

FLOMASS[®] NOAC IN SERUM

The development of NOACs represented an important progress in therapy for the prevention of arterial and venous thromboembolism.

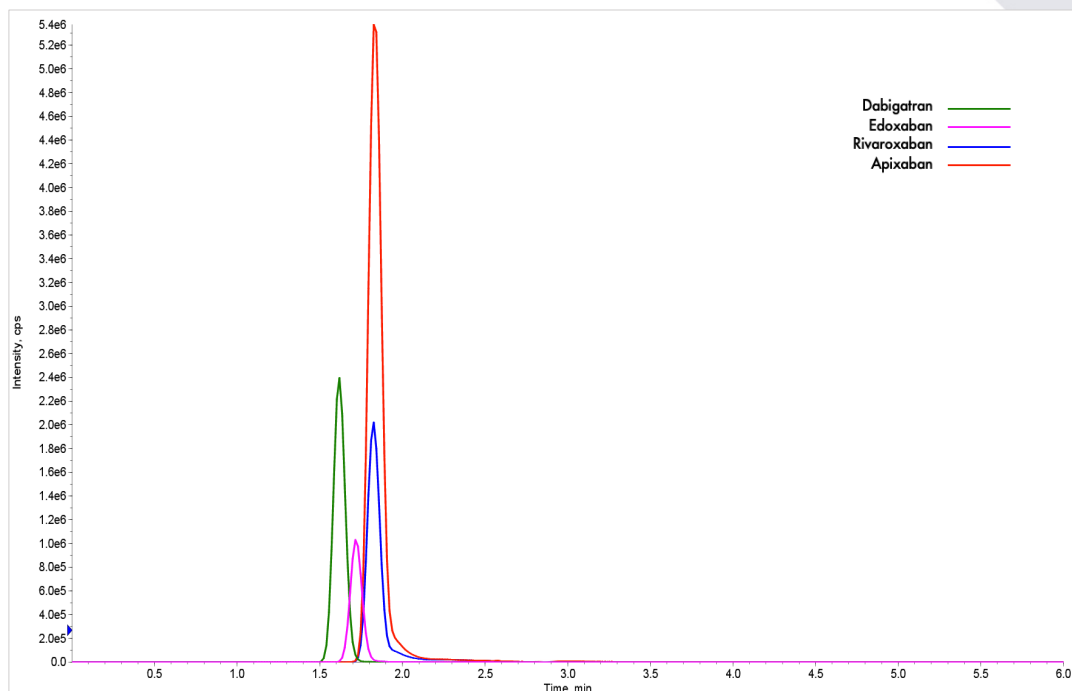
The "direct oral anticoagulants" DOACs or "new oral anticoagulants" NOACs are represented by Edoxaban, Rivaroxaban, Apixaban (inhibitors of coagulation factor Xa) and by Dabigatran (direct thrombin inhibitor).

Although NOACs show many advantages, the reduction in hepatic metabolism and impairment of renal function can cause an increase in the plasma concentration of the drug, inducing the risk of bleeding and developing a thromboembolic episode.

Since it appears that there is a direct association between the plasmatic NOAC concentration and the anticoagulant effect, it is possible to predict the existence of therapeutic plasma concentration ranges where the risk of these effects is lower.

TDM (Therapeutic Drug Monitoring) is generally recommended for drugs with large pharmacokinetic variability, drugs with a narrow therapeutic index, and drugs that have no clear association between drug concentration and therapeutic effect and/or adverse reaction.

Since all these points fit to NOACs, a targeted dosage is necessary for a good TDM and optimization of therapy.



HPLC-MS/MS system conditions

Ionization: ESI positive mode

MS/MS: specific MRM

Injection volume: 1-10 µL (variable according to instrumental sensitivity)

Running time: 5 min

Column heater: 30°C

Column conditioning: column should be conditioned for 5 min at chromatographic gradient initial condition. Then, run 3 blank injections (MPA only) using the gradient as indicated in IFU

Sample preparation

- Prepare a mix with 195 µL of Precipitant Solution + 5 µL of Internal standard sufficient for the number of samples to be analyzed
- Resuspend 100 µL serum in a vial
- Add 200 µL of Mix Solution obtained in step 1 of the procedure
- Vortex for 30 sec
- Incubate at room temperature for 10 min
- Centrifuge at 12000 rpm for 10 min
- Transfer supernatant into an auto samples vial
- Inject 1-10 µL and analyze with HPLC-MS/MS technique

Performance

ANALYTE	LINEARITY (ng/mL)	LLOD (ng/mL)	LLOQ (ng/mL)	CV% INTRA	CV% INTER
Apixaban	0.21 - 1000	0.06	0.21	4.1 - 4.2	4.0 - 10.3
Edoxaban	0.31 - 1000	0.09	0.31	4.2 - 6.0	5.7 - 12.7
Rivaroxaban	0.21 - 1000	0.06	0.21	3.3 - 5.2	8.8 - 14.3
Dabigatran	0.41 - 1000	0.12	0.41	2.3 - 7.2	3.0 - 13.4

Ordering guide

EUM12100	FloMass® NOAC in Serum	100 assays
EUM12041	7-Levels Calibrators, lyophil.	2 x 7 x 1.0 mL
EUM12051	3-Levels Controls, lyophil.	2 x 3 x 1.0 mL
EUM00C12	Chromatographic Column	1 pc

CHR-01-21-REV.0