



Metanephrines in (EDTA) plasma

Value Data Sheet 1062 CON M MET

Plasma Controls for LCMSMS Assay in (EDTA) plasma

REF 1062 CON M MET

LOT K12G20/02

 2023/07

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: 1.1
Replaces: 1.0
Date of release: 07-07-2020

 98/79/EC - IVD Medical Devices

Intended use:

This product is for the purpose of verifying the Metanephrines assay. These lyophilized Methanephrines controls are prepared from bovine serum. Stabilizers are added to stabilize the analytes for accurate verification of the Metanephrines procedure. After reconstitution these lyophilized controls should be treated as a patient sample.

Reconstitution:

Add exactly 2.0 ml of deionized water to the vial and let stand for 15 minutes. Swirl the vial carefully and mix thoroughly. Let the vial stand for another 15 minutes and swirl one last time. Use the solution as a patient sample when all material is dissolved.

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: 2 weeks at 2 - 8 °C
 1 month at - 20 °C

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

Caution:

The serum used for manufacturing the controls is free from infectious and contagious diseases. Nevertheless, the controls should be considered as potentially infectious and treated with appropriate care.

Pack size:

Metanephrines Control Set
 3 x 3 x 2 ml, Control 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:

1062 CON M MET		Metanephrine		Normetanephrine		3-MT	
		Mean	Range	Mean	Range	Mean	Range
Control I 1075	11K19/07 2023/07	0.11 nmol/l	0.08 - 0.14 nmol/l	0.15 nmol/l	0.12 - 0.18 nmol/l	0.11 nmol/l	0.08 - 0.14 nmol/l
Control II 1076	11K19/08 2023/07	0.51 nmol/l	0.40 - 0.62 nmol/l	0.58 nmol/l	0.46 - 0.70 nmol/l	0.47 nmol/l	0.38 - 0.56 nmol/l
Control III 1077	11K19/09 2023/07	3.44 nmol/l	2.75 - 4.13 nmol/l	3.85 nmol/l	3.08 - 4.62 nmol/l	2.98 nmol/l	2.38 - 3.58 nmol/l