



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	Edoxaban	LMWH	UFH	Orgaran® and other Sodium Danaparoids	Arixtra® and other Pentasaccharides
		Low Standard			Low Standard	Low Standard	Low Standard				
Dedicated calibrators and controls		Cal: 222901 Ctl: 225001 Cal: 222801 Ctl: 224701	Cal: SC030K Ctl: SC035K	Cal: SC020K Ctl: SC020L Ctl: SC025K	Cal: 226001 Ctl: 225101 Cal: 222701 Ctl: 224501	Cal: 226101 Ctl: 225201 Cal: 226201 Ctl: 225301	Cal: 226401 Ctl: 225401 Cal: 226501 Ctl: 225501	Cal: 223001 Ctl: 223001 Ctl: 223701	Cal: 222301 Ctl: 223101	Cal: 222201 Ctl: 223501	Cal: 222501 Ctl: 224001
HEMOCLOT™ Thrombin Inhibitors CE, IVD		CK002K, CK002L	⊙	⊙	⊙						
BIOPHEN™ DTI CE, IVD		220202	⊙		⊙						
BIOPHEN™ Heparin (LRT) CE, IVD		221011, 221013, 221015			⊙	⊙	⊙	⊙	⊙	⊙	⊙
BIOPHEN™ Heparin CE, IVD		221003, 221006			⊙	⊙	⊙	⊙	⊙	⊙	⊙
BIOPHEN™ DIXal CE, IVD		221030			⊙	⊙	⊙				
BIOPHEN™ Heparin Anti-IIa (kinetics) RUO		221020							⊙		
BIOPHEN™ Anti-IIa (2 stage) RUO		221025							⊙		
NEW! BIOPHEN™ Anti-IIa (2 Stages Heparin Assay) RUO		220005						⊙	⊙		
BIOPHEN™ Heparin (AT+) RUO		221007						⊙	⊙	⊙	⊙
BIOPHEN™ Anti-Xa (2 stage) RUO		221010						⊙	⊙	⊙	⊙
NEW! BIOPHEN™ Anti-Xa (2 Stages Heparin Assay) RUO		221005						⊙	⊙	⊙	⊙

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

HYPHEN BioMed (France) - destination - générique - Réf. HBM020V9_EN - Date de création : 09/2013 - Révision : 12/2018

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



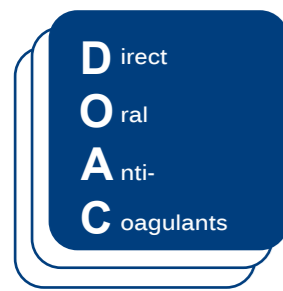
Direct Oral Anticoagulants (DOACs)

Our innovative reagents fulfil your requirements for measuring DOACs

- Methods**
- Automated:** Compatible with the current coagulation equipment in your laboratory - no additional equipment is required
 - Standardized:** 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)



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

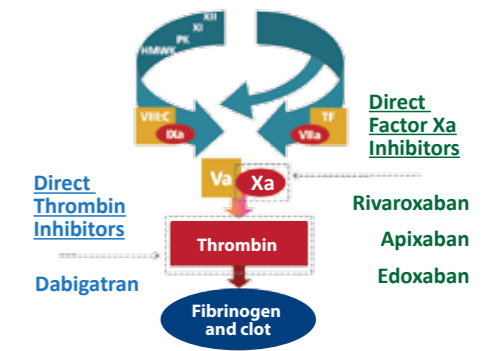
Product Name	Assay Principle	Packaging Size	Ref.
BIOPHEN™ Heparin (LRT) CE, IVD	Chromogenic assay for <i>in vitro</i> quantitative measurement of indirect or direct Factor Xa inhibitors, such as Rivaroxaban, Apixaban and Edoxaban. ■ liquid reagent, ready to use	R1 FXa specific chromogenic substrate (Sxa-11) R2 Bovine FXa R1: 3 x 3 mL, R2: 3 x 3 mL R1: 4 x 5 mL, R2: 4 x 5 mL R1: 4 x 7.5 mL, R2: 4 x 7.5 mL	221013 221015 221011
BIOPHEN™ DiXal CE, IVD	Chromogenic assay for <i>in vitro</i> quantitative measurement of Direct Factor Xa Inhibitors (DiXal), such as Rivaroxaban, Apixaban or Edoxaban, 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 600 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 700 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

EDOxabAN (Lixiana®, Savaysa®)

■ **Low Range : 0 - 120 ng/mL***

Product Name	Packaging Size	Ref.
BIOPHEN™ Edoxaban Calibrator Low CE, IVD	12 vials (3 levels, 4 x 1 mL each)	226401
BIOPHEN™ Edoxaban Control Low CE, IVD	12 vials (2 levels, 6 x 1 mL each)	225401

■ **Standard Range : up to 600 ng/mL***

Product Name	Packaging Size	Ref.
BIOPHEN™ Edoxaban Calibrator CE, IVD	12 vials (3 levels, 4 x 1 mL each)	226501
BIOPHEN™ Edoxaban Control CE, IVD	12 vials (2 levels, 6 x 1 mL each)	225501

* examples on Sysmex CS-series (depends on instruments & calibrators)

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

* may vary depending on the reagents and instruments

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. [Douxifis J. et al. Thromb Haemost 2015; 113]