




EUH06051 - 2-Levels Controls, lyophil.

LYOPHILIZED CONTROLS
FOR IOHEXOL IN SERUM

Ref. EUH06051
Lot. H0651XXXX
 XX/XXXX
 

Intended use:

Lyophilized controls, consisting of human serum, are used to verify the accuracy and the precision of analytical procedures for the quantitative determination of Iohexol in serum or plasma samples. 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 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

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 serum for Iohexol; 2 Levels, 2 x 2 x 1.0 mL
Catalogue number: EUH06051

Precautions for use:

This product is based on no reactive human serum with antibodies against HIV 1+2, HCV, HBV-DNA, HBsAg and HBc tests. 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.

Controls concentration values:

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

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE
Iohexol Endo	mg/L	19.3	15.4 - 23.2	48.1	38.5 - 57.7
Iohexol Eso	mg/L	20.7	16.6 - 24.8	51.9	41.5 - 62.3

ANALYTE	UNIT OF MEASUREMENT	L1	RANGE	L 2	RANGE
Iohexol Endo	µmol/L	23.5	18.8 - 28.2	58.6	46.9 - 70.3
Iohexol Eso	µmol/L	25.2	20.2 - 30.3	63.2	50.6 - 75.8

* The above-mentioned concentrations are referred exclusively to EUH06051 with batch H0651 XXXX and expiry date XX/XXXX.

NOTE: the two structural isomers of the molecule are separated chromatographically. Therefore, the values indicated in the table are valid for the quantification of both drug's isomers.