EUH06041 - Calibrator, lyophil.

LYOPHILIZED CALIBRATOR
FOR IOHEXOL IN SERUM

Ref. EUH06041
Lot. H0641XXXX
XX/XXXX
IVD CE

Intended use:

Lyophilized calibrators are used for Iohexol quantitative determination in serum/plasma 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 1.0 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. Calibrators in serum - Iohexol; 1 x 1.0 mL
Catalogue number: EUH06041

Precautions for use:

This product is based on no reactive human serum with antibodies against HIV 1+2, HCV, HBV-DNA, HbsAg and HBc. 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. This product may contain unknown infectious agents or pathogens and test may not exist. For all these reasons, it's recommended to handle this product wearing protective glasses, lab garments and chemical-biological resistant disposable gloves.

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Calibrators concentration values:

Average concentrations and analytes included in calibrators: *

ANALYTE	UNIT OF MEASUREMENT	CONCENTRATION
Iohexol Endo	mg/L	77.0
Iohexol Eso	mg/L	83.0

ANALYTE	UNIT OF MEASUREMENT	CONCENTRATION
Iohexol Endo	µmol/L	93.8
Iohexol Eso	µmol/L	101

* The above-mentioned concentrations are referred exclusively to EUH06041 with batch H0641XXXX and expiry date XX/XXXX.

Please note: the two structural isomers of the molecule are separated chromatographically and individually dosed. Therefore, Iohexol values in calibrator is obtained from total amount of both isomers' concentrations.

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