diagnotix•••

Vitamin A & E in serum/plasma

Value Data Sheet 2001 CAL HM VAE

Plasma Calibrators for LCMSMS Assay in serum/plasma



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 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 μ l 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 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 calibrator 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. When calibrating vitamin E with an LCMS analyser with a high sensitivity only calibrator 1 through 5 should be used.
- 2. 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		Vitamin A	Vitamin E
Calibrator 1 2003	22K20/01 2023/07	0.02 µmol/l	0.3 µmol/l
Calibrator 2 2004	22K20/02 2023/07	0.15 µmol/l	4.6 µmol/l
Calibrator 3 2005	22K20/03 2023/07	0.44 µmol/l	9.0 µmol/l
Calibrator 4 2006	22K20/04 2023/07	0.91 µmol/l	21.0 µmol/l
Calibrator 5 2007	22K20/05 2023/07	2.04 µmol/l	47.0 µmol/l
Calibrator 6 20081	22K20/06 2023/07	4.53 µmol/l	90.0 µmol/l1