

EUM06051 - 3-Level Controls, lyophil.

LYOPHILIZED CONTROLS IN URINE

FOR FREE URINARY CORTISOL AND CORTISONE

Ref. EUM06051

Lot. M0651XXXX

 XX/XXXX

 CE

Intended use:

Lyophilized controls (EUM02055), based on lyophilized human urine, are used to verify the accuracy and precision of the analytical procedures for their quantitative determination. After following reconstitution instructions, calibrators should be handled in the same way as real samples.

Reconstitution and spiking:

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. Its content 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: stock at -20 °C avoiding direct light and heat exposure.

Stability:

- Before reconstitution: until the expiry date on the label has been reached.
- After reconstitution: 10 days if well closed and avoided direct light exposure at +2 - 8 °C
up to 3 months if well closed and avoided direct light exposure 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 urine – Cortisol and Cortisone in Urine; Levels 1-3, 2 x 3 x 1.0 mL
Catalogue number: EUM06051

Precaution for use:

This product may contain unknown infectious agents and for this reason, it's recommended to handle the product using adequate safety measures.

Calibration levels and concentrations*:

ANALYTE	UNIT OF MEASURE	L1	RANGE	L 2	RANGE	L 3	RANGE
Cortisol	ng/mL	4.00	3.20 - 4.80	20.0	16.0 - 24.0	200	160 - 200
Cortisone	ng/mL	4.00	3.20 - 4.80	20.0	16.0 - 24.0	200	160 - 200

ANALYTE	UNIT OF MEASURE	L1	RANGE	L 2	RANGE	L 3	RANGE
Cortisol	nmol/L	11.0	8.80 - 13.2	55.2	44.2 - 66.2	552	442 - 662
Cortisone	nmol/L	11.1	8.88 - 13.3	55.5	44.4 - 66.6	555	444 - 666

* The above-mentioned concentrations are referred exclusively to EUM06051 lot M0651XXXX expiring on XX/XXXX.