

ST-EUM14051(eng) Rev: 0 Data: <mark>28.09.2021</mark>

EUM14051 - 3-Levels Controls, lyophil.

LYOPHILIZED CONTROLS FOR CORTISOL AND CORTISONE IN SALIVA



Intended use:

Lyophilized controls, consisting of human saliva, are used to verify the accuracy and precision of the analytical procedures for the quantitative determination of Cortisol and Cortisone in saliva. 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 2.0 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 $+2 - 8 \degree C$

up to 2 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 Iyophil. human saliva - for Cortisol e Cortisone; Levels 1-3, 2 x 3 x 2.0 mL Catalogue number: EUM14051

Precautions for use:

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



Controls concentrations values:

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

| ANALYTE | UNIT OF MEASUREMENT | u | RANGE | L 2 | RANGE | L 3 | RANGE |
|-----------|------------------------|------|-------------|------|-------------|------|-------------|
| Cortisol | ng/mL | 0.98 | 0.78 - 1.18 | 7.50 | 6.00 - 9.00 | 37.5 | 30.0 - 45.0 |
| Cortisone | ng/mL | 1.95 | 1.56 - 2.34 | 15.0 | 12.0 - 18.0 | 75.0 | 60.0 - 90.0 |

| ANALYTE | UNIT OF MEASUREMENT | IJ | RANGE | L 2 | RANGE | L 3 | RANGE |
|-----------|------------------------|------|-------------|------|-------------|-----|------------|
| Cortisol | nmol/L | 2.70 | 2.16 - 3.25 | 20.7 | 16.6 - 24.8 | 104 | 82.8 - 124 |
| Cortisone | nmol/L | 5.40 | 4.32 - 6.48 | 51.6 | 33.2 - 49.9 | 208 | 166 - 249 |

* The above-mentioned concentrations are referred exclusively to EUM14051with batch M1451XXXX and expiry date XX/XXXX.