

EUM23051 - 2-Levels Controls lyophil

LYOPHYLIZED CONTROLS IN PLASMA
FOR BIOGENIC AMINES

Ref. EUM23051

Lot. M2351XXXX

 XX/XXXX



Intended use:

Lyophilized controls (EUM23051), based on human plasma, are used to verify the accuracy and precision of the analytical procedures for the quantitative determination of Biogenic Amines in plasma. After following the reconstitution instructions, controls should be handled in the same way as a real sample.

Reconstitution:

Carefully remove the rubber stopper from the bottle and add exactly 1.0 mL of bi-distilled water. Cap the bottles and let stand for 10-15 minutes at room temperature. Shake and dissolve the contents until homogeneity. To ensure proper homogenisation, mix gently by inversion 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: 7 days if well preserved and away from the light at +2 - 8°C
up to 7 days 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, lyophilized human plasma - For Biogenic Amines; Levels 1-2, 2 x 2 x 1.0 mL
Catalogue number: EUM23051

Precaution 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 concentration values:

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

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L2	RANGE
Adrenaline	ng/L	93.8	75.0 - 113	750	600 - 900
Noradrenaline	ng/L	375	300 - 450	3000	2400 - 3600
Dopamine	ng/L	37.5	30.0 - 45.0	300	240 - 360
Metanephrine	ng/L	37.5	30.0 - 45.0	300	240 - 360
Normetanephrine	ng/L	93.8	75.0 - 113	750	600 - 900
3-Methoxytyramine	ng/L	18.8	15.0 - 22.6	150	120 - 180
Serotonin	µg/L	93.8	75.0 - 113	750	600 - 900
L-DOPA	µg/L	4.69	3.75 - 5.63	37.5	30.0 - 45.0

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE
Adrenaline	nmol/L	0.51	0.41 - 0.61	4.09	3.27 - 4.91
Noradrenaline	nmol/L	2.22	1.77 - 2.66	17.7	14.2 - 21.3
Dopamine	nmol/L	0.24	0.20 - 0.29	1.96	1.57 - 2.35
Metanephrine	nmol/L	0.19	0.15 - 0.23	1.52	1.22 - 1.83
Normetanephrine	nmol/L	0.51	0.41 - 0.61	4.09	3.27 - 4.91
3-Methoxytyramine	nmol/L	0.11	0.10 - 0.13	0.90	0.72 - 1.08
Serotonin	µmol/L	0.53	0.43 - 0.64	4.26	3.40 - 5.11
L-DOPA	nmol/L	23.7	19.0 - 28.4	190	152 - 228

* The above-mentioned concentrations are referred exclusively to EUM23051 with batch M2351XXXX and expiry date XX/XXXX.