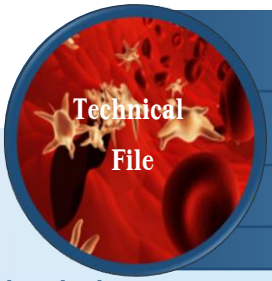


Anti–FXa activity of Edoxaban

Product Ref. N°	BIOPHEN™ Edoxaban Control Low / Control (A225401-RUO/A225501-RUO) BIOPHEN™ Edoxaban Calibrator Low / Calibrator (A226401-RUO/A226501-RUO)
Kit presentation	Set of plasma calibrators (3 levels) and quality controls (2 levels) for Edoxaban measurements by chromogenic method.
Status	RUO

Intended use:

A set of lyophilized human plasmas supplemented with Edoxaban at different concentrations for measuring its anti-FXa activity. One stage (BIOPHEN™ Heparin LRT) and two stages (BIOPHEN™ DiXaI) Anti-FXa chromogenic methods are used with specific Edoxaban calibrators and controls Low (0 to 120 ng/mL) and Standard (0 to 500 ng/mL), calibration ranges are developed for measuring Anti-FXa activity of Edoxaban and its metabolites in plasma.

Assay principle:

With BIOPHEN™ DiXaI:
This anti-FXa method is based on the inhibition of a constant and in excess quantity of Factor Xa (FXa) by Edoxaban. The residual FXa hydrolyses the FXa-specific chromogenic substrate, releasing paranitroaniline (pNa) which is measured by absorbance at 405 nm.

With BIOPHEN™ Heparin (LRT):
This method is a kinetics assay based on the inhibition of a constant and in excess quantity of Factor Xa (FXa) by Edoxaban, and simultabneously the excess of FXa hydrolyses FXa-specific chromogenic sbstrate, releasing paranitroaniline (pNa) measured at 405 nm.

[Edox] + [FXa (excess)] ➔ [FXa-Edox] + [FXa in excess]
[FXa (in excess)] + Substrate ➔ Peptide + pNA

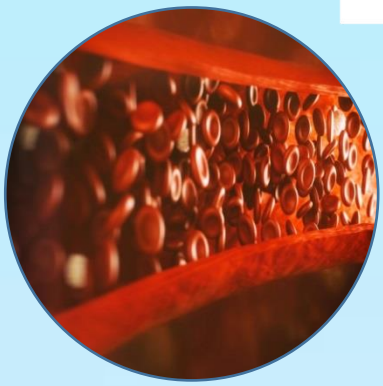
Edoxaban in practice

- **Research Applications:**
  - Edoxaban is an oral anticoagulant drug, used for curative or preventive indications. Although measuring the Edoxaban levels is not necessary, when required, measuring the Edoxaban concentration can be helpful in some research applications.
  - BIOPHEN™ Edoxaban Calibrator (Standard/Low) is proposed to establish the calibration curve for Edoxaban measurements in plasma using anti-Xa chromogenic assays.
  - BIOPHEN™ Edoxaban Control plasmas are proposed for the quality control of Edoxaban measurements in plasma using anti-Xa chromogenic assays.
- **Market requirements & challenges:**

✓ Standardised automated assay, with good stability, safe and effective, polyvalent for use on major automated coagulation analyzers.
✓ BIOPHEN™ Edoxaban Calibrator and Control plasmas are qualified against an Internal Reference Standard, whose qualification is linked to the reference method by HPLC-MS/MS.

Dedicated methods to support your needs

Key Characteristics & Advantages:



Easy and fast Automation:
- Simple, rapid (3 to 5min), fully automatable on any coagulation analyzer,
- Method applications in combination with anti-FXa reagents: Sysmex CS-series, STA-R® series , ACL TOP® family and BCS® XP.

Optimized consumption with extended stability for Edoxaban calibrators and controls
- 17 hours onboard (CS series, STA-R® series, and ACL TOP® family)
- Long shelf life at 2-8°C in original packaging

Extended measurement with two ranges, for the various clinical situations
Low range: from about 5 to 120 ng/mL of Edoxaban
Standard range: from about 20 to 900 ng/mL of Edoxaban

Excellent Precision with low CVs:
- Within-run < 5% on various analyzers
- Between-run < 7% on various analyzers

Specific and reliable assay, without interferences related to sample content
(Hemoglobin, bilirubin, triglycerides, heparins, Dabigatran)

Safe and standardized method for optimal testing
- Improved lot-to-lot variability; High quality raw materials used
- Traceability calibrators/controls, qualified against an Internal Reference Standard and LC:MS/MS

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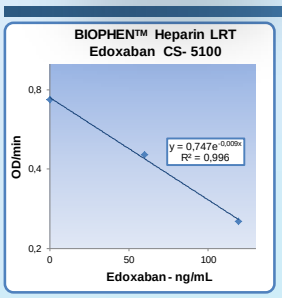
Anti-FXa activity of Edoxaban

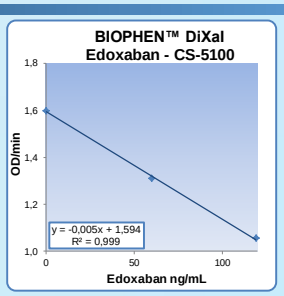
Technical File

Product Ref. N°	BIOPHEN™ Edoxaban Control Low / Control (A225401-RUO/A225501-RUO) BIOPHEN™ Edoxaban Calibrator Low / Calibrator (A226401-RUO/A226501-RUO)
Kit presentation	Set of plasma calibrators (3 levels) and quality controls (2 levels) for Edoxaban measurements by chromogenic method.
Status	RUO

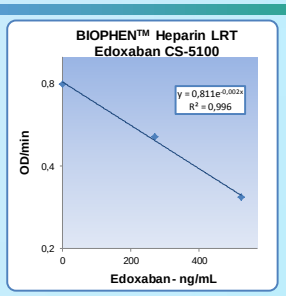
Assay Characteristics*: Multiplatform, easy to use, low CVs , no interferences

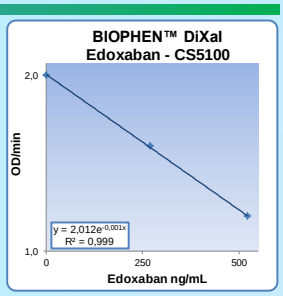
Calibration curves:





Edoxaban Low Range





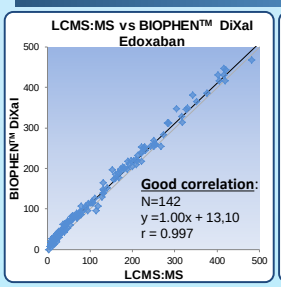
Edoxaban Standard Range

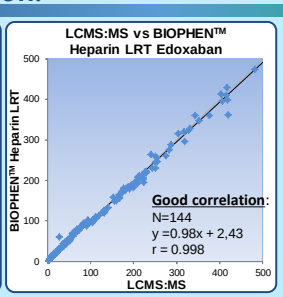
Precision:

Edoxaban Low Range		BIOPHEN™ Heparin LRT				BIOPHEN™ DiXal			
		CS-5100	STA-R®	ACL TOP®	BCS® XP	CS-5100	STA-R®	ACL TOP®	BCS® XP
Precision intra-assay	n	40	40	40	15	40	40	40	11
	CV % (QC1L)	1.9	3.4	2.9	3.5	6.0	5.1	7.8	7.2
	CV % (QC2L)	1.1	2.0	2.5	3.3	2.0	2.7	3.3	2.0
Precision inter-assays	n	120	30	30		120	30	30	
	CV % (QC1L)	5.0	3.4	2.4		7.0	8.2	6.2	
	CV % (QC2L)	5.1	3.6	1.8		5.1	4.5	2.4	

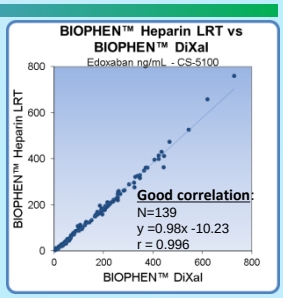
Edoxaban Standard Range		BIOPHEN™ Heparin LRT				BIOPHEN™ DiXal			
		CS-5100	STA-R®	ACL TOP®	BCS® XP	CS-5100	STA-R®	ACL TOP®	BCS® XP
Precision intra-assay	n	40	40	40	40	40	40	40	10
	CV % (QC1)	1.6	3.5	2.8	2.4	3.5	4.5	4.7	4.4
	CV % (QC2)	1.5	2.7	1.9	2.2	2.1	2.4	3.5	3.8
Precision inter-assays	n	120	30	30		120	30	30	
	CV % (QC1)	1.8	3.1	1.8		3.7	3.2	3.4	
	CV % (QC2)	2.3	2.1	1.5		2.7	2.9	3.0	

Method Comparison:



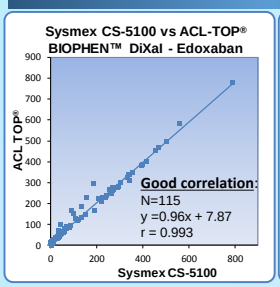


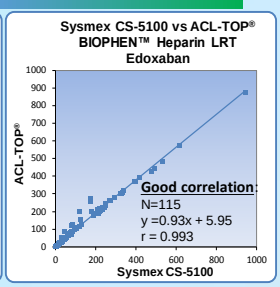
LCMS:MS vs Anti-Xa assay



Anti-Xa assays

Analyzer Comparison (good correlation for all):





* The values cited for the performance characteristics of the assay represent example of typical results and are not to be regarded as specifications for the test

Stability for Calibrators and Controls:

Shelf life in original packaging

30 months at 2-8°C

Onboard

17 hours on CS series, STA-R® and ACL® TOP

After Opening

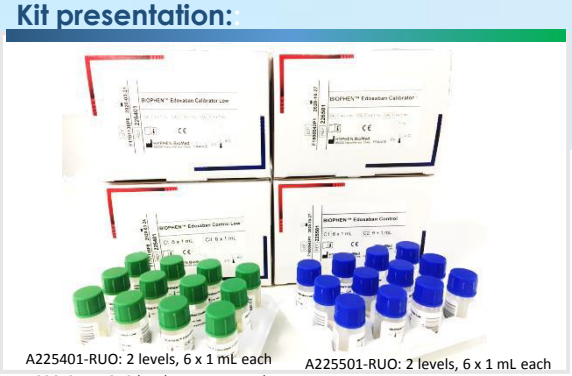
7 days at 2-8°C
24 hours at room temperature (18-25°C)
6 months at -20°C or less

Interferences:

No interference of usual interferents up to

10 to 60 mg/dL Bilirubin, 125 to 1000 mg/dL Hb, 500 to 1000 mg/dL Intralipids and 400 ng/mL Dabigatran.

Kit presentation:



A225401-RUO: 2 levels, 6 x 1 mL each
A226401-RUO: 3 levels, 4 x 1 mL each

A225501-RUO: 2 levels, 6 x 1 mL each
A226501-RUO: 3 levels, 4 x 1 mL each

Related products:

Needed	Product name	Ref N°:
Reagents	BIOPHEN™ DiXal BIOPHEN™ Heparin LRT BIOPHEN™ Heparin	A221030-RUO A221011-RUO/A221013-RUO/A221015-RUO A221003/A221006

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