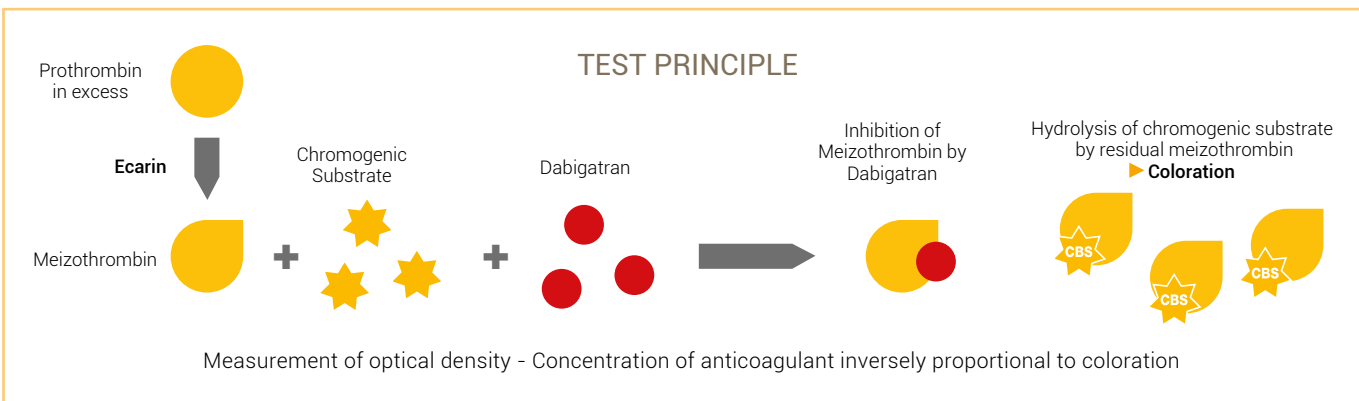


Innovation for quantification of Direct Thrombin Inhibitor

STA-ECA II - Colorimetric assay of Dabigatran



Improvement of Ecarin Clotting Time with using Chromogenic Method

	Working Range on STA-R® Line	Correlation with LCMS (R)
Dabigatran	15-460 ng/mL	0.988

Optimisation

- Stable 3 days on board on STA-R Max and STA Compact Max and 28 days at 2-8°C

Ease of Use

- Automated & Barcoded

Precision

Repeatability* - CV (%)		Within-laboratory precision - CV (%)	
Low level	High level*	Low level	High level
3.6	2	5.2	3.1

* Over 20 days, 2 sets/day

Reliable at low concentration with only one calibration curve (vs Diluted Thrombin Time ⁽¹¹⁾)

Insensitive to Heparin when employing bridging anticoagulation strategies ⁽¹²⁾

Not influenced by changes in coagulation factors, lupus anticoagulants, heparin or VKA

Expected Plasma DOAC concentrations ⁽¹⁰⁾

Drug	Dosage (mg)	Trough concentration (ng/mL) Mean (25th- 75th percentiles)	Peak concentration (ng/mL) Mean (25th- 75th percentiles)
Dabigatran	150 (x2/day)	91 (61-143)	175 (117-275)

Anti-Xa range	Drug	UFH	LMWH	Fondaparinux
	Reagent	STA-Liquid Anti-Xa		
	Volume	4 mL (x 6) Cat. Nr. 00311		8 mL (x 6) Cat. Nr. 00322
	Calibrator	STA-Multi Hep Calibrator Cat. Nr. 00348		STA-Fondaparinux Calibrator Cat. Nr. 00354
	Quality Control	STA-Quality HNF/UFH Cat. Nr. 00381	STA-Quality HBPM/LMWH Cat. Nr. 00686	STA-Fondaparinux Control Cat. Nr. 00355

Anti-Xa range	Drug	Rivaroxaban	Apixaban	Edoxaban
	Reagent	STA-Liquid Anti-Xa		
	Volume	4 mL (x 6) Cat. Nr. 00311		8 mL (x 6) Cat. Nr. 00322
	Calibrator	STA-Rivaroxaban Calibrator Cat. Nr. 00704	STA-Apixaban Calibrator Cat. Nr. 01075	STA-Edoxaban Calibrator Cat. Nr. 01073
	Quality Control	STA-Rivaroxaban Control Cat. Nr. 00706	STA-Apixaban Control Cat. Nr. 01074	STA-Edoxaban Control Cat. Nr. 01072

ECA range	Drug	Dabigatran
	Reagent	STA-ECA II
	Volume	25 tests (x2) Cat. Nr. 00992
	Calibrator	STA-Dabigatran Calibrator Cat. Nr. 00993
	Quality Control	STA-Dabigatran Control Cat. Nr. 00994

REFERENCES

- Ilgenjatic V, Summerhayes R, Gan A, Than J, Chan A, Cochrane A, Bennett M, et al. "Monitoring Unfractionated Heparin (UFH) Therapy: Which Anti-Factor Xa Assay is Appropriate?" *Thrombosis Research* 120, no. 3 (2007): 347-51.
- Guyatt GH, Akl EA, Crowther M, Gutterman DD, Schünemann HJ. "Executive Summary: Antithrombotic Therapy and Prevention of Thrombosis, 9th Ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines." *Chest* 141, no. 2, suppl (2012): 7S-47S.
- Brill-Edwards P, Ginsberg JS, Johnston M, Hirsh J. "Establishing a Therapeutic Range for Heparin Therapy." *Annals of Internal Medicine* 119, no. 2 (1993): 104-9.
- Guervil DJ, Rosenberg AF, Winterstein AG, Harris NS, Johns TE, Zumberg MS. "Activated Partial Thromboplastin Time versus Antifactor Xa Heparin Assay in Monitoring Unfractionated Heparin by Continuous Intravenous Infusion." *The Annals of Pharmacotherapy* 45, no. 7-8 (2011): 861-68.
- Gearhart A, Dorman N, Scott D, Rahman O. "Time to Therapeutic Levels: Comparison of the Anti Xa Assay vs Ptt in Critical Care." *Chest* 140, no. 4, MeetingAbstracts (2011): 286A-286A.
- Van Roessel S, Middeldorp S, Cheung YW, Zwinderman AH, de Pont AC. "Accuracy of aPTT Monitoring in Critically Ill Patients Treated with Unfractionated Heparin." *The Netherlands Journal of Medicine* 72, no. 6 (2014): 305-10.
- Rosborough TK, Shepherd MF. "Achieving Target Antifactor Xa Activity with a Heparin Protocol Based on Sex, Age, Height, and Weight." *Pharmacotherapy* 24, no. 6 (2004): 713-19.
- Gosselin RC, Adcock DM. "Assessing Nonvitamin K Antagonist Oral Anticoagulants (NOACs) in the Laboratory." *International Journal of Laboratory Hematology* 37 (2015): 46-51.
- Baglin T, Hillarp A, Tripodi A, Elalamy I, Buller H, Ageno W. "Measuring Oral Direct Inhibitors of Thrombin and Factor Xa: A Recommendation from the Subcommittee on Control of Anticoagulation of the Scientific and Standardization Committee of the International Society on Thrombosis and Haemostasis." *Journal of Thrombosis and Haemostasis* 11, no. 4 (2013): 756-60.
- Douxflis J, Ageno W, Samama CM et al. Laboratory testing in patients treated with direct oral anticoagulants: a practical guide for clinicians. *Journal of Thrombosis and Haemostasis* 16 n° 2 (2018): 209-19.
- Antovic JP, Skeppholm M, Eintrei J, Bojja EE, Söderblom L, Norberg EM, Onelöv L, et al. "Evaluation of Coagulation Assays versus LC-MS/MS for Determinations of Dabigatran Concentrations in Plasma." *European Journal of Clinical Pharmacology* 69, no. 11 (2013): 1875-81.
- Douxflis J, Lessire S, Dincq AS, Hjemdahl P, Rönquist-Nii Y, Pohanka A, Gourdin M, Chatelein B, Dogné JM, Muller F. "Estimation of Dabigatran Plasma Concentrations in the Perioperative Setting: An Ex Vivo Study Using Dedicated Coagulation Assays." *Thrombosis and Haemostasis* 113, no. 4 (2014): 862-69.
- Montes R.P. et al. "Comparison of Three Thromboplastin Reagents for International Normalized Ratio (INR) Measurement in Patients on Vitamin K Antagonist Therapy".

Diagnostica Stago S.A.S
Always read the label and instructions for use – follow the instructions for use

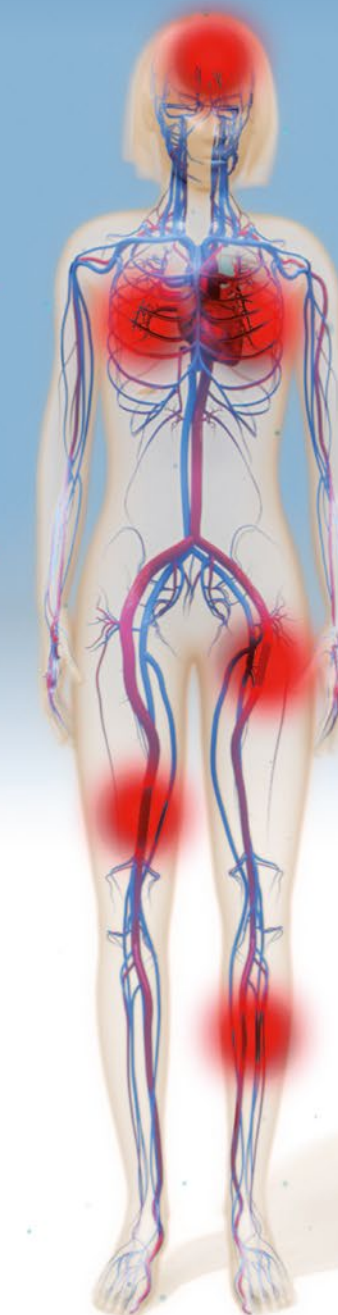
STA, STA-NeoPTimal, STA R Max, STA-Fondaparinux Calibrator, STA Compact Max, STA-Rivaroxaban Control, STA-R Line are trademarks of the Stago Group. The rights of the trademarks and logos used in this document belong to the Stago Group. The use of these trademarks is not permitted without permission from the Stago Group



Diagnostica Stago S.A.S.
3 allée Thérèse - CS 10009
92600 Asnières sur Seine Cedex - France
+33 (0)1 46 88 20 20
+33 (0)1 47 91 08 91
webmaster@stago.com
www.stago.com

Conception: L2R.fr - ©2023 Diagnostica Stago - All rights reserved - Non-contractual photos - 12/2023 - Ref. 29335
This document contains information on products which is targeted to a wide range of audiences and could contain product details or information otherwise not accessible or valid in your country.

Anticoagulant Line



THERE IS A STAGO SOLUTION, FOR YOUR PATIENTS ON ANTICOAGULANT



ANTICOAGULANT LINE

Full Stago solution for your anticoagulant blood determinations

Stago is committed to providing a comprehensive range of anticoagulant measuring solutions. All assays are fully automated and standardised, ensuring ease of use, traceability and confidence in the results.

VKA

PT-INR range

STA-NeoPTimal
INR Determination

Heparin

Anti-Xa range

STA-Liquid Anti-Xa

UFH LMWH Fondaparinux

Edoxaban Apixaban Rivaroxaban

Thrombin Inhibitors

ECA range

STA-ECA II
Dabigatran

Monitoring of Vitamin K Antagonists

NEOPTIMAL 10
PT-INR range

STA-NeoPTimal

Reliable reagent with unique performances

- Highly sensitive PT reagent with ISI near 1
- No interference from UFH Up to 1 IU/mL, or LMWH Up to 1.5 anti-Xa IU/mL
- Optimal sensitivity to changes in factor concentrations for a better follow up of patients under VKA treatment

Standardised results for reliable diagnosis

- STA range specific ISI assayed against the international standard
- Excellent lot to lot reproducibility⁽¹³⁾
- Unique Viscosity-Based Detection System insensitive to analytical interferences

Optimal workflow management

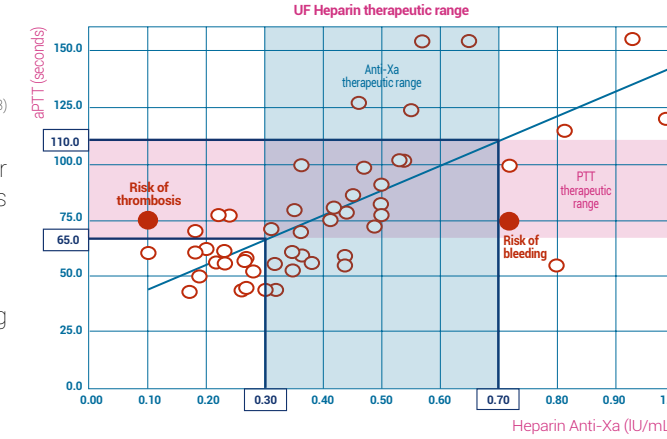
- Choice of 3 packaging sizes (5, 10 or 20 mL)
- "All in one"
- Precalibrated PT reagent
- Extended stability for 24/24 availability

High performance for your heparin monitoring needs

Determination of anti-Xa activity is the method of choice for heparin monitoring⁽²⁾

International standard range for UFH therapeutic range: 0.3 - 0.7 IU/mL⁽³⁾

- Specific assay vs aPTT: no interferences** with factor deficiencies, other diseases (lupus anticoagulants, DIC), nor concomitant treatments (VKA, fibrinolytics, DT)
- Cost saving assay**^(4, 5, 6, 7):
 - Shorter hospital stays from 25 days using a PTT to 17 days using anti-Xa method
 - Therapeutic range reached in 48 h in 100% of cases**
 - Reduced number of assays per day to adjust treatment



Accurate

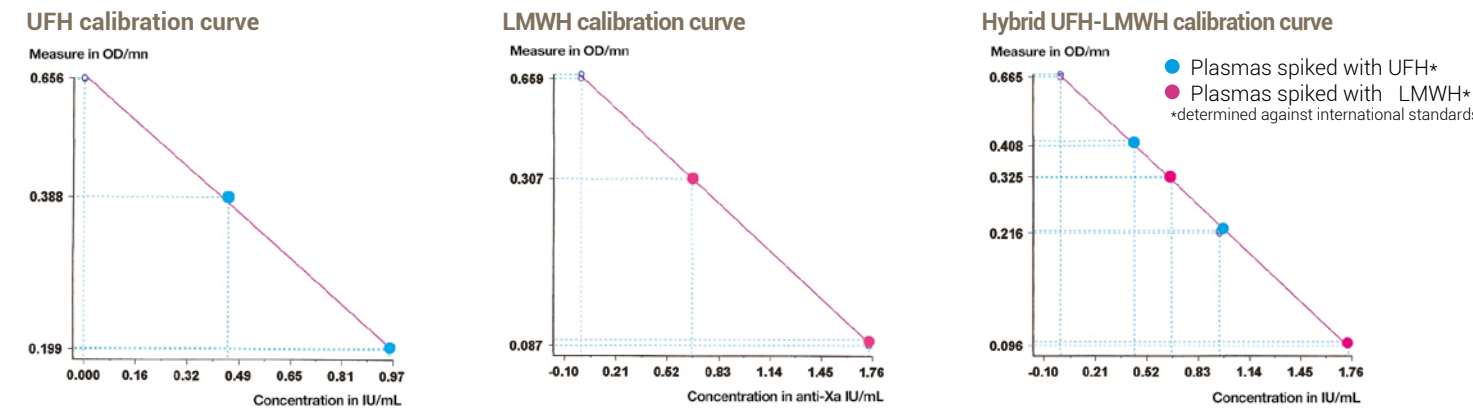
- Wide working range (0.1 to 2 anti-Xa IU/mL for LMWH and 1.1 IU/mL for UFH)

Reliable

- Validated by large scale studies in 3 countries with more than 1800 patients

Easy to implement

- Select either specific or hybrid calibration



Innovation for your DOAC measurements

Quantification of drug concentration is necessary in specific cases^(8, 9)

- Acute bleeding
- Emergency surgery
- Renal insufficiency
- Stroke
- Reversal of anticoagulation
- Suspicion of overdose
- Assessment of compliance

Dedicated calibrators and controls for measuring all direct anti-Xa anticoagulants

	Working range	Correlation with LCMS (R ²)
Rivaroxaban	25-500 ng/mL	R ² =0.9899
Apixaban	23-500 ng/mL	R=0.989
Edoxaban	20-400 ng/mL	R ² =0.9909

Expected plasma DOAC concentrations⁽¹⁰⁾

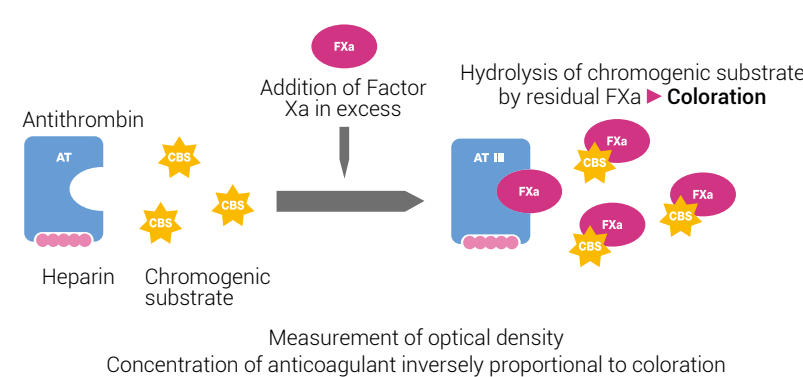
Drug	Dosage (mg)	Trough concentration (ng/mL) Mean (5th- 95th percentiles)	Peak concentration (ng/mL) Mean (5th- 95th percentiles)
Rivaroxaban	20 (x1/day)	26 (6-87)	270 (189-419)
Apixaban	5 (x2/day)	63 (22-177)	132 (59-302)
Edoxaban	60 (x1/day)	19 (10-39)	234 (149-317)



STA-Liquid Anti-Xa: Universal reagent, liquid and ready-to-use



TEST PRINCIPLE: ANTI-XA ACTIVITY MEASUREMENT



Ease of Use

- Ready-to-use, automated & barcoded

Optimisation

- Stable 7 days on board on STA-R Max and STA Compact Max and 3 months at 2-8°C

Polyvalence: 1 reagent for 6 analytes

- UFH, LMWH, Fondaparinux, Rivaroxaban, Apixaban & Edoxaban

Reliability

- No dextran sulfate which could falsely elevate results⁽¹¹⁾

Flexibility for all lab activities

- 4 mL & 8 mL vials format

Precision

	Repeatability CV (%)		Within-laboratory precision - CV (%)	
	Low level	High level	Low level	High level
LMWH	3.0	3.8	3.5	4.8
UFH	5.9	2.6	7.2	4.5
Fondaparinux	3.5	2.6	3.3	2.3
Rivaroxaban	2.5	1.9	3.3	2.8
Apixaban	3.9	2.0	4.3	2.6
Edoxaban	2.8	2.0	6.0	4.4