



## EUM15051 - 2-Levels Controls lyophil.

LYOPHILIZED CONTROLS  
FOR ANTIBIOTICS IN SERUM

Ref. EUM15051  
Lot. M1551XXXX  
 XX/XXXX  
 CE

### Intended use:

Lyophilized controls, consisting of human serum, are used to verify the accuracy and precision of the analytical procedures for the quantitative determination of antibiotics in serum samples. After following the reconstitution instructions, controls 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

### 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 in lyophil. serum for Antibiotics; Levels 1-2 – 2 x 2 x 1.0 mL.  
Catalogue number: EUM15051

### Precautions 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 concentrations values:

Average concentrations and analytes acceptable range related to LC-MS/MS technique \*:

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE
Amikacin	µg/mL	3.75	3.00 - 4.50	37.5	30.0 - 45.0
Gentamicin C1	µg/mL	0.17	0.13 - 0.20	1.68	1.34 - 2.02
Gentamicin C2	µg/mL	0.40	0.32 - 0.48	3.99	3.19 - 4.79
Gentamicin C3	µg/mL	0.18	0.15 - 0.23	1.82	1.46 - 2.18
Vancomycin	µg/mL	7.50	6.00 - 9.00	75.0	60.0 - 90.0
Teicoplanin A2-1	µg/mL	0.41	0.33 - 0.50	4.13	3.30 - 4.96
Teicoplanin A2-2\A2-3	µg/mL	4.69	3.75 - 5.63	46.9	37.5 - 56.3
Teicoplanin A2-4\A2-5	µg/mL	2.40	1.92 - 2.88	24.0	19.2 - 28.8
Linezolid	µg/mL	3.75	3.00 - 4.50	37.5	30.0 - 45.0

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE
Amikacin	µmol/L	6.40	5.12 - 7.68	64.0	51.2 - 76.8
Gentamicin C1	µmol/L	0.35	0.28 - 0.42	3.51	2.81 - 4.21
Gentamicin C2	µmol/L	0.89	0.71 - 1.06	8.86	7.09 - 10.6
Gentamicin C3	µmol/L	0.39	0.31 - 0.47	3.92	3.14 - 4.70
Vancomycin	µmol/L	5.17	4.14 - 6.21	51.8	41.4 - 62.1
Teicoplanin A2-1	µmol/L	0.44	0.35 - 0.53	4.40	3.52 - 5.28
Teicoplanin A2-2\A2-3	µmol/L	4.99	3.99 - 5.99	49.9	39.9 - 59.9
Teicoplanin A2-4\A2-5	µmol/L	2.53	2.03 - 3.04	25.4	20.3 - 30.4
Linezolid	µmol/L	11.1	8.89 - 13.3	111	88.9 - 133

\* The above-mentioned concentrations are referred exclusively to EUM15051 with batch M1551XXXX and expiry date XX/XXXX.