



Methylmalonic Acid in serum/plasma/urine

Value Data Sheet 1001 CAL M MMA

Serum Calibrators for LCMSMS Assay in serum/plasma

REF 1001 CAL M MMA

LOT K11D20/02

 2023/12

IVD For in vitro diagnostic use

diagnostix BV
De Plassen 4
9902 SE Appingedam
The Netherlands

+31 (0)596 - 20 10 62
info@diagnostix.com
order@diagnostix.com

Document version: 2.1
Replaces: 2.0
Date of release: 22-04-2020

 98/79/EC - IVD Medical Devices

Intended use:

This product is for the purpose of calibrating the Methyl Malonic Acid (MMA) assay. These lyophilized MMA calibrators are prepared from human serum. Stabilizers are added to stabilize the analytes for accurate calibration of the MMA procedure. After reconstitution these lyophilized calibrators should be treated like a patient sample.

Reconstitution:

Add exactly 1,0 ml of deionized water to the vial and let stand for 15 minutes. Mix gently for another 15 minutes. When all material is dissolved the solution is ready for use.

Storage and Stability

This product will be stable until the expiration date when stored unopened at 2 - 8 °C. After reconstitution the stability of the analytes is: 1 week at 2 - 8 °C
2 weeks at - 20 °C

The stated stabilities are only valid in case of no bacterial contamination. Avoid repeated freezing and thawing.

Caution:

The human serum used for manufacturing the calibrators was tested for the following infectious markers and found negative: HIV1/2-, HBV- and HCV-antibodies, Hepatitis B-surface antigen, HIV1- and HCV-RNA, HBV-DNA (NAT). Nevertheless, the serum calibrator should be considered as potentially infectious and treated with appropriate care.


Pack size:

Methylmalonic Acid Calibrator Set
6 x 2 x 1 ml, Calibrator 1 - 6

Notes:

The concentrations of the analytes are chosen in ranges where valid results can be obtained. The variation of the filling volume (CV) is < 1 %.

Concentrations:

1001 CAL M MMA		MMA (nmol/l)
Calibrator 1 1002	09Q19/01 2023/12	< 50 nmol/l
Calibrator 2 1003	09Q19/02 2023/12	158 nmol/l
Calibrator 3 1004	09Q19/03 2023/12	253 nmol/l
Calibrator 4 1005	09Q19/04 2023/12	343 nmol/l
Calibrator 5 1006	09Q19/05 2023/12	992 nmol/l
Calibrator 6 1007	09Q19/06 2023/12	1927 nmol/l