EUM12041 - 7-Levels Calibrators, lyophil.

LYOPHILIZED CALIBRATORS
FOR NOAC IN SERUM

Ref. EUM12041
Lot. M1241XXXX
XX/XXXX
IVD CE

Intended use:

EUM12041 is the lyophilized calibrator used for the calibration of the analytical system. The calibrator is available in 7 levels (Cal0 – Cal6) and consists of human serum. After reconstitution, calibrators should be handled in the same way as a real sample.

Reconstitution:

Carefully remove the rubber cup from the vial and add exactly 1.0 mL of bi-distilled water. Close the vials and allow it to stand at room temperature for 10-15 min. The content of the bottle should be shaken and melted until completely blended. In order to ensure a proper homogenization, mix gently for reversal before use.

Storage and stability:

Storage: -20 °C. Keep it away from light and heat.
Stability:
- Before reconstitution: until the expiry date on the label has been reached
- After reconstitution: 10 days if well preserved and away from the light at +2 - 8 °C
  up to 3 months if well preserved and away from the light at -20 °C

Packaging:

Calibrators, in human serum, lyophil. – for NOAC; Levels 0-6, 2 x 7 x 1.0 mL
Catalogue number: EUM12041

Precautions for use:

This product is based on no reactive human serum with antibodies against HIV 1+2, HCV e HBV-DNA, HBs antigen, and HBc. There is a possible risk of infection with biological agents since there are no test able to grant absolute certainty that products that contain human fluids are infective agent free. This product may contain unknown infectious agents or pathogens and test may not exist. For all these reasons, it's recommended to handle this product wearing protective glasses, lab garments and chemical-biological resistant disposable gloves.

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Calibrators concentration values:

Average concentrations and analytes included in calibrators: *

ANALYTE	UNIT OF MEASUREMENT	CAL 0	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5	CAL 6
Apixaban	ng/mL	0.00	2.00	5.00	20.0	100	500	1000
Edoxaban	ng/mL	0.00	2.00	5.00	20.0	100	500	1000
Rivaroxaban	ng/mL	0.00	2.00	5.00	20.0	100	500	1000
Dabigatran	ng/mL	0.00	2.00	5.00	20.0	100	500	1000

ANALYTE	UNIT OF MEASUREMENT	CAL 0	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5	CAL 6
Apixaban	nmol/L	0.00	4.35	10.9	43.5	218	1088	2176
Edoxaban	nmol/L	0.00	3.65	9.12	36.5	182	912	1824
Rivaroxaban	nmol/L	0.00	4.59	11.5	45.9	229	1147	2294
Dabigatran	nmol/L	9.08	3.19	7.97	31.9	159	797	1593

* The above-mentioned concentrations are referred exclusively to EUM12041 with batch M1241XXXX and expiry dare XX/XXXX.

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