

EUM01051 – 3-Levels Controls, lyophil

LYOPHILIZED CONTROLS IN SERUM
FOR STEROID HORMONES

Ref. EUM01051
Lot. M0151XXXX
 XX/XXXX
 CE

Intended use:

Lyophilized controls (EUM01051), based on human serum, are used to verify the accuracy and precision of the analytical procedures for quantitative determination of steroid hormones in serum/plasma. After following reconstitution instructions, calibrators should be handled in the same way as a real sample.

Reconstitution:

Carefully remove the rubber cap from the bottle and add exactly 2.5 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 mesi if well stored 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 Steroids; Levels 1-3, 2 x 3 x 2.5 mL
Catalogue number: EUM01051

Precaution 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 LC-MS/MS technique*:

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE	L 3	RANGE
Aldosterone	ng/mL	0.08	0.06 - 0.10	0.40	0.32 - 0.48	4.00	3.20 - 4.80
Androstenedione	ng/mL	0.12	0.10 - 0.14	0.60	0.48 - 0.72	6.00	4.80 - 7.20
Corticosterone	ng/mL	0.48	0.38 - 0.58	2.40	1.92 - 2.88	24.0	19.2 - 28.8
Cortisol	ng/mL	15.0	12.0 - 18.0	75.0	60.0 - 90.0	750	600 - 900
11-Deoxycortisol	ng/mL	0.12	0.10 - 0.14	0.60	0.48 - 0.72	6.00	4.80 - 7.20
DHEA	ng/mL	0.48	0.38 - 0.58	2.40	1.92 - 2.88	24.0	19.2 - 28.8
Progesterone	ng/mL	0.12	0.10 - 0.14	0.60	0.48 - 0.72	6.00	4.80 - 7.20
17OH-Progesterone	ng/mL	0.48	0.38 - 0.58	2.40	1.92 - 2.88	24.0	19.2 - 28.8
DHEAS	ng/mL	75.0	60.0 - 90.0	375	300 - 450	3750	3000 - 4500
Testosterone	ng/mL	0.12	0.10 - 0.14	0.60	0.48 - 0.72	6.00	4.80 - 7.20

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE	L 3	RANGE
Aldosterone	nmol/L	0.22	0.18 - 0.27	1.11	0.89 - 1.33	11.1	8.86 - 13.3
Androstenedione	nmol/L	0.42	0.34 - 0.50	2.09	1.68 - 2.51	20.9	16.8 - 25.1
Corticosterone	nmol/L	1.39	1.11 - 1.66	6.94	5.55 - 8.32	69.4	55.5 - 83.2
Cortisol	nmol/L	41.4	33.1 - 49.7	207	166 - 248	2070	1656 - 2484
11-Deoxycortisol	nmol/L	0.35	0.28 - 0.42	1.73	1.39 - 2.08	17.3	13.9 - 20.8
DHEA	nmol/L	1.67	1.33 - 2.00	8.33	6.66 - 9.99	83.3	66.6 - 99.9
Progesterone	nmol/L	0.38	0.31 - 0.46	1.91	1.53 - 2.29	19.1	15.3 - 22.9
17OH-Progesterone	nmol/L	1.45	1.16 - 1.75	7.27	5.82 - 8.73	72.7	58.2 - 87.3
DHEAS	nmol/L	203	163 - 244	1016	813 - 1220	10163	8130 - 12195
Testosterone	nmol/L	0.42	0.33 - 0.50	2.08	1.67 - 2.50	20.8	16.7 - 25.0

* The above-mentioned concentrations are referred exclusively to EUM01051 with batch M0151XXXX and expiry date XX/XXXX.