

EUH02051 - 2-Levels Controls, lyophil.

LYOPHILIZED CONTROLS

FOR HIPPURIC ACID AND STYRENE METABOLITES IN URINE

Ref. EUH02051

Lot. H0251XXXX

 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 hippuric acid and styrene metabolites 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 0.5 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 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 lyophil. human urine - for hippuric acid and styrene metabolites; 2 Levels, 5 x 2 x 0.5 mL
Catalogue number: EUH02051

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 |
|------------------------|---------------------|------|-------------|-----|-----------|
| Phenyl Glyoxylic Acid | µg/mL | 66.7 | 53.4 - 80.0 | 200 | 160 - 240 |
| Mandelic Acid | µg/mL | 167 | 133 - 200 | 500 | 400 - 600 |
| Hippuric Acid | µg/mL | 267 | 213 - 320 | 500 | 400 - 600 |
| o-Methyl Hippuric Acid | µg/mL | 33.3 | 26.6 - 40.0 | 100 | 80 - 120 |
| p-Methyl Hippuric Acid | µg/mL | 66.7 | 53.4 - 80.0 | 200 | 160 - 240 |
| m-Methyl Hippuric Acid | µg/mL | 66.7 | 53.4 - 80.0 | 200 | 160 - 240 |

| ANALYTE | UNIT OF MEASUREMENT | L1 | RANGE | L 2 | RANGE |
|------------------------|---------------------|------|-------------|------|-------------|
| Phenyl Glyoxylic Acid | µmol/L | 444 | 355 - 533 | 1332 | 1066 - 1599 |
| Mandelic Acid | µmol/L | 1098 | 878 - 1317 | 3286 | 2629 - 3944 |
| Hippuric Acid | µmol/L | 1490 | 1192 - 1788 | 2791 | 2233 - 3349 |
| o-Methyl Hippuric Acid | µmol/L | 172 | 138 - 207 | 518 | 414 - 621 |
| p-Methyl Hippuric Acid | µmol/L | 345 | 276 - 414 | 1035 | 828 - 1242 |
| m-Methyl Hippuric Acid | µmol/L | 345 | 276 - 414 | 1035 | 828 - 1242 |

* The above-mentioned concentrations are referred exclusively to EUH02051 with batch H0251XXXX and expiry date XX/XXXX.