



EUM17051 - 3-Level Controls, lyophil.

LYOPHILIZED CONTROLS IN URINE
FOR BIOGENIC AMINES IN URINE

Ref. EUM17051
Lot. M1751XXXX
 XX/XXXX
 CE

Intended use:

Lyophilized controls (EUM17051), based on lyophilized human urine, are used to verify the accuracy and precision of the analytical procedures for quantitative determination of biogenic amines in urine. After following reconstitution instructions, calibrators should be handled in the same way as real samples.

Reconstitution and spinking:

Carefully remove the rubber cup from the vial and add exactly 2.0 mL of HCl 0.1 M. Close the vials and allow it to stand at room temperature for 10-15 min. Its content 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: stock at -20 °C avoiding direct light and heat exposure.

Stability:

- Before reconstitution: until the expiry date on the label has been reached.
- After reconstitution: 10 days if well closed and avoided direct light exposure at +2 - 8 °C
up to 3 months if well closed and avoided direct light exposure 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 urine – Biogenic Amines in Urine; Levels 1-3, 2 x 2 x 2.0 mL
Catalogue number: EUM17051

Precaution for use:

This product may contain unknown infectious agents and for this reason, it's recommended to handle the product using adequate safety measures.

Calibration levels and concentrations*:

ANALYTE	UNIT OF MEASURE	L1	RANGE	L 2	RANGE
Adrenaline	ng/mL	16.0	15.4 – 23.0	400	31.0 – 46.6
Noradrenaline	ng/mL	16.0	49.1 – 73.7	400	99.2 – 149
Dopamine	ng/mL	40.0	88.8 – 133	1000	180 – 270
Metanephrine	ng/mL	40.0	37.2 – 55.8	1000	910 – 1365
Normetanephrine	ng/mL	40.0	36.6 – 55.0	1000	897 – 1345
3-Methoxytyramine	ng/mL	20.0	19.2 – 28.8	500	470 – 706
Serotonine	ng/mL	64.0	67.1 – 101	1600	1643 – 2465
VMA	µg/mL	2.40	1.86 – 2.80	60.0	45.6 – 68.4
5-HIAA	µg/mL	2.40	1.84 – 2.76	60.0	45.1 – 67.7
HVA	µg/mL	2.40	1.74 – 2.62	60.0	42.6 – 64.0
Creatinine	µg/mL	32.0	22.7 – 34.1	800	556 – 834

ANALYTE	UNIT OF MEASURE	L1	RANGE	L 2	RANGE
Adrenaline	nmol/L	87.3	69.9 - 105	2183	1747 - 2620
Noradrenaline	nmol/L	94.6	75.7 - 113	2364	1892 - 2837
Dopamine	nmol/L	261	209 - 313	6528	5222 - 7834
Metanephrine	nmol/L	203	162 - 243	5070	4056 - 6084
Normetanephrine	nmol/L	218	175 - 262	5459	4367 - 6550
3-Methoxytyramine	nmol/L	120	95.7 - 144	2990	2392 - 3588
Serotonine	nmol/L	363	291 - 436	9080	7264 - 10896
VMA	µmol/L	12.1	9.69 - 14.5	303	242 - 363
5-HIAA	µmol/L	12.6	10.0 - 15.1	314	251 - 377
HVA	µmol/L	13.2	10.5 - 15.8	329	263 - 395
Creatinine	µmol/L	282.9	226 - 339	7072	5658 - 8487

* The above-mentioned concentrations are referred exclusively to EUM17051 lot M1751XXXX expiring on XX/XXXX.