

EUM12051 - 3-Levels Controls, lyophil.

LYOPHILIZED CONTROLS

FOR NOAC IN SERUM

Ref. EUM12051

Lot. M1251XXXX

 XX/XXXX

 CE

Intended use:

Lyophilized controls, consisting of human serum, are used to verify the accuracy and precision of the analytical procedures for the quantitative determination of NOAC in serum/plasma. After following the reconstitution instructions, controls 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

Values assignment:

Average values and acceptability ranges are determined from a representative sample of this batch' controls. These values are specific only for calibrators of this batch. Average values and acceptability ranges should be established by every laboratory according to instruments, reagents and intra-lab changes. They may vary slightly due to reagents and procedural modifications.

Packaging:

Controls in human serum, lyophil. – for NOAC; Levels 1-3, 2 x 3 x 1.0 mL
Catalogue number: EUM12051

Precautions for use:

This product is based on no reactive human serum with antibodies against HIV 1 + 2, HCV, HBV-DNA, HBsAg and HBc tests. 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.

Controls concentrations values:

Average concentrations and analytes acceptable range related to LC-MS/MS technique *:

ANALYTE	UNIT OF MEASURE	L1	RANGE	L 2	RANGE	L 3	RANGE
Apixaban	ng/mL	4.00	3.20 - 4.80	50.0	40.0 - 60.0	750	600 - 900
Edoxaban	ng/mL	4.00	3.20 - 4.80	50.0	40.0 - 60.0	750	600 - 900
Rivaroxaban	ng/mL	4.00	3.20 - 4.80	50.0	40.0 - 60.0	750	600 - 900
Dabigatran	ng/mL	4.00	3.20 - 4.80	50.0	40.0 - 60.0	750	600 - 900

ANALYTE	UNIT OF MEASURE	L1	RANGE	L 2	RANGE	L 3	RANGE
Apixaban	nmol/L	8.70	6.96 - 10.4	109	87.0 - 131	1632	1306 - 1958
Edoxaban	nmol/L	7.30	5.84 - 8.76	91.2	73.0 - 109	1368	1094 - 1642
Rivaroxaban	nmol/L	9.18	7.34 - 11.0	115	91.8 - 138	1721	1376 - 2065
Dabigatran	nmol/L	6.37	5.10 - 7.65	79.7	63.7 - 95.6	1195	956 - 1434

* The above-mentioned concentrations are referred exclusively to EUM12051 with batch M1251XXXX and expiry date XX/XXXX.