Vitamin A & E in serum/plasma

Value Data Sheet 2002 CON HM VAE

Plasma Controls for LCMSMS Assay in serum/plasma

REF 2002 CON HM VAE

LOT K24M20/02

2023/07

IVD For in vitro diagnostic use

diagnotix BV
De Plassen 4
9902 SE Appingedam
The Netherlands

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

Document version: 1.0
Replaces:
Date of release: 24-09-2020

CE 98/79/EC - IVD Medical Devices

Intended use:

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

Reconstitution:

Add exactly 500 µl 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: 48 hours at 2 - 8 °C
1 week 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 control should be considered as potentially infectious and treated with appropriate care.

Pack size:

Vitamin A & E Control Set
3 x 3 x 500 µl, 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:

2002 CON HM VAE	LOT	Vitamin A		Vitamin E	
		Mean (µmol/)	Range (µmol/)	Mean (µmol/)	Range (µmol/)
Control I 2012	22K20/07 2023/07	0.20	0.13 - 0.27	7.0	5.5 – 8.5
Control II 2013	22K20/08 2023/07	0.96	0.76 - 1.16	22.0	17.0 – 27.0
Control III 2014	22K20/09 2023/07	2.25	1.75 - 2.75	53.0	42.0 – 64.0