



Vitamin A&E in Serum/Plasma

Metrological Traceability of calibrators and controls

REF 2001 CAL

LOT 21K24/S

REF 2002 CON

LOT 21K24/C

 2027/07

IVD For in vitro diagnostic use

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Statement on Metrological Traceability

In accordance with Annex I, section 9.3 and Annex II section 6.1.2.4 (EU) 2017/746 manufacturers of in-vitro diagnostic medical devices are obliged to provide supervisory authorities with the metrological traceability of values assigned to calibrators and/or control materials where the performance of devices depends on the use of such materials.

During the design & development of calibrators and controls, an extensive validation is performed according to the specifications set out in the IVDR directive.

This document identifies the reference material used.

Highest order reference material (ERM – CRM)

Not available according to the best of our knowledge.

Proficiency tests material used as reference material:

SKML (or Dutch Foundation for Quality Assessment in Medical Laboratories)

Vitamin A/E and beta-carotene:

2022 1A	2022 2A	2022 2F	2023 1E	2023 2D
2022 1B	2022 2B	2023 1A	2023 1F	2023 2E
2022 1C	2022 2C	2023 1B	2023 2A	2023 2F
2022 1D	2022 2D	2023 1C	2023 2B	2024 1A
2022 1E	2022 2E	2023 1D	2023 2C	2024 1B

QC material used as reference material:

SKML (or Dutch Foundation for Quality Assessment in Medical Laboratories)

Vitamin A/E beta-carotene:

Low	VTA-01-1	LOT	2020.0481
Mid	VTA-01.2	LOT	2020.0482
High	VTA-01.3	LOT	2020.0483

Diagnostix previous batch

2001 CAL M VAE I UTAI 6	LOT	02D24/S
2002 CON M VAE I UTAI III	LOT	02D24/C
2001 CAL M VAE I UTAI 6	LOT	08H24/S

Number of independent LC-MS systems used: 2

Individual products included:

Vitamin A&E Calibrator 1, 2003 HM VAE	21K24/01
Vitamin A&E Calibrator 2, 2004 HM VAE	21K24/02
Vitamin A&E Calibrator 3, 2005 HM VAE	21K24/03
Vitamin A&E Calibrator 4, 2006 HM VAE	21K24/04
Vitamin A&E Calibrator 5, 2007 HM VAE	21K24/05
Vitamin A&E Calibrator 6, 2008 HM VAE	21K24/06

Vitamin A&E Control I, 2012 HM VAE	21K24/07
Vitamin A&E Control II, 2013 HM VAE	21K24/08
Vitamin A&E Control III, 2014 HM VAE	21K24/09