



For Diagnostic, Research and Industrial use :

Complete Assay Line for Anticoagulants



- Complete range of reagents, calibrators and controls (HEMOCLOT and BIOPHEN®) for measurement of direct anticoagulants, heparins and their analogues for Diagnostic, Research and Pharmaceutical Industry use (methods adhere to recommendations of the European Pharmacopoeia).

Description of Reagent	Ref.	Direct Anti-IIa			Direct Anti-Xa		Heparins and their Analogues			
		Dabigatran	Argatroban	Hirudin	Rivaroxaban	Apixaban	LMWH	UFH	Orgaran® and other Sodium Danaparoids	Arixtra® and other Pentasaccharides
		Low Standard			Low Standard	Low Standard				
Dedicated calibrators and controls		Cal: 222901 Ctl: 225001 Cal: 222801 Ctl: 224701	Cal: SC030K Ctl: SC035K	Cal: SC020K Cal: SC020L Ctl: SC025K	Cal: 226001 Ctl: 225101 Cal: 222701 Ctl: 224501	Cal: 226101 Ctl: 225201 Cal: 226201 Ctl: 225301	Cal: 222001 Ctl: 223001 Ctl: 223701	Cal: 222301 Ctl: 223101	Cal: 222201 Ctl: 223501	Cal: 222501 Ctl: 224001
HEMOCLOT Thrombin Inhibitors CE, IVD	Test concentration of Dabigatran and other direct thrombin inhibitors by chromometric "anti-thrombin" method.	CK002K or CK002L	⊙	⊙	⊙					
BIOPHEN® DTI CE, IVD	Test direct thrombin inhibitors by chromogenic method. Insensitive to the presence of heparin.	220202	⊙		⊙					
BIOPHEN® Heparin (LRT) CE, IVD	Test heparins and their analogues by chromogenic anti-Xa method with ready-to-use, liquid reagent technology.	221013 or 221011			⊙	⊙	⊙	⊙	⊙	⊙
BIOPHEN® Heparin CE, IVD	Test heparins and their analogues by chromogenic anti-Xa method.	221003 or 221006			⊙	⊙	⊙	⊙	⊙	⊙
BIOPHEN® DiXal CE, IVD	Test direct Factor Xa inhibitors by chromogenic method. Insensitive to the presence of heparin.	221030			⊙	⊙				
BIOPHEN® Heparin Anti-IIa (kinetics) RUO	Test heparins and their analogues in buffer or purified systems by kinetic/competitive chromogenic anti-IIa method in the presence of exogenous antithrombin.	221020						⊙		
BIOPHEN® Anti-IIa (2 stage) RUO	Test heparins on plasma or purified systems, by chromogenic 2-stage anti-IIa method, adhering to the recommendations of Pharmacopoeia.	221025						⊙		
BIOPHEN® Heparin (AT+) RUO	Test heparin and their analogues by kinetic chromogenic anti-Xa method with addition of Antithrombin. Exogenous Antithrombin addition in the assay is useful especially for assaying heparin in samples with low Antithrombin content (eg. neonates), or for Arixtra®.	221007					⊙	⊙	⊙	⊙
BIOPHEN® Anti-Xa (2 stage) RUO	Test heparin in plasma or purified systems, by 2-stage chromogenic anti-Xa method, adhering to the recommendations of Pharmacopoeia.	221010					⊙	⊙	⊙	⊙

Lire attentivement les instructions figurant sur l'étiquetage et/ou la notice d'utilisation des réactifs.



Direct Oral Anticoagulants (DOACs)

Our innovative reagents fulfil your requirements for monitoring DOACs

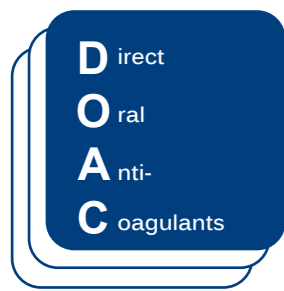
Methods

- Automated:** Compatible with the current coagulation equipment in your laboratory - no additional equipment is required
- Standardised:** Results are expressed in concentration (ng/mL)
- Fast:** Can be used in emergency situations
- Specific:** Calibrators and Controls for each assay
- Excellent correlation with **reference method** (LC-MS/MS)



More information on HYPHEN BioMed and product catalog is available at : www.hyphen-biomed.com

Experience the innovation!



Measurement in Plasma, when needed : Direct Oral Anticoagulants (DOACs)

HYPHEN BioMed offers ;

- A choice of assays meeting your specific needs
- Complete range of calibrators and controls which are specific for each assay ("Like-to-Like")

Reagent

▶▶▶ Assay for Direct Factor Xa Inhibitors

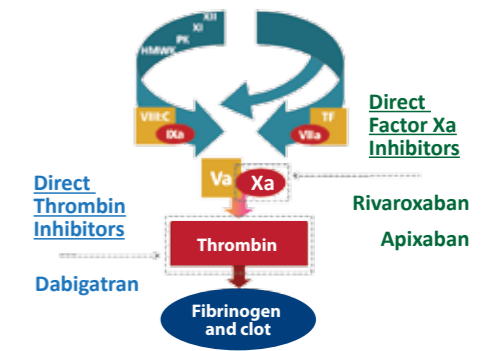
Product Name	Assay Principle	Packaging Size	Ref.
BIOPHEN® Heparin (LRT) CE, IVD	Chromogenic assay for <i>in vitro</i> quantitative measurement of indirect or direct Factor Xa inhibitors, such as Rivaroxaban and Apixaban. ■ liquid reagent, ready to use	R1 FXa specific chromogenic substrate (Sxa-11) R2 Bovine FXa R1: 3 x 3 mL, R2: 3 x 3 mL R1: 4 x 7.5 mL, R2: 4 x 7.5 mL	221013 221011
BIOPHEN® DiXal CE, IVD	Chromogenic assay for <i>in vitro</i> quantitative measurement of Direct Factor Xa Inhibitors (DiXal), such as Rivaroxaban or Apixaban, in plasma. ■ specific method for concentration of the DiXal ■ insensitive to indirect inhibitors of Factor Xa (LMWH, UFH, Orgaran® and Arixtra®) - suitable in patients switching from heparin therapy to DiXals.	R1 3 x 2.5 mL Human FXa R2 3 x 2.5 mL FXa specific chromogenic substrate R3 4 x 25 mL Buffer	221030

▶▶▶ Assay for Direct Thrombin Inhibitors

Product Name	Assay Principle	Packaging Size	Ref.
HEMOCLOT Thrombin Inhibitors CE, IVD	Clotting assay for the quantitative measurement of Dabigatran and other Direct Thrombin Inhibitors (DTIs) such as Hirudin and Argatroban in plasma. ■ the most frequently used reagent for DTI measurement	R1 Normal pooled plasma R2 Human calcium thrombin R1: 3 x 1 mL, R2: 3 x 1 mL R1: 3 x 2.5 mL, R2: 3 x 2.5 mL	CK002K CK002L
BIOPHEN® DTI CE, IVD	Chromogenic assay for the <i>in vitro</i> quantitative measurement of anti-IIa activity of Dabigatran in plasma. ■ contains heparin neutralizing substance	R1 2 x 2.5 mL Thrombin specific chromogenic substrate R2 2 x 2.5 mL Human thrombin R3 2 x 25 mL Tris-BSA Buffer	220202

When do we measure DOACs?

- Suspected overdose (High range)
- Unexplained prolonged clotting tests
- Bleeding in ICU/Emergency (unknown treatment)
- Renal dysfunction (long term treatment)
- Control of bleeding risk before surgery (Low range) by measuring the residual concentration



HYPHEN BioMed continues to innovate and extend the solutions to measure DOACs.

- ☑ **Low Range:** High sensitivity for accurate measurement of the residual concentration
- ☑ **Standard Range:** Large measurement range

Specific Calibrators and Controls

RIVAROXABAN (Xarelto®)

■ Low Range : 0 - 100 ng/mL

Product Name	Packaging Size	Ref.
BIOPHEN® Rivaroxaban Calibrator Low CE, IVD	12 vials (3 levels, 4 x 1 mL each)	226001
BIOPHEN® Rivaroxaban Control Low CE, IVD	12 vials (2 levels, 6 x 1 mL each)	225101

■ Standard Range : up to 500 ng/mL

Product Name	Packaging Size	Ref.
BIOPHEN® Rivaroxaban Plasma Calibrator CE, IVD	12 vials (3 levels, 4 x 1 mL each)	222701
BIOPHEN® Rivaroxaban Control Plasma CE, IVD	12 vials (2 levels, 6 x 1 mL each)	224501

APIXABAN (Eliquis®)

■ Low Range : 0 - 120 ng/mL

Product Name	Packaging Size	Ref.
BIOPHEN® Apixaban Calibrator Low CE, IVD	12 vials (3 levels, 4 x 1 mL each)	226101
BIOPHEN® Apixaban Control Low CE, IVD	12 vials (2 levels, 6 x 1 mL each)	225201

■ Standard Range : up to 600 ng/mL

Product Name	Packaging Size	Ref.
BIOPHEN® Apixaban Calibrator CE, IVD	12 vials (3 levels, 4 x 1 mL each)	226201
BIOPHEN® Apixaban Control CE, IVD	12 vials (2 levels, 6 x 1 mL each)	225301

DABIGATRAN (Pradaxa®)

■ Low Range : 0 - 120 ng/mL

Product Name	Packaging Size	Ref.
BIOPHEN® Dabigatran Calibrator Low CE, IVD	12 vials (3 levels, 4 x 1 mL each)	222901
BIOPHEN® Dabigatran Control Low CE, IVD	12 vials (2 levels, 6 x 1 mL each)	225001

■ Standard Range : up to 500 ng/mL

Product Name	Packaging Size	Ref.
Dabigatran Plasma Calibrator CE, IVD	12 vials (3 levels, 4 x 1 mL each)	222801
Dabigatran Control Plasma CE, IVD	12 vials (2 levels, 6 x 1 mL each)	224701

References:

- Using the HEMOCLOT direct thrombin inhibitor assay to determine plasma concentrations of dabigatran. [Stangier J, Feuring M. Blood Coagulation and Fibrinolysis. 2012;23(2):138-143.]
- Canadian Product monograph. Boehringer Ingelheim, 2010
- Monitoring plasma levels of factor Xa inhibitors: how, why and when? [Samama MM. et al. Expert Rev Hematol. 2013 Apr;6(2):155-64.]
- Dabigatran etexilate for stroke prevention in patients with atrial fibrillation: Resolving uncertainties in routine practice. [Huisman MV. et al. Thromb Haemost 2012; 107: 838-847]
- Estimation of dabigatran plasma concentrations in the perioperative setting. [Douxflis J. et al. Thromb Haemost 2015; 113]