



Product name Homocystein

Product code

Level	Product code	Colour cap
Low	HOM-01.1	Green
Medium	HOM-01.2	Blue
High	HOM-01.3	Red

Date of issue 01-05-2017

Batch numbers and Expiry date

Level	Batch number	Exp. date stored at +2°C to +8°C
Low	LOT 2016.0471	2021-09
Medium	LOT 2013.0472	2018-08
High	LOT 2013.0473	≅ 2018-08

Reconstitution volume 1.0 mL

Assigned values

Level	Homocysteïn (µmol/L)
Low	13
Medium	35
High	52

Intended purpose

Check-up of methods for the assay of homocystein in serum/plasma.

Contents

Lyophilized human serum.

Value Assignment

The samples were measured in duplicate in more than 20 laboratories by HPLC (1). The assigned value is the mean value.

Storage and stability

The product in lyophilized form is stable for 5 years when stored at +2°C to +8°C. Expiration dates are found on the enclosed product certificate.

The stability of the reconstituted product is 48 hours when handled appropriately: pure water, replacement of stopper and storage at 2-8°C in the dark.

Instructions for use

- a. Remove cap and stopper
- b. Add 1.0 mL aqua destillata
- c. Replace stopper
- d. Let stand for 15 minutes at room temperature
- e. Mix carefully during 20 minutes at room temperature
- f. Process product as patient sample

Precautions and warnings

- 1. For in vitro diagnostic use only.
- 2. Tested and found negative for Hepatitis B Surface Antigen (HbsAg), antibody to hepatitis C (HCV) and antibody to HIV.
- 3. This product should be handled as potentially infectious material. Outdated and left-over material should be discarded as potentially infectious material, according to the procedures in your institute.

References

Spaanen LJM, Waterval WAH, Bakker JA, Luijckx GJ, Vles JSH.
 Detectie van hyperhomocysteïnemie bij vroegtijdige cerebrovasculaire ziekte. Tijdschr. NVKC 1992; 17: 194-9.

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