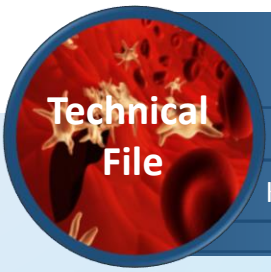


Neutralization of heparin interferences in DOAC's measurement with Anti-Xa chromogenic assays

Product Ref. N°	A221011-RUO/A221013-RUO/A221015-RUO BIOPHEN™ Heparin LRT, with: AAR032A-RUO-MIN / AAR032K-RUO buffer
Kit presentation	A221011-RUO/A221013-RUO/A221015-RUO (R1: FXa Substrate; R2: bovine FXa) AAR032A-RUO-MIN / AAR032K-RUO (Tris-NaCl-EDTA buffer, pH 7.85)
Status	RUO

Intended use:

Neutralization of Heparin interference with special dilution buffer, Tris-NaCl-EDTA buffer – pH 7.85 (AAR032A-RUO-MIN/AAR032K-RUO), for measurement of DOACs with anti-Xa chromogenic assays, especially using BIOPHEN™ Heparin kits (A221011-RUO / A221013-RUO / A221015-RUO).

Reagents and assay principle:

Tris-NaCl-EDTA buffer, pH 7.85 is a ready to use buffer. Contains 1% PEG and an heparin neutralizing substance.

BIOPHEN™ Heparin LRT is a one stage chromogenic assay based on the inhibition of a constant and in excess quantity of Factor Xa (FXa) by anti-Xa drugs to be assayed, in the presence of endogenous AT.

AAR032 buffer in practice

- For BIOPHEN™ Heparin LRT assay, the usual sample dilution buffer is just replaced by Tris-NaCl-EDTA buffer – pH 7.85 (AAR032A-RUO-MIN / AAR032K-RUO).

Research Applications:

- AAR032-RUO buffer allows to measure the true concentration of DOACs anti-Xa activity without heparin interferences at usual concentrations at switching of heparin to DOAC therapy.

Market requirements & challenges:

- Automated, highly performing , stable .
- Method applications available with BIOPHEN™ Heparin LRT kits: Sysmex CS-series, STA-R® series, ACL TOP® family and BCS XP®.

Key Characteristics & Advantages:

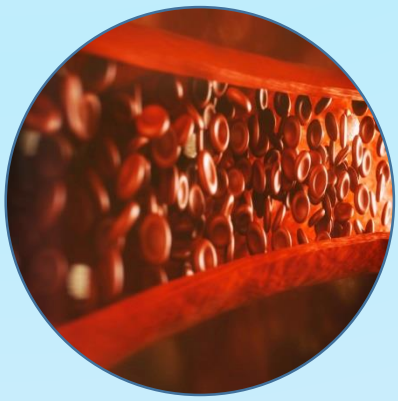
Innovative solution for DOAC testing

Test time with AAR032-RUO buffer unchanged :

- Only sample dilution buffer of anti-Xa chromogenic assays is replaced by AAR032-RUO buffer.

Optimized consumption with good stability

- 7 days on board (CS series)
- Long shelf life at 2-8°C in original packaging (18 months)
- Stability after opening: 6 months at 2-8°C, 14 days at room temperature (18-25°C)



Measurement range of tests unchanged (CS series)

- Apixaban Low / Standard Range: 10 – 200 ng/mL and 15 – 617 ng/mL
- Edoxaban Low / Standard Range: 2 – 180 ng/mL and 23 – 916 ng/mL
- Rivaroxaban Low / Standard Range: 8 – 302 ng/mL and 13 – 525 ng/mL

Excellent Precision with very low CVs:

Compared to the usual sample dilution buffer, CVs are unchanged.

- Within-run CV ≤ 5% for CII and ≤ 8% for CI of Rivaroxaban, Apixaban and Edoxaban, with BIOPHEN™ Heparin LRT on CS series, STA-R®, ACL TOP® and BCS XP®.

Neutralization of Heparin interferences in DOAC Testing with anti-Xa assays (at usual concentrations)

Safe and standardized product for optimal testing

- High quality raw materials used
- Calibrators and controls traceable to an International Standard

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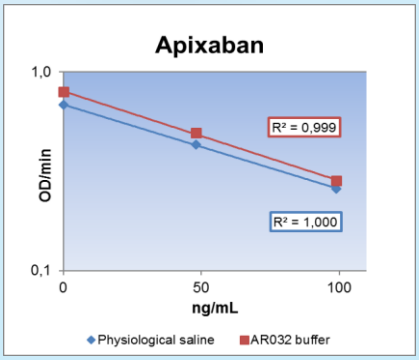
Neutralization of heparin interferences in DOAC's measurement with Anti-Xa chromogenic assays

Technical File

Product Ref. N°	A221011-RUO/A221013-RUO/A221015-RUO BIOPHEN™ Heparin LRT, with: AAR032A-RUO-MIN / AAR032K-RUO buffer
Kit presentation	A221011-RUO/A221013-RUO/A221015-RUO (R1: FXa Substrate; R2: bovine FXa) AAR032A-RUO-MIN / AAR032K-RUO (Tris-NaCl-EDTA buffer, pH 7.85)
Status	RUO

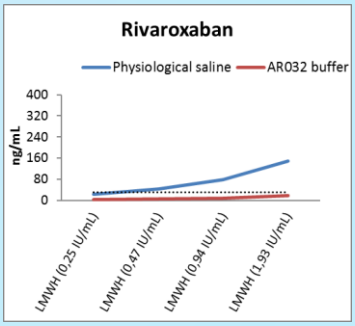
Assay Characteristics*: comparison physiological saline vs AAR032-RUO buffer with BIOPHEN™ Heparin LRT

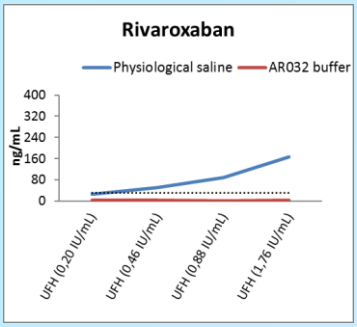
Calibration curve (CS-5100):

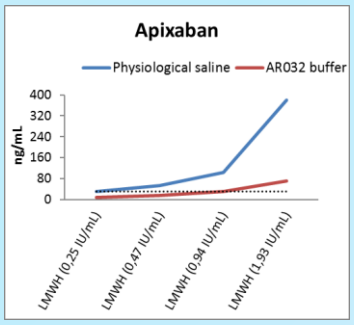


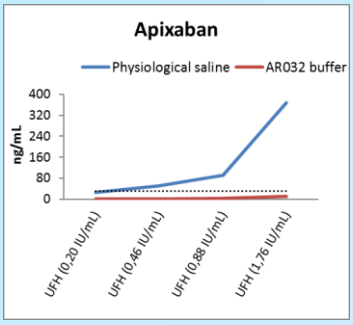
Similar profile with Rivaroxaban and Edoxaban calibrators.

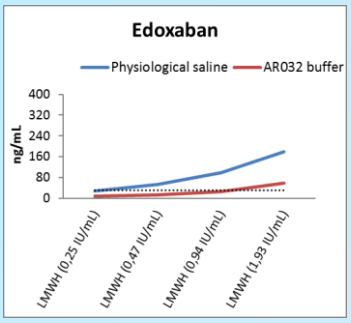
Controls and samples spiked with heparins (CS-5100):

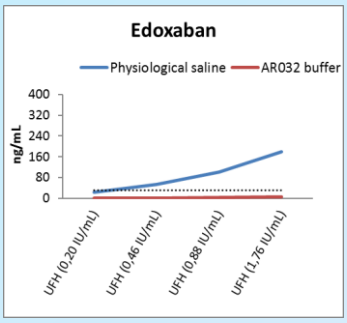












Summary of results: 3 DOACs on 4 instruments :

Instruments	DOAC (Low Range)	Linearity		Within run (CV%)	
		Physiological saline	AAR032-RUO buffer	Physiological saline	AR032 buffer
CS-5100	Rivaroxaban	R^2= 0.998	R^2= 0.988	CI = 6.8% CII = 2.6%	CI = 7.2% CII = 2.1%
	Apixaban	R^2= 1.000	R^2= 0.999	CI = 1.3% CII = 1.5%	CI = 2.9% CII = 1.1%
	Edoxaban	R^2= 0.997	R^2= 0.996	CI = 0.4% CII = 0.4%	CI = 2.1% CII = 0.8%
STA-R®	Rivaroxaban	R^2= 0.998	R^2= 0.998	CI = 0.0% CII = 0.7%	CI = 0.0% CII = 0.7%
	Apixaban	R^2= 1.000	R^2= 1.000	CI = 2.9% CII = 0.0%	CI = 2.9% CII = 2.9%
	Edoxaban	R^2= 0.996	R^2= 0.996	CI = 6.6% CII =1.5%	CI = 4.2% CII =1.3%
ACL Top®	Rivaroxaban	R^2= 1.000	R^2= 1.000	CI = 3.4% CII =1.0%	CI = 3.0% CII = 2.6%
	Apixaban	R^2= 0.998	R^2= 0.999	CI = 4.5% CII = 0.4%	CI = 2.0% CII = 0.9%
	Edoxaban	R^2= 0.999	R^2= 0.999	CI = 4.3% CII =1.0%	CI =2.6% CII =0.6%
BCS XP®	Rivaroxaban	R^2= 1.000	R^2= 1.000	CI = 1.8% CII = 0.4%	CI = 0.4% CII = 0.9%
	Apixaban	R^2= 1.000	R^2= 0.999	CI = 2.4% CII = 1.0%	CI = 0.6% CII = 1.8%
	Edoxaban	R^2= 0.998	R^2= 0.997	CI = 4.1% CII =5.8%	CI = 5.2% CII =3.5%

Kit presentation:

Kit contents: 1x20 mL (AAR032A-RUO-MIN) and 4x20 mL (AAR032K-RUO)

Related products:

Needed	Product name	Ref N°:
Calibrators / Controls	BIOPHEN™ Apixaban Calibrator / Low	A226201-RUO/A226101-RUO
	BIOPHEN™ Apixaban Control / Low	A225301-RUO/A225201-RUO
	BIOPHEN™ Rivaroxaban Calibrator / Low	A222701-RUO/A226001-RUO
	BIOPHEN™ Rivaroxaban Control / Low	A224501-RUO/A225101-RUO
	BIOPHEN™ Edoxaban Calibrator / Low	A226501-RUO/A226401-RUO
	BIOPHEN™ Edoxaban Control / Low	A225501-RUO/A225401-RUO

* 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.

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