

ST-EUM16041(eng)

Rev: 0

Data: 28.09.2021

EUM16041 - 6-Levels Calibrators lyophil.

LYOPHILIZED CALIBRATORS IN SERUM FOR METHOTREXATE

Ref. EUM16041 Lot. M1641XXXX





Intended use:

EUM16041 is the lyophilized calibrator used for the calibration of the analytical system. The calibrator is available in 7 levels (Cal0 – Cal6) and consists of human serum. After reconstitution, calibrators should be handled in the same way as a real sample.

Reconstitution:

Carefully remove the rubber stopper from the bottle and add exactly 0.5 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

Packaging:

Calibrators, lyphilized human serum - For Methotrexate; Levels 0-6, 2 x 7 x 0.5 mL Catalogue number: EUM16041

Precaution for use:

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



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Calibrators concentration values:

Average concentrations and analytes included in calibrators: *

ANALYTE	UNIT OF MEASUREMENT	CAL 0	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5	CAL 6
Methotrexate	ng/mL	0.00	5.00	25.0	100	500	2000	5000
70H-Methotrexate	ng/mL	0.00	10.0	50.0	200	1000	4000	10000
DAMPA	ng/mL	0.00	4.00	20.0	80.0	400	1600	4000

ANALYTE	UNIT OF MEASUREMENT	CAL 0	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5	CAL 6
Methotrexate	µmol/L	0.00	0.01	0.06	0.22	1.10	4.40	11.0
70H-Methotrexate	µmol/L	0.00	0.02	0.11	0.43	2.13	8.50	21.3
DAMPA	µmol/L	0.00	0.01	0.06	0.25	1.23	4.92	12.3

^{*}The above-mentioned concentrations are referred exclusively to EUM16041 with batch M1641XXXX and expiry date XX/XXXX.