

EUM15041 - 6-Levels Calibrators lyophil.

LYOPHILIZED CALIBRATORS

FOR ANTIBIOTICS IN SERUM

Ref. EUM15041

Lot. M1541XXXX

 XX/XXXX

 CE

Intended use:

EUM15041 is the lyophilized calibrator used for the calibration of the analytical system. The calibrator is available in 6 levels (Cal0-Cal5) and consists of human serum. After reconstitution, calibrators should be handled in the same way as a real sample.

Reconstitution:

Carefully remove the rubber cup from the vial and add exactly 1.0 mL of bi-distilled water. Close the vials and allow it to stand at room temperature for 10-15 min. The content of the bottle 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: -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 in lyophil. serum for Antibiotics; Levels 0-6, 2 x 6 x 1.0 mL

Catalogue number: EUM15041

Precautions 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.

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
Amikacin	µg/mL	0.00	1.00	5.00	10.0	25.0	50.0
Gentamicin C1	µg/mL	0.00	0.05	0.22	0.45	1.12	2.24
Gentamicin C2	µg/mL	0.00	0.11	0.53	1.07	2.67	5.33
Gentamicin C3	µg/mL	0.00	0.05	0.24	0.49	1.22	2.43
Vancomycin	µg/mL	0.00	2.00	10.0	20.0	50.0	100
Teicoplanin A2-1	µg/mL	0.00	0.11	0.55	1.10	2.75	5.50
Teicoplanin A2-2\A2-3	µg/mL	0.00	1.25	6.25	12.5	31.3	62.5
Teicoplanin A2-4\A2-5	µg/mL	0.00	0.64	3.20	6.40	16.0	32.0
Linezolid	µg/mL	0.00	1.00	5.00	10.0	25.0	50.0

ANALYTE	UNIT OF MEASUREMENT	CAL 0	CAL 1	CAL 2	CAL 3	CAL 4	CAL 5
Amikacin	µmol/L	0.00	1.71	8.54	17.7	42.7	85.4
Gentamicin C1	µmol/L	0.00	0.09	0.46	0.94	2.34	4.68
Gentamicin C2	µmol/L	0.00	0.24	1.18	2.38	5.93	11.8
Gentamicin C3	µmol/L	0.00	0.11	0.52	1.06	2.63	5.23
Vancomycin	µmol/L	0.00	1.38	6.90	13.8	34.5	69.0
Teicoplanin A2-1	µmol/L	0.00	0.12	0.59	1.17	2.93	5.86
Teicoplanin A2-2\A2-3	µmol/L	0.00	1.33	6.65	13.3	33.3	66.5
Teicoplanin A2-4\A2-5	µmol/L	0.00	0.68	3.38	6.76	16.9	33.8
Linezolid	µmol/L	0.00	2.96	14.8	29.6	74.1	148

* The above-mentioned concentrations are referred exclusively to EUM15041 with batch M1541XXXX and expiry date XX/XXXX.