

EUM04051 - 2-Levels Controls, lyophil

LYOPHILIZED CONTROLS IN EXTRACTED HAIRS
FOR ETHYLGLUCURONIDE

Ref. EUM04051

Lot. M0451XXXX

 XX/XXXX

 IVD  CE

Intende use:

Lyophilized controls (EUM04051), based on extracted hairs, sono utilizzati are used to verify the accuracy and precision of the analytical procedures for quantitative determination of Ethylglucuronide in hairs samples. After following reconstitution instructions, calibrators should be handled in the same way as a real sample.

Reconstitution:

Carefully remove the rubber stopper from the bottle and add exactly 0.2 mL of double 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: 10 days if well preserved and away from the light at +2 - 8°C
till 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, lyophilized human extracted hairs - For Ethylglucuronide; Levels 1-2, 3 x 2 x 0.2 mL
Catalogue number: EUM04051

Precaution for use:

Since no test can offer complete assurance that infectious agents are absent, this product should be handled observing the same safety precautions used when handling any type of potentially infectious material.

Controls concentration values:

Average concentrations and range of acceptability of the analytes referred to the technique LC-MS/MS *:

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE
Etilglucuronide	ng/mL	2.25	1.80 - 2.70	3.75	3.00 - 4.50

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE
Etilglucuronide	pg/mg	22.5	18.0 - 27.0	37.5	30.0 - 45.0

* The above-mentioned concentrations are referred exclusively to EUM04051 with batch M0451XXXX and expiry date XX/XXXX.