



Vitamin B1 & B6 in whole blood

Value Data Sheet 1021 CON M VB1B6

Blood Controls for LCMSMS Assay in whole blood

REF 1021 CON M VB1B6

LOT 21M20/C

 2024/09

IVD For in vitro diagnostic use

diagnostix BV
De Plassen 4
9902 SE Appingedam
The Netherlands

+31 (0)596 - 20 10 62
info@diagnostix.com
order@diagnostix.com

Document version: 1.0
Replaces:
Date of release: 02-11-2020

 98/79/EC - IVD Medical Devices

Intended use:

This product is to be used as a means of verifying the Vitamin B1 & B6 assay. These lyophilized Vitamin B1 & B6 controls are hemolysates prepared from packed human erythrocytes. Stabilizers are added to stabilize the analytes for accurate verification of the Vitamin B1 & B6 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. 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 controls 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 controls should be considered as potentially infectious and treated with appropriate care.


Pack size:

Vitamin B1 & B6 Control Set
3 x 3 x 500µl, 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:

1021 CON M VB1B6		Vitamin B1 (nmol/l) Thiaminepyrophosphate TPP		Vitamin B6 (nmol/l) Pyridoxal -5- phosphate (PLP)	
		Mean	Range	Mean	Range
Control I 1033	21M20/09 2024/09	43 nmol/l	32 - 54 nmol/l	27 nmol/l	20 - 34 nmol/l
Control II 1034	21M20/10 2024/09	102 nmol/l	76 - 128 nmol/l	66 nmol/l	49 - 83 nmol/l
Control III 1035	21M20/11 2024/09	305 nmol/l	229-381 nmol/l	196 nmol/l	147-245 nmol/l