



EUM16051 - 3-Levels Controls lyophil

LYOPHYLIZED CONTROLS IN SERUM
FOR METHOTREXATE

Ref. EUM16051
Lot. M1651XXXX
 XX/XXXX
 CE

Intended use:

Lyophilized controls (EUM16051), based on human serum, are used to verify the accuracy and precision of the analytical procedures for the quantitative determination of Methotrexate and its metabolites 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 stopper from the bottle and add exactly 0.5 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: 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, lyophilized human serum - For Methotrexate; Levels 1-3, 2 x 3 x 0.5 mL
Catalogue number: EUM16051

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	L 2	RANGE	L 3	RANGE
Methotrexate	ng/mL	50.0	40.0 - 60.0	400	320 - 480	2500	2000 - 3000
7OH-Methotrexate	ng/mL	100	80.0 - 120	800	640 - 960	5000	4000 - 6000
DAMPA	ng/mL	40.0	32.0 - 48.0	320	256 - 384	2000	1600 - 2400

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE	L 3	RANGE
Methotrexate	µmol/L	0.11	0.09 - 0.13	0.88	0.70 - 1.06	5.50	4.40 - 6.60
7OH-Methotrexate	µmol/L	0.21	0.17 - 0.26	1.70	1.36 - 2.04	10.6	8.50 - 12.8
DAMPA	µmol/L	0.12	0.10 - 0.15	0.98	0.79 - 1.18	6.15	4.92 - 7.38

* The above-mentioned concentrations are referred exclusively to EUM16051 with batch M1651XXXX and expiry date XX/XXXX.