diagnotix•••

Vitamin A & E in serum/plasma

Value Data Sheet 2002 CON HM VAE

Serum Controls for LCMSMS Assay in serum/plasma

REF 2002 CON HM VAE

LOT 25D22/C

2023/09

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: 02-05-2022



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 has been tested and found non-reactive for HbsAG and antibody to HIV-1 and HIV-2 and HIV p24 Ag by combo assay, Anti-HTLV 1&2 and to HCV and HIV genome. It has also been tested and found negative for syphilis. 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 \(\text{\text{\$\sigma}} \)	Vitamin A		Vitamin E	
		Mean (µmol/)	Range (µmol/)	Mean (µmol/)	Range (µmol/)
Control 2012	25D22/07 2023/09	0.67	0.50 - 0.84	6.72	5.04 – 8.40
Control II 2013	25D22/08 2023/09	1.48	1.11 – 1.85	21,20	15.90 – 26.50
Control III 2014	25D22/09 2023/09	3.06	2.30 – 3.82	34,33	25.75 – 42.91