

## EUH01051 - 2-Levels Controls, lyophil.

LYOPHILIZED CONTROLS  
FOR CATECHOLAMINES IN URINE

Ref. EUH01051  
Lot. H0151XXXX  
XX/XXXX  
IVD CE

### Intended use:

Lyophilized controls, consisting of human urine, are used to verify the accuracy and the precision of analytical procedures for the quantitative determination of Catecholamines in urine. 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 2.5 mL of HCl 0.1 M. 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 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 batch' controls. These values are specific only for controls 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. human urine – for Catecholamines; 2 Levels, 5 x 2 x 2.5 mL  
Catalogue number: EUH01051

### Precautions for use:

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. It's recommended to handle this product wearing protective glasses, lab garments and chemical-biological resistant disposable gloves.

## Controls concentration values:

Average concentrations and analytes acceptable range related to HPLC technique\*:

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE
Adrenaline	µg/L	25.0	15.4 - 23.0	50.0	31.0 - 46.6
Noradrenaline	µg/L	62.5	49.1 - 73.7	125	99.2 - 149
Dopamine	µg/L	125	88.8 - 133	250	180 - 270

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE
Adrenaline	nmol/L	136	109 - 164	273	218 - 327
Noradrenaline	nmol/L	369	296 - 443	739	591 - 887
Dopamine	nmol/L	816	653 - 979	1632	1306 - 1958

\* The above-mentioned concentrations are referred exclusively to EUH01051 with batch H0151XXXX and expiry date XX/XXXX.