Application Guide for Coatron X and anti-Xa

Order information

All required products must be ordered from

Technoclone
Herstellung von Diagnostika und Arzneimitteln GmbH
Brunner Str. 67 - 1230 Vienna, Austria

Reagent	TECHNOCHROM® anti-Xa
Calibrators	TECHNOVIEW® Con-H (for Edoxaban, Apixaban, Rivaroxaban, LMW Heparin)
Controls	TECHNOVIEW® Con-L (for Edoxaban, Apixaban, Rivaroxaban, LMW Heparin)
Zero plasma	TECHNOCLOT® Control N
Diluent	TECHNOCHROM® Dilution Buffer
Determinations	160 Det (on Coatron-X)

Setting of Coatron X

Required software. 1.04.52 Edition 2 (X52E2)

Procedure on Coatron X

Sample preparation:

Dilute 1:10: 100µL plasma (patients, control, calib.) + 900µL diluent

Pipetting:

1. Pipette to empty cuvette	25 µl sample 1:10 diluted
2. Add	Factor Xa Reagent
3. Incubate at 37°C	60s (exactly !)
4. Add	25µl Factor Xa Substrate.

Screening of anti-Xa agents (principle):

The test AF10 reports the anticoagulation activity by DOACs/Heparin in %
250% = full anti-coagulation
0% = no anti-coagulation
25% = cut-off (DOAC negative below ~40 ng/ml Edoxaban)

AF10 Scroll button (principle):

Run test AF10. The results are reported as % activity. Touch the scroll button to convert into ng/mL.

Calibration (HEP, APIX, RIVA,EDOX)

Prepare four concentrations by mixing Technoview (Con-H) and Technoclot control N(Con-zero) according to table below. Run in duplicates on device as described in chapter procedure. Transfer manually the mean results to its calibration curve.

	TECHNOVIEW Con-H	TECHNOCLOT Control N	Example (LMWH)
STD1 (1:1)	200µL	0µL	1.00 IU/ml = 0.240E
STD2 (1:2)	100µL	100µL	0.50 IU/ml = 0.520E
STD3 (1:4)	100µL	300µL	0.25 IU/ml = 0.720E
STD4 (zero)	0µL	200µL	0.01 IU/ml = 0.900E

Calibration (AF10)

Run CAL-zero in duplicates and transfer manually the mean to its calibration curve as table below.

	Signal
STD1: 250% (always*)	0.000 E (always)
STD2: 1% (always)	0.900 E (example for CAL-zero)

*must not be measured

Analytical performance

Analytical performance	Parameter	Result
Limit of detection	LoD (min)	LMWH=0,09 IU/ml EDOX=25ng/ml
	LoD (max)	LMWH=1,40 IU/ml EDOX=450ng/ml
Precision C.V. (intra assay)	EDOX=342ng/ml	3,1%
	EDOX=126ng/ml	5,4%
	EDOX=33ng/ml	14,9%
	LMWH=1.00 IU/ml	2,5%
	LMWH=0.70 IU/ml	4,9%
	LMWH=0.36 IU/ml	9,5%
Trueness (versus mass spectrometry HPLC-MS)	EDOX=126ng/ml	121 ng/ml (-3.8%)
	EDOX=33ng/ml	34 ng/mL (+1,7%)
	LMWH=0.70 IU/ml	0,73 IU/ml (+3,2%)
	LMWH=0.36 IU/ml	0,38 IU/ml (+6,4%)
Linearity	linear range	LMWH: 0.1 - 1.2 IU/ml EDOX: 25 - 350 ng/mL
	regression R^2	LMWH: R^2=0,998 EDOX: R^2=0,994
Cut-Off	anti-Xa activity	AF10= 25 % EDOX=40 ng/mL
Interferences	Bilirubin	see IFU(TC)
	Hemoglobin	see IFU(TC)
	Antithrombin	see IFU(TC)