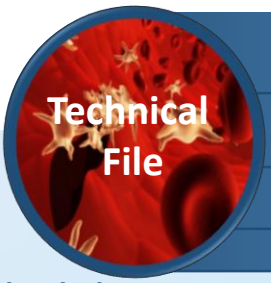


Anti-FXa activity of Rivaroxaban

Product Ref. N°	BIOPHEN™ Rivaroxaban Control Low / Control (A225101-RUO / A224501-RUO) BIOPHEN™ Rivaroxaban Calibrator Low / Calibrator (A226001-RUO/A222701-RUO)
Kit presentation	Set of plasma calibrators (3 levels) and quality controls (2 levels) for Rivaroxaban measurements by chromogenic method.
Status	RUO

Intended use:

A set of lyophilized human plasmas supplemented with Rivaroxaban 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 Rivaroxaban 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 Rivaroxaban 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 Rivaroxaban. The residual FXa hydrolyses the FXa-specific chromogenic substrate, releasing paranitroaniline (pNa) 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 Rivaroxaban, and simultaneously the excess of FXa hydrolyses FXa-specific chromogenic substrate, releasing paranitroaniline (pNa) measured at 405 nm.

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

Rivaroxaban in practice

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

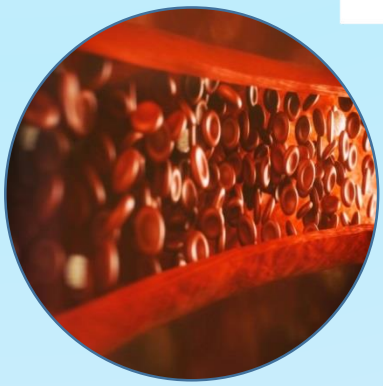
✓ Standardised automated assay, with good stability, safe and effective, polyvalent for use on major automated coagulation analyzers.
✓ BIOPHEN™ Rivaroxaban Calibrator and Control plasmas are qualified against an Internal Reference Standard, whose qualification is linked to the reference method by LC-MS/MS.

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 high stability for Rivaroxaban calibrators and controls
- 24 hours onboard (CS series, STA-R® series, ..) ; 7 days at 2-8°C; 6 months at -20°C
- Long shelf life at 2-8°C in original packaging



Extended measurement with two ranges, for the various clinical situations
Low range: from about 10 to 120 ng/mL of Rivaroxaban
Standard range: from about 15 to 500 ng/mL of Rivaroxaban

Excellent Precision with low CVs:
- Within-run ≤ 5% (CS-5100)
- Between-run ≤ 7% (CS-5100)

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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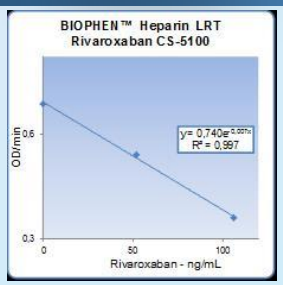
Anti-FXa activity of Rivaroxaban

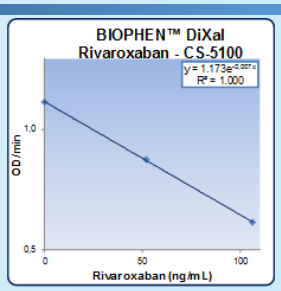
Technical File

Product Ref. N°	BIOPHEN™ Rivaroxaban Control Low / Control (A225101-RUO/A224501-RUO) BIOPHEN™ Rivaroxaban Calibrator Low / Calibrator (A226001-RUO/A222701-RUO)
Kit presentation	Set of plasma calibrators (3 levels) and quality controls (2 levels) for Rivaroxaban measurements by chromogenic method.
Status	RUO

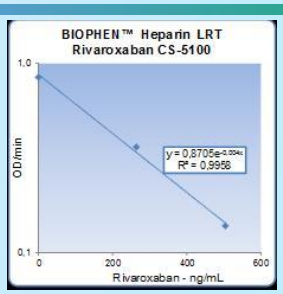
Assay Characteristics*: Multiplatform, easy to use, stable, low CVs , no interferences

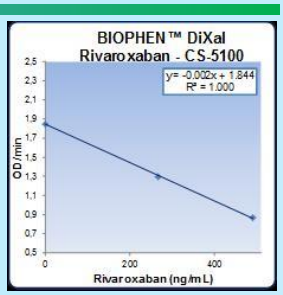
Calibration curves:





Rivaroxaban Low Range





Rivaroxaban Standard Range

Precision:

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	30	30	30	10	30	30	30	10
	CV% (QC1L)	1.8	2.4	2.6	2.8	4.8	4.7	4.1	5.4
	CV% (QC2L)	0.7	0.8	3.2	2.7	1.7	2.5	3.3	2.4
Precision inter-assays	n	22	20	30		20	20	30	8
	CV% (QC1L)	5.8	2.3	5.0		6.3	7.0	10	9.5
	CV% (QC2L)	4.1	2.0	2.1		2.2	9.6	5.6	6.5

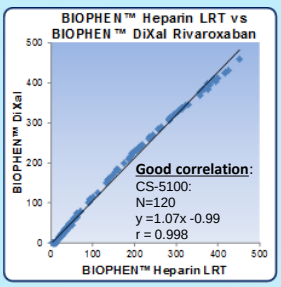
Standard Range		BIOPHEN™ Heparin LRT				BIOPHEN™DiXal			
		CS-5100	STA-R®	ACL TOP®	BCS® XP	CS-5100	STA-R®	ACL TOP®	BCS® XP
Precision intra-assay	n	30	30	30	10	30	30	30	10
	CV% (QC1L)	1.1	3.1	2.5	2.9	3.1	5.2	3.3	8.9
	CV% (QC2L)	0.9	2.0	1.9	1.3	1.5	2.2	2.0	2.7
Precision inter-assays	n	20	20	30		20	10	20	8
	CV% (QC1L)	2.0	5.9	6.1		8.2	5.5	6.9	6.7
	CV% (QC2L)	1.2	2.8	3.6		2.3	3.4	3.5	5.1

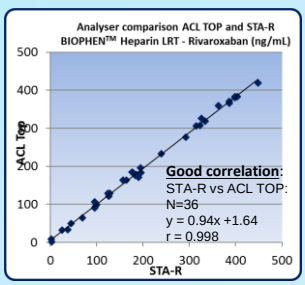
Methods & analyzers Comparison:

Example: HPLC vs Anti-Xa assay

Rivaroxaban (ng/mL)	Chromogenic (HBM anti-Xa assay)	HPLC
Level 1	<LLOQ	< LLOQ
Level 2	100	101
Level 3	260	244
Level 4	310	293
Level 5	490	494

Anti-Xa assays





* The values cited for the assay 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

24 hours on CS series, STA-R® …

After Opening

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

Interferences:

No interference of usual interferents up to

10 to 80 mg/dL Bilirubin, 150 to 1000 mg/dL Hb, 150 to 1200 mg/dL Intralipids and 400 ng/mL Dabigatran.

Kit presentation:

A224501-RUO: 2 levels, 6 x 1 mL each
A222701-RUO: 3 levels, 4 x 1 mL each
A225101-RUO: 2 levels, 6 x 1 mL each
A226001-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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