

ST-EUH10051(eng) Rev: 0 Date: <mark>28.09.2021</mark>

# EUH10051 – 2-Levels Controls, lyophil.

Ref.	EUH10051				
Lot.	H1051 <mark>XXXX</mark>				
$\Box$	<mark>XX</mark> /XXXX				
IVD	CE				

LYOPHILIZED CONTROLS FOR OCCUPATIONAL MEDICINE

#### 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 o-Cresol, Phenol and t,t-Muconic Acid 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 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:

until the expiry date on the label has been reached. 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

## Value 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 intralab changes. They may vary slightly due to reagents and procedural modifications.

## **Packaging:**

Lyophil, Controls in urine – for Occupational Medicine; 2 Levels, 5 x 2 x 2.5 mL Catalogue number: EUH10051

## **Precaution 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 chemicalbiological resistant disposable gloves.

Via Coelli, 18 26012 Castelleone (CR)



## **Controls concentration values:**

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

ANALYTE	UNIT OF MEASUREMENT	u	RANGE	L 2	RANGE
o-Cresol	mg/L	0.50	0.40 - 0.60	2.50	2.00 - 3.00
Phenol	mg/L	8.00	3.20 - 4.80	40.0	16.0 - 24.0
t,t-MA	mg/L	0.40	0.32 - 0.48	2.00	1.60 - 2.40

ANALYTE	UNIT OF MEASUREMENT	u	RANGE	L 2	RANGE
o-Cresol	µmol/L	4.60	3.70 - 5.55	23.1	18.5 - 27.7
Phenol	µmol/L	84.8	67.8 - 101.8	424	339 - 509
t,t-MA	µmol/L	3.38	2.70 - 4.05	16.9	13.5 - 20.3

\* The above-mentioned concentrations are referred exclusively to EUH10051 with batch H1051XXXX and expiry date XX/XXXX.