Vitamin A & E in serum/plasma

Value Data Sheet 2001 CAL HM VAE

Serum Calibrators for LCMSMS Assay in serum/plasma

REF 2001 CAL HM VAE

LOT 14M21/S

2023/03

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: 1.1
Replaces: 1.0
Date of release: 10-02-2022

CE 98/79/EC - IVD Medical Devices

Intended use:

This product is for the purpose of calibrating the Vitamin A & E assay. These lyophilized Vitamin A & E calibrators are prepared from human serum. Stabilizers are added to stabilize the analytes for accurate calibration of the Vitamin A & E procedure.
After reconstitution these lyophilized calibrators 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 more 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 calibrators 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 calibrators should be considered as potentially infectious and treated with appropriate care.

Pack size:

Vitamin A & E Calibrator Set
6 x 2 x 500 µl, Calibrator 1 - 6

Notes:

1. 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:

2001 CAL HM VAE	LOT	Vitamin A	Vitamin E
Calibrator 1 2003	14M21/01 2023/03	0,00 µmol/l	0,00 µmol/l
Calibrator 2 2004	14M21/02 2023/03	0,52 µmol/l	6,62 µmol/l
Calibrator 3 2005	14M21/03 2023/03	1,08 µmol/l	15,03 µmol/l
Calibrator 4 2006	14M21/04 2023/03	2,22 µmol/l	29,64 µmol/l
Calibrator 5 2007	14M21/05 2023/03	3,18 µmol/l	43,60 µmol/l
Calibrator 6 2008	14M21/11 2023/03	4,52 µmol/l	50,92 µmol/l