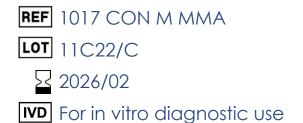
diagnotix•••

Methylmalonic Acid in serum/plasma

Value Data Sheet 1017 CON MMMA

Serum Controls for LC-MS/MS Assay in serum/plasma



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CE 98/79/EC - IVD Medical Devices

Intended use:

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

Reconstitution:

Add exactly 500 μ l 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 controls 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 controls should be considered as potentially infectious and treated with appropriate care.

Pack size:

Methylmalonic Acid Control Set 3 x 3 x 500 µl, Controls I - III

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:

1017 CON M MMA		MMA (nmol/l)	
		Mean	Range
Control I 1014	11C22/07 2026/02	167 nmol/l	125 – 209 nmol/l
Control II 1015	11C22/08 2026/02	465 nmol/l	349 – 581 nmol/l
Control III 1016	11C22/09 2026/02	1266 nmol/l	950 – 1582 nmol/l