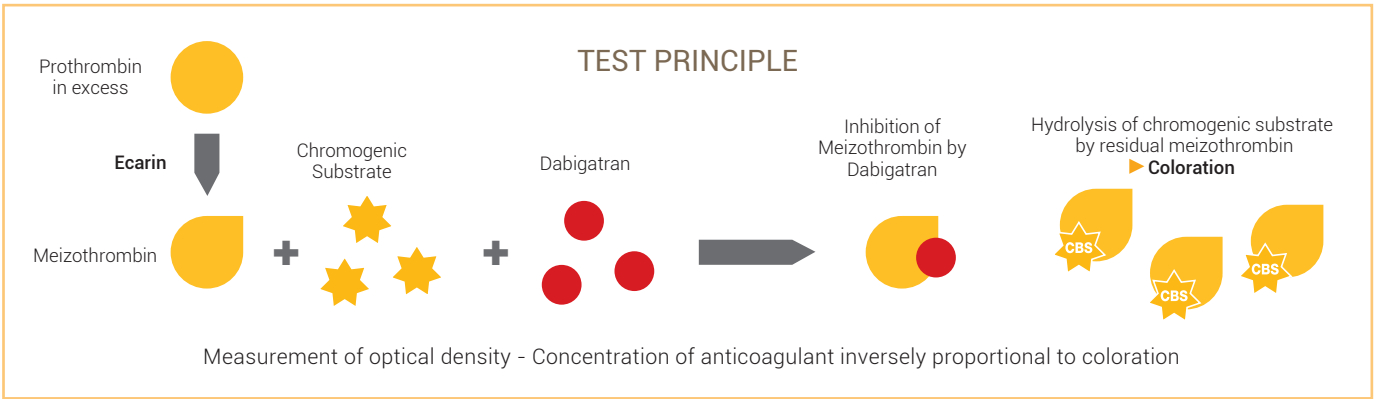


Innovation for quantification of Direct Thrombin Inhibitor

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 <sup>(11)</sup> ) | Insensitive to Heparin when employing bridging anticoagulation strategies <sup>(12)</sup> | Not influenced by changes in coagulation factors, lupus anticoagulants, heparin or VKA |
|-----------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|

Expected Plasma DOAC concentrations <sup>(10)</sup>

| 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)<br>Cat. Nr. 00311               |                                         | 8 mL (x 6)<br>Cat. Nr. 00322                  |
|               | Calibrator      | STA-Multi Hep Calibrator<br>Cat. Nr. 00348 |                                         | STA-Fondaparinux Calibrator<br>Cat. Nr. 00354 |
|               | Quality Control | STA-Quality HNF/UFH<br>Cat. Nr. 00381      | STA-Quality HBPM/LMWH<br>Cat. Nr. 00686 | STA-Fondaparinux Control<br>Cat. Nr. 00355    |

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

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

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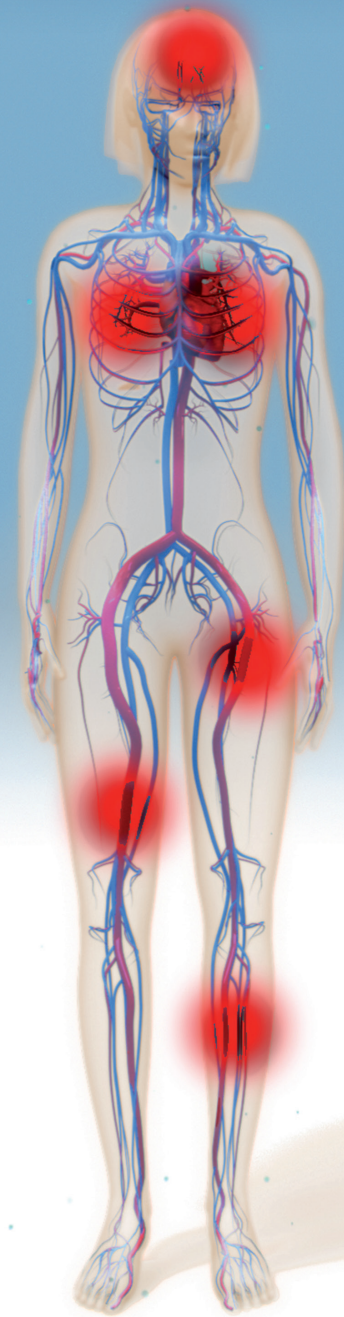
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Anticoagulant Line



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

Direct Anti-Xa Inhibitors

ECA range

STA-ECA II

Dabigatran

Thrombin Inhibitors

ECA range

STA-ECA II

Dabigatran

STA-NeoPTimal

INR Determination

STA-Liquid Anti-Xa

UFH LMWH Fondaparinux

Edoxaban Apixaban Rivaroxaban

STA-ECA II

Dabigatran

Monitoring of Vitamin K Antagonists

PT-INR range

NEOPTIMAL 10

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<sup>(13)</sup>
  - Unique Viscosity-Based Detection System insensitive to analytical interferences
- Optimal workflow management**

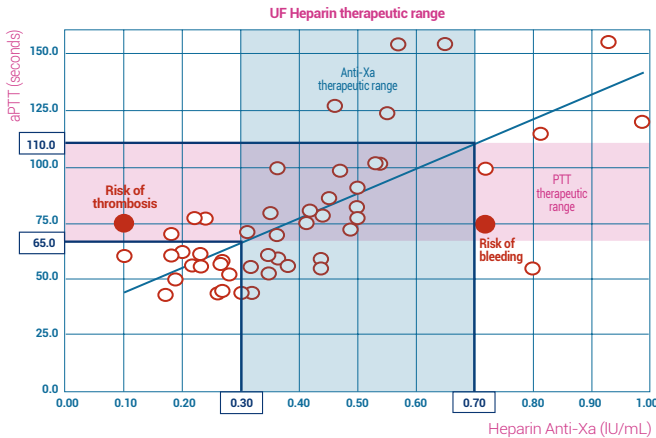
  - Choice of 3 packaging sizes (5, 10 or 20 mL)
  - “All in one”
  - Precalibrated PT reagent
  - Extended stability for 24/24 availability

High performance for your heparin monitoring needs

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

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

- Specific assay vs aPTT: no interferences** with factor deficiencies, other diseases (lupus anticoagulants, DIC), nor concomitant treatments (VKA, fibrinolytics, DTI)
- Cost saving assay**<sup>(4, 5, 6, 7):</sup>
  - 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**

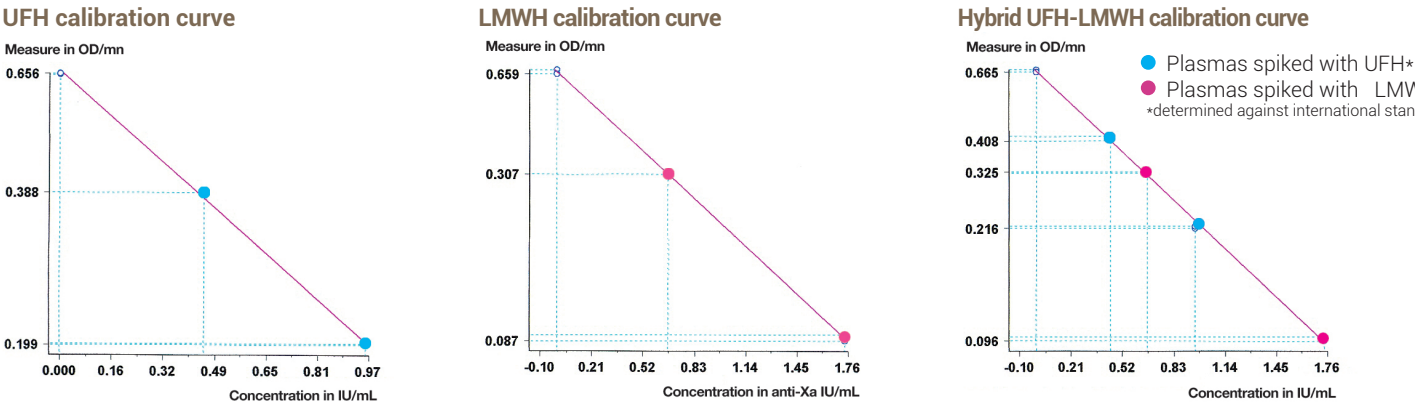
- Wide working range (0.1 to 2 anti-Xa IU/mL for LMWH and 1.1 IU/mL for UFH)

**Reliable**

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

**Easy to implement**

- Select either specific or hybrid calibration

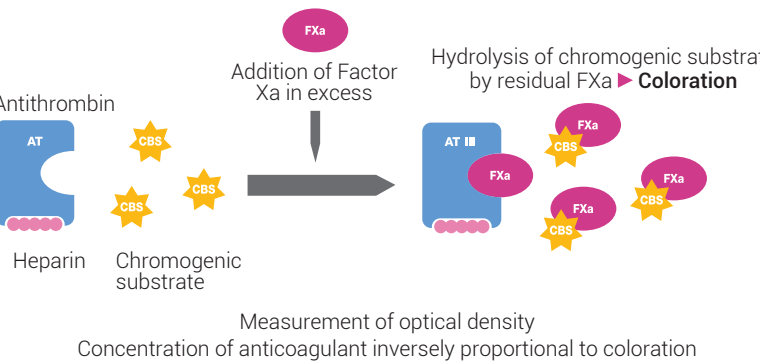


STA-Liquid Anti-Xa: Universal reagent, liquid and ready-to-use

Anti-Xa range

LIQUID ANTI-Xa

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<sup>(1)</sup>
- Flexibility for all lab activities**

  - 4 mL & 8 mL vials format

Innovation for your DOAC measurements

Quantification of drug concentration is necessary in specific cases<sup>(8, 9)</sup>

- 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 (R²) |
|-------------|---------------|----------------------------|
| Rivaroxaban | 25-500 ng/mL  | R²=0.9899                  |
| Apixaban    | 23-500 ng/mL  | R=0.989                    |
| Edoxaban    | 20-400 ng/mL  | R²=0.9909                  |

Expected plasma DOAC concentrations<sup>(10)</sup>

| 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)                                           |

EDOXABAN CALIBRATOR

EDOXABAN CONTROL

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        |