

ST-EUH09041(eng)

Rev: 0

Data: 28.09.2021

EUH09041 - Calibrator, lyophil.

LYOPHILIZED CALIBRATOR FOR CROSSLINKS IN URINE Ref. EUH09041 Lot. H0941XXXX XX/XXXX CE

IVD

Intended use:

Lyophilized calibrators are used for the quantitative determination of Pyridinoline and Deoxypyridinoline in urine samples. After following the reconstitution instructions, calibrators should be handled in the same way as a real sample.

Reconstitution:

Carefully remove the rubber cup from the vial and add exactly 2.2 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.

Packaging:

Lyophil. Calibrator in urine - for Crosslinks; 6 x 2.2 mL

Catalogue number: EUH09041

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 chemicalbiological resistant disposable gloves.



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Calibrators concentration values:

Average concentrations and analytes included in calibrators: *

ANALYTE	UNIT OF MEASUREMENT	CONCENTRATION
Pyridinoline	ng/L	428
Deoxypyridinoline	ng/L	165

ANALYTE	UNIT OF MEASUREMENT	CONCENTRATION
Pyridinoline	pmol/L	1000
Deoxypyridinoline	pmol/L	400

^{*} The above-mentioned concentrations are referred exclusively to EUH09041 with batch H0941XXXX and expiry date XX/XXXX.