIIa	CE-IVD	For the calibration of FVIIa activity measurements	226301	6 x 2 mL	400 mIU/mL							●
CONTROLS	**LA Control Plasma**	CE-IVD	Quality control plasmas, weak and high positive, of Lupus Anticoagulant	SC081K	C1: 6 x 0.5 mL	Ratio 1.40		●		●			
					C2: 6 x 0.5 mL	Ratio 2.40							
	LA Control Plasma Weak	CE-IVD	Quality control plasmas, weak positive, of Lupus Anticoagulant	SC082K	C1: 6 x 0.5 mL	Ratio 1.40		●		●			
	LA Control Plasma High	CE-IVD	Quality control plasmas, high positive, of Lupus Anticoagulant	SC083K	C2: 6 x 0.5 mL	Ratio 2.40		●		●			
	BIOPHEN™ V-L Control Plasma	CE-IVD 510(k)	Quality control of FV-L	223405	12 x 0.5 mL	40 %			●				
	BIOPHEN™ FVIIa Control Set	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	PT	aPTT	ACTIVATED PROTEIN C RESISTANCE	LUPUS ANTICOAGULANT	FXIa	FIXa	FVIIa	OTHER
CONTROLS	**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	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								

ANTICOAGULANTS CALIBRATORS

CALIBRATORS

Product Name	RS	Description	Ref.	Presentation	Approximative Content	UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN
BIOPHEN™ UFH Calibrator	CE-IVD 510(K)	UFH calibrator plasma set	222301	C1: 4 x 1 mL	0.00 IU/mL										
				C2: 4 x 1 mL	0.35 IU/mL										
				C3: 4 x 1 mL	0.70 IU/mL	●									
				C4: 4 x 1 mL	1.05 IU/mL										
				C5: 4 x 1 mL	1.40 IU/mL										
BIOPHEN™ Heparin Calibrator	CE-IVD 510(K)	LMWH calibrator plasma set	222001	C1: 4 x 1 mL	0.00 IU/mL										
				C2: 4 x 1 mL	0.35 IU/mL										
				C3: 4 x 1 mL	0.70 IU/mL	●	●								
				C4: 4 x 1 mL	1.05 IU/mL										
				C5: 4 x 1 mL	1.40 IU/mL										
BIOPHEN™ Arixtra® Calibrator	CE-IVD	Arixtra® calibrator plasma set	222501	C1: 3 x 1 mL	0.00 µg/mL										
				C2: 3 x 1 mL	0.50 µg/mL			●							
				C3: 3 x 1 mL	1.00 µg/mL										
				C4: 3 x 1 mL	1.50 µg/mL										
BIOPHEN™ Riva-roxaban Plasma Calibrator	CE-IVD	Riva-roxaban calibrator plasma set, standard range	222701	C1: 4 x 1 mL	50.00 ng/mL										
				C2: 4 x 1 mL	250.00 ng/mL				●						
				C3: 4 x 1 mL	500.00 ng/mL										
BIOPHEN™ Riva-roxaban Calibrator Low	CE-IVD	Riva-roxaban calibrator plasma set, low range	226001	CI: 4 x 1 mL	0.00 ng/mL										
				CII: 4 x 1 mL	50.00 ng/mL				●						
				CIII: 4 x 1 mL	100.00 ng/mL										
BIOPHEN™ Apixaban Calibrator	CE-IVD	Apixaban calibrator plasma set, standard range	226201	C1: 4 x 1 mL	50.00 ng/mL										
				C2: 4 x 1 mL	300.00 ng/mL					●					
				C3: 4 x 1 mL	600.00 ng/mL										
BIOPHEN™ Apixaban Calibrator Low	CE-IVD	Apixaban calibrator plasma set, low range	226101	CI: 4 x 1 mL	0.00 ng/mL										
				CII: 4 x 1 mL	50.00 ng/mL					●					
				CIII: 4 x 1 mL	100.00 ng/mL										

ANTICOAGULANTS CALIBRATORS

CALIBRATORS

Product Name	RS	Description	Ref.	Presentation	Approximative Content	UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN
BIOPHEN™ Edoxaban Calibrator	CE-IVD	Edoxaban calibrator plasma set, standard range	226501	C1: 4 x 1 mL	0.00 ng/mL										
				C2: 4 x 1 mL	250.00 ng/mL							●			
				C3: 4 x 1 mL	500.00 ng/mL										
BIOPHEN™ Edoxaban Calibrator Low	CE-IVD	Edoxaban calibrator plasma set, low range	226401	CI: 4 x 1 mL	0.00 ng/mL										
				CII: 4 x 1 mL	50.00 ng/mL							●			
				CIII: 4 x 1 mL	100.00 ng/mL										
BIOPHEN™ Orgaran® Calibrator	CE-IVD	Orgaran® calibrator plasma set	222201	C1: 4 x 1 mL	0.00 U/mL										
				C2: 4 x 1 mL	0.40 U/mL										
				C3: 4 x 1 mL	0.80 U/mL								●		
				C4: 4 x 1 mL	1.20 U/mL										
				C5: 4 x 1 mL	1.60 U/mL										
Argatroban Plasma Calibrator	CE-IVD	Argatroban calibrator plasma set	SC030K	C1: 4 x 1 mL	0.00 µg/mL										
				C2: 4 x 1 mL	0.50 µg/mL										
				C3: 4 x 1 mL	1.00 µg/mL								●		
				C4: 4 x 1 mL	1.50 µg/mL										
				C5: 4 x 1 mL	2.00 µg/mL										
BIOPHEN™ Bivalirudin Calibrator	CE-IVD	Bivalirudin calibrator plasma set	226701	C1: 2 x 1 mL	0.00 µg/mL										
				C2: 2 x 1 mL	1.00 µg/mL										
				C3: 2 x 1 mL	2.00 µg/mL									●	
				C4: 2 x 1 mL	3.50 µg/mL										
				C5: 2 x 1 mL	5.00 µg/mL										
BIOPHEN™ Dabigatran Plasma Calibrator	CE-IVD	Dabigatran calibrator plasma set, standard range	222801	C1: 4 x 1 mL	50.00 ng/mL										
				C2: 4 x 1 mL	250.00 ng/mL										●
				C3: 4 x 1 mL	500.00 ng/mL										
BIOPHEN™ Dabigatran Calibrator Low	CE-IVD	Dabigatran calibrator plasma set, low range	222901	CI: 4 x 1 mL	0.00 ng/mL										
				CII: 4 x 1 mL	50.00 ng/mL										●
				CIII: 4 x 1 mL	100.00 ng/mL										

ANTICOAGULANTS CONTROLS

	Product Name	RS	Description	Ref.	Presentation	Approximative Content	UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN
CONTROLS	**BIOPHEN™ UFH Control**	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	●									
	BIOPHEN™ LMWH Control Plasma	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		●								
	BIOPHEN™ LMWH Control Low	CE-IVD 510(K)	LMWH quality control plasma set, low range	223701	CI: 6 x 1 mL	0.25 IU/mL		●								
					CII: 6 x 1 mL	0.50 IU/mL										
				224301	CI: 12 x 1 mL	0.25 IU/mL		●								
				224401	CII: 12 x 1 mL	0.50 IU/mL		●								
	BIOPHEN™ Arixtra® Control Plasma	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										
	BIOPHEN™ Riva-roxaban Control Plasma	CE-IVD	Riva-roxaban quality control plasma set, standard range	224501	C1: 6 x 1 mL	100.00 ng/mL				●						
					C2: 6 x 1 mL	300.00 ng/mL										
	BIOPHEN™ Riva-roxaban Control Low	CE-IVD	Riva-roxaban quality control plasma set, low range	225101	CI: 6 x 1 mL	25.00 ng/mL				●						
					CII: 6 x 1 mL	75.00 ng/mL										
	BIOPHEN™ Apixaban Control	CE-IVD	Apixaban quality control plasma set, standard range	225301	C1: 6 x 1 mL	200.00 ng/mL						●				
					C2: 6 x 1 mL	400.00 ng/mL										

ANTICOAGULANTS CONTROLS

	Product Name	RS	Description	Ref.	Presentation	Approximative Content	UFH	LMWH	FONDAPARINUX	RIVAROXABAN	APIXABAN	EDOXABAN	DANAPAROID	ARGATROBAN	BIVALIRUDIN	DABIGATRAN
CONTROLS	**BIOPHEN™ Apixaban Control Low**	CE-IVD	Apixaban quality control plasma set, low range	225201	CI: 6 x 1 mL	25.00 ng/mL						●				
					CII: 6 x 1 mL	75.00 ng/mL										
	BIOPHEN™ Edoxaban Control	CE-IVD	Edoxaban quality control plasma set, standard range	225501	C1: 6 x 1 mL	150.00 ng/mL							●			
					C2: 6 x 1 mL	300.00 ng/mL										
	BIOPHEN™ Edoxaban Control Low	CE-IVD	Edoxaban quality control plasma set, low range	225401	CI: 6 x 1 mL	25.00 ng/mL							●			
					CII: 6 x 1 mL	75.00 ng/mL										
	BIOPHEN™ Orgaran® Control	CE-IVD	Orgaran® quality control plasma set	223501	C1: 6 x 1 mL	0.50 U/mL								●		
					C2: 6 x 1 mL	1.00 U/mL										
	Argatroban Control Plasma	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										
	BIOPHEN™ Bivalirudin Control	CE-IVD	Bivalirudin quality control plasma set	225701	C1: 3 x 1 mL	1.50 µg/mL										●
					C2: 3 x 1 mL	4.00 µg/mL										
	BIOPHEN™ Dabigatran Control Plasma	CE-IVD	Dabigatran quality control plasma set, standard range	224701	C1: 6 x 1 mL	100.00 ng/mL										●
					C2: 6 x 1 mL	300.00 ng/mL										
	BIOPHEN™ Dabigatran Control Low	CE-IVD	Dabigatran quality control plasma set, low range	225001	CI: 6 x 1 mL	25.00 ng/mL										●
					CII: 6 x 1 mL	75.00 ng/mL										

RESEARCH

You need specific coagulation proteins or enzymes?
We can provide you with frozen, liquid or lyophilized formats.
For more detail on the terms and conditions, please contact your local distributors.

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	EZ004B on-demand	1 x 10 µg
		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*(a)
		PP004L	10 x 10 IU*(a)
		PP004D	1 x 25 IU*(a)
		PP004M	10 x 25 IU*(a)
		PP004C	1 x 10 mg

**(a): 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*[a]
		EZ006K	6 x 10 NIH*[a]
		EZ006A	1 x 100 NIH*[a]
		EZ006L	10 x 100 NIH*[a]
		EZ006B	1 x 1000 NIH*[a]

**(a): 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*[a]
		BE102K	6 x 21 NIH*[a]
		BE102C	1 x 1000 NIH*[a]

**(a): 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
• **BIOPHEN™ CS-01(38)** Thrombin Chromogenic Substrate	RUO	229001	1 x 25 mg	H-D-Phe-Pip-Arg-pNa, 2HCl
	RUO	229001C	12 x 25 mg	
• **BIOPHEN™ CS-01(81)** Thrombin Chromogenic Substrate	RUO	229005 on-demand	1 x 25 mg	Tos-Gly-Pro-Arg-pNa. AcOH
• **BIOPHEN™ CS-11(32)** Factor Xa Chromogenic Substrate	RUO	229011	1 x 25 mg	Suc-Ile-Glu (γ Pip)Gly-Arg-pNa, HCl
• **BIOPHEN™ CS-11(65)** Factor Xa Chromogenic Substrate	RUO	229014	1 x 25 mg	-D-Arg-Gly-Arg-pNA, 2HCl
	RUO	229014C	12 x 25 mg	
• **BIOPHEN™ CS-11(22)** Factor Xa Chromogenic Substrate	RUO	229015 on-demand	1 x 25 mg	Mixture (50%-50%) of Bz-Ile-Glu (γOCH3)-Gly-Arg-pNa (form 1) and Bz-Ile-Glu (γOH)Gly-Arg-pNa (form 2)
• **BIOPHEN™ CS-21(66)** Activated Protein C Chromogenic substrate	RUO	229021	1 x 25 mg	p-Glu-Pro-Arg-pNa. HCl
• **BIOPHEN™ CS-31(02)** Kallicrein Chromogenic substrate	RUO	229031	1 x 25 mg	D-Pr0-Phe-Arg-pNa, 2HCl
• **BIOPHEN™ CS-41(03)** Plasmin and Plasminogen-SK Chromogenic substrate	RUO	229041 on-demand	1 x 25 mg	PyroGlu--Phe-Lys-pNa-HCl
• **BIOPHEN™ CS-61(44)** Urokinase Chromogenic Substrate	RUO	229061	1 x 25 mg	pyro-Glu-Gly-Arg-pNa.HCl
• **BIOPHEN™ CS-05(88)** 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, or in any fluid where Fibrinogen can be present, with an Elisa method.

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

ZYMUTEST™ PF4

Measurement of human Platelet Factor 4 (PF4) by Elisa in platelet depleted plasma, or in any fluid where PF4 must be measured.

COMPLETE SOLUTION			
Product Name	RS	Ref.	Presentation
• **ZYMUTEST™ PF4**	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
• **ZYMUTEST™ Factor IX**	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			
Product Name	RS	Ref.	Presentation
• **BIOPHEN™ FVII**	RUO	221304	R1: 2 x 4 mL R2: 2 x 2 mL R3: 2 x 4 mL R4: 4 x 25 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ Plasma Calibrator	222101

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma	223201
• BIOPHEN™ Abnormal Control Plasma	223301

ZYMUTEST™ Factor VII

Measurement of FVII antigen in human plasma, or in any biological medium where FVII can be present, 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			
Product Name	RS	Ref.	Presentation
• **BIOPHEN™ Factor X**	RUO	221705	R1: 4 x 2.5 mL R2: 4 x 2.5 mL R3: 4 x 5 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ Plasma Calibrator	222101

CONTROLS	
Product Name	Ref.
• BIOPHEN™ Normal Control Plasma	223201
• BIOPHEN™ Abnormal Control Plasma	223301

ZYMUTEST™ Factor X

Measurement of human FX antigen in human plasma, or in any biological medium where FX is present, 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, or in any fluid where FV can be present, 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, or in any biological medium where FXIII is present, 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, or in any fluid, 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 or serum or in any biological fluid where autoantibodies to Annexin V must be measured.

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 or serum or in any biological fluid where autoantibodies to Annexin V must be measured.

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 or in any biological fluid where autoantibodies to PS must be measured.

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 or in any biological fluid where autoantibodies to PS must be measured.

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 or in any biological fluid where autoantibodies to Protein Z must be measured.

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 or in any biological fluid where autoantibodies to Protein Z must be measured.

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 or in any biological fluid where autoantibodies to Prothrombin must be measured.

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 Glyocoprotein I (β2GPI) in plasma, or in any fluid where β2GPI can be present, 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, or in any fluid where DDimer can be present, 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, or in any fluid where FPA can be present, 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, or in any fluid where CRP can be present, 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, or in any biological fluid where FL-TF can be present.

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, or in any biological fluid where TF can be present.
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 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	-	-	• BIOPHEN™ FXIa Control Set	224801

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 R2: 2 x 2.5 mL R3: 2 x 2.5 mL R4: 2 x 25 mL Cal: 2 x 1 mL	-	-	• BIOPHEN™ FIXa Control Set	224601

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	-	-	-	-

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			
Product Name	RS	Ref.	Presentation
• **BIOPHEN™ HEPARIN (AT+)**	RUO	221007	R1: 2 x 7.5 mL R2: 2 x 7.5 mL R3: 2 x 2.5 mL

CALIBRATORS	
Product Name	Ref.
• BIOPHEN™ UFH Calibrator	222301
• BIOPHEN™ Heparin Calibrator	222001
• BIOPHEN™ Arixtra® Calibrator	222501

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

CALIBRATORS	
Product Name	Ref.
• BIOPHEN™ UFH Calibrator	222301
• BIOPHEN™ Heparin Calibrator	222001

CONTROLS	
Product Name	Ref.
• BIOPHEN™ UFH Control	223101
• BIOPHEN™ LMWH Control	223001 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			
Product Name	RS	Ref.	Presentation
• **BIOPHEN™ ANTI-IIa** (2 Stages Heparin Assay)	RUO	220005	R1: 2 x 1 mL R2: 2 x 1 mL R3: 2 x 1 mL

CALIBRATOR	
Product Name	Ref.
• BIOPHEN™ UFH Calibrator	222301

CONTROL	
Product Name	Ref.
• BIOPHEN™ UFH Control	223101

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			
Product Name	RS	Ref.	Presentation
• **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

CALIBRATOR	
Product Name	Ref.
-	-

CONTROL	
Product Name	Ref.
-	-

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, or in any fluid where active PAI-1 can be present, 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, or in any fluid where Total TAFI can be present. 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, or in any fluid where human TAFI zymogen can be present. 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 or in purified milieu, 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 - pH 7.50

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 - pH 7.50 (TBS)** 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 Pharmacopoiea 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 Pharmacopoiea 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 - pH 7.5

REAGENT			
Product Name	RS	Ref.	Presentation
• **Phosphate NaCl (PBS) buffer - pH 7.5** Ready to use	RUO	AR006K on-demand	3 x 50 mL

Phosphate NaCl (PBSA) buffer - pH 7.50

Isotonic Phosphate Buffer containing 0.15 M of Sodium chloride (PBSA)
Diluent for purified proteins and enzymes. Can’t be used for tests in presence of calcium.

REAGENT			
Product Name	RS	Ref.	Presentation
• **Phosphate NaCl (PBSA) buffer - pH 7.50** Ready to use	RUO	AR007K on-demand	3 x 50 mL

Tris buffer

Buffer for chromogenic assays.

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

Tris-NaCl buffer

Buffer for chromogenic assays.

REAGENT			
Product Name	RS	Ref.	Presentation
• **Tris-NaCl buffer - pH 8.40 (I = 0.30)** Ready to use	RUO	AR009K 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 - pH 8.40**	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 Pharmacopoiea 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 Pharmacopoiea 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 Pharmacopoiea 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
• **Prothrombin Activator Diluent** 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
• **AT-Tris buffer Anti-Xa** 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
• **AT-Tris buffer Anti-IIa** Ready to use	RUO	AR104A	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
• **Elisa dilution buffer, with albumin** 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
• **FPA anticoagulant solution** Ready to use	RUO	AR013A	1 x 20 mL

Wash solution for Elisa

For enzyme immunoassays.

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

Bentonite suspension

Removal of Fibrinogen from plasma for testing FPA.

REAGENT			
Product Name	RS	Ref.	Presentation
• **Bentonite suspension** Ready to use	RUO	AR024A	1 x 50 mL

OTHER SOLUTIONS

Tetramethylbenzidine (TMB) substrate

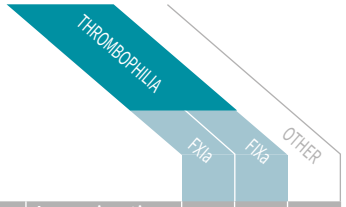
Peroxidase substrate for the color development step of the Elisa methods.

REAGENT			
Product Name	RS	Ref.	Presentation
• **Tetramethylbenzidine (TMB) substrate** Ready to use	RUO	AR012A on-demand	1 x 25 mL

High Sensitivity Tetramethylbenzidine substrate (TMB-HS)

Peroxidase substrate for the color development step of the Elisa methods.

REAGENT			
Product Name	RS	Ref.	Presentation
• **High Sensitivity Tetramethylbenzidine substrate (TMB-HS)** Ready to use	RUO	AR027A	1 x 25 mL



	Product Name	RS	Description	Ref.	Presentation	Approximative Content	FXIa	FIXa	OTHER
CONTROLS	**BIOPHEN™ FXIa Control Set**	RUO	Quality control of FXIa activity measurements	224801	C1: 3 x 1 mL C2: 3 x 1 mL	10.00 mIU/mL 30.00 mIU/mL	●		
	BIOPHEN™ FIXa Control Set	RUO	Quality control of FIXa activity measurements	224601	C1: 6 x 1 mL C2: 6 x 1 mL	6.00 mIU/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
• **Imidazole buffer** Ready to use	CE-IVD	AR021B	1 x 15 mL[(b)]
		AR021M	3 x 15 mL[(b)]
		AR021K	3 x 25 mL
		AR021N	12 x 15 mL[(b)]
		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
• **Calcium Chloride 0.025M (M/40)** Ready to use	CE-IVD	AR001B	3 x 15 mL[(b)]
		AR001L	12 x 15 mL[(b)]
		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
• **Special Tris-BSA buffer**	CE-IVD	AR026A	3 x 25 mL
		AR026K	12 x 25 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
• **Tris-NaCl buffer - pH 7.50 (TBS)** 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 EU Pharmacopoiea 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 (TBS)** 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 Pharmacopoiea for Heparin anti-IIa assay.

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

Phosphate NaCl (PBS) buffer

Phosphate Buffer Saline (PBS).

REAGENT			
Product Name	RS	Ref.	Presentation
• **Phosphate NaCl (PBS) buffer - pH 7.5** Ready to use	RUO	AR006K on-demand	3 x 50 mL

Phosphate NaCl (PBSA) buffer

Isotonic Phosphate Buffer containing 0.15M of Sodium chloride (PBSA)
Diluent for purified proteins and enzymes. Can't be used for tests in presence of calcium.

REAGENT			
Product Name	RS	Ref.	Presentation
• **Phosphate NaCl (PBSA) buffer - pH 7.50** Ready to use	RUO	AR007K on-demand	3 x 50 mL

Tris buffer

Buffer for chromogenic assays.

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

Tris-NaCl buffer

Buffer for chromogenic assays.

REAGENT			
Product Name	RS	Ref.	Presentation
• **Tris-NaCl buffer - pH 8.40 (I = 0.30)** Ready to use	RUO	AR009K 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 conc.) - pH 8.40**	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 Pharmacopoiea 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

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 Pharmacopoiea 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 NaCl EDTA buffer - pH 7.85

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

REAGENT			
Product Name	RS	Ref.	Presentation
• **Tris NaCl EDTA buffer - pH 7.85** Ready to use	CE-IVD	AR032A	1 x 20 mL
		AR032K	4 x 20 mL

Research

Tris EDTA NaCl - pH 8.40

Dilution buffer for biological tests.
Can be used as buffer recommended by the US and EU Pharmacopoiea 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	1 x 10 mL

· 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** Ready to use	RUO	AR011K	3 x 50 mL

· Research ·

Bentonite suspension

Removal of Fibrinogen from plasma for testing FPA.

REAGENT			
Product Name	RS	Ref.	Presentation
• **Bentonite suspension** Ready to use	RUO	AR024A	1 x 50 mL

BIOPHEN™ NormalPlasma

Pool of normal human plasma.

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

· Research ·

Tetramethylbenzidine (TMB) substrate

Peroxidase substrate for the color development step of the Elisa methods.

REAGENT			
Product Name	RS	Ref.	Presentation
• **Tetramethylbenzidine (TMB) substrate** Ready to use	RUO	AR012A on-demand	1 x 25 mL

· Research ·

High Sensitivity Tetramethylbenzidine substrate (TMB-HS)

Peroxidase substrate for the color development step of the Elisa methods.

REAGENT			
Product Name	RS	Ref.	Presentation
• **High Sensitivity Tetramethyl-benzidine substrate (TMB-HS)** Ready to use	RUO	AR027A	1 x 25 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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