

EUM03051 - 2-Levels Controls, lyophil

LYOPHILIZED CONTROLS IN SERUM

FOR PARACRESOL SULFATE AND INDOXYL SULFATE

Ref. EUM03051

Lot. M0351XXXX



XX/XXXX



Intended use:

Lyophilized controls (EUM03051), based on human serum, sono utilizzati are used to verify the accuracy and precision of the analytical procedures for quantitative determination of p-Cresol Sulfate and Indoxyl Sulfate in serum/plasma. 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 0.5 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
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 serum - For pCS and IS; 2 Levels, 2 x 2 x 0.5 mL
Catalogue number: EUM03051

Precautions for use:

This product was obtained from human serum non-reactive in anti-HIV 1+2, anti-HCV, HBV-DNA, HBsAg and anti-HBc tests. Since there are no tests capable of giving absolute certainty that products containing human fluids are free from infectious agents, a possible risk of infection from a biological agent must be considered. This product may also contain unknown infectious agents or pathogens for which there is no analytical test. For all these reasons it is recommended to handle this product wearing laboratory goggles, protective clothing and disposable gloves resistant to chemical-biological agents.

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
p-Cresol Sulfate	µg/mL	7.50	6.00 - 9.00	75.0	60.0 - 90.0
Indoxyl Sulfate	µg/mL	9.37	7.50 - 11.2	93.7	75.0 - 112

ANALYTE	UNIT IF MEASUREMENT	L1	RANGE	L 2	RANGE
p-Cresol Sulfate	µmol/L	33.1	26.5 - 39.7	331	265 - 397
Indoxyl Sulfate	µmol/L	43.9	35.2 - 52.7	439	352 - 527

* The above-mentioned concentrations are referred exclusively to EUM03051 with batch M0351XXXX and expiry date XX/XXXX.