diagnotix•••

Vitamin B1 & B6 in whole blood

Value Data Sheet 1022 CAL M VB1B6

Blood Calibrators for LCMSMS Assay in whole blood

REF 1022 CAL M VB1B6

LOT K20K20/02

2024/06

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: 20-07-2020



Intended use:

This product is to be used as a means of calibrating the Vitamin B1 & B6 assay. These lyophilized Vitamin B1 & B6 calibrators are hemolysates prepared from packed human erythrocytes. Stabilizers are added to stabilize the analytes for accurate calibration of the Vitamin B1 & B6 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. Mix gently for another 15 minutes. When all material is dissolved the solution is ready for use.

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

2 weeks at - 20 °C

The stated stabilities are only valid in case of no bacterial contamination. Avoid repeated freezing and thawing.

Caution:

The human whole blood 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 whole blood calibrators should be considered as potentially infectious and treated with appropriate care.

Pack size:

Vitamin B1 & B6 Calibrator Set 6 x 2 x 500µl, Calibrator 1 - 6

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:

1022 CAL M VB1B6	LOT	Vitamin B1 (nmol/l) Thiaminepyrophosphate TPP	Vitamin B6 (nmol/l) Pyridoxal -5- phosphate (PLP)
Calibrator 1 1023	04H20/01 2024/06	41 nmol/l	25 nmol/l
Calibrator 2 1024	04H20/02 2024/06	64 nmol/l	40 nmol/l
Calibrator 3 1025	04H20/03 2024/06	95 nmol/l	61 nmol/l
Calibrator 4 1026	04H20/04 2024/06	182 nmol/l	116 nmol/l
Calibrator 5 1027	04H20/05 2024/06	450 nmol/l	247 nmol/l
Calibrator 6 1028	04H20/06 2024/06	700 nmol/l	413 nmol/l