IDS-iSYS InaKtif MGP (dp-ucMGP)

Features and benefits

- **Chemiluminescence immunoassay (ChLIA) for the quantitative determination of the inactive dephosphorylated-uncarboxylated (dp-uc) isoform of matrix Gla protein (MGP) in plasma for the assessment of vitamin K status in the arterial walls**
- **Wide assay range suitable for use in patients with chronic kidney disease who are undergoing haemodialysis and vitamin K antagonist treatment**
- **The first fully automated dp-ucMGP test with CE-IVD marking for fast and highly reproducible results**
- **Use of conformation-specific monoclonal antibodies to ensure accurate results for levels of circulating dp-ucMGP**
- **High correlation to the established lab-developed dp-ucMGP ELISA method**

Matrix Gla protein (MGP), the most potent inhibitor of tissue calcification presently known, is an 11 kDa protein comprising 84 amino acids. It is mainly expressed and secreted by chondrocytes and vascular smooth muscle cells.[1] To be fully functional, MGP requires posttranslational modification by the vitamin K-dependent γ-glutamyl carboxylase, which converts glutamate residues into γ-carboxyglutamate (Gla). These Gla residues serve as calcium-binding groups and are essential for the calcification inhibitory activity of MGP. Besides carboxylation, MGP also undergoes posttranslational serine phosphorylation during maturation, which enhances its cellular secretion.[2, 3] At least four different MGP species are formed with varying states of phosphorylation and/or carboxylation: phosphorylated carboxylated MGP (p-cGMP), phosphorylated uncarboxylated MGP (p-ucMGP), dephospho-carboxylated MGP (dp-cMGP), and dephospho-uncarboxylated MGP (dp-ucMGP). Circulating forms of MGP have no known biological function, but reflect the extent of vascular calcification and availability of Vitamin K in the vessel wall.[2, 4, 5]

A large body of evidence indicates that there is a link between disturbances due to chronic kidney disease (CKD) and vascular calcification (VC). VC is associated with increased cardiovascular morbidity as well as cardiovascular mortality for which it is recognised as a significant independent risk factor. Various studies describe a decreased availability of vitamin K (both K1 and K2) in CKD patients. Vitamin K supplementation has been shown to significantly decrease the levels of dp-ucMGP both in the general population and in haemodialysis patients. Conversely, it has been documented that vitamin K antagonists are associated with higher dp-ucMGP levels.

Vitamin K status can be assessed either by measuring vitamin K concentration in plasma or by determining the amount of inactive vitamin K-dependent proteins such as dp-ucMGP. The current concentration of circulating vitamin K is influenced by triglyceride concentrations and recent vitamin K intake and thus gives little information about vitamin K utilisation in the tissue. Measuring dp-ucMGP levels is therefore preferable for determining the vitamin K status in the arterial wall.

Specifications

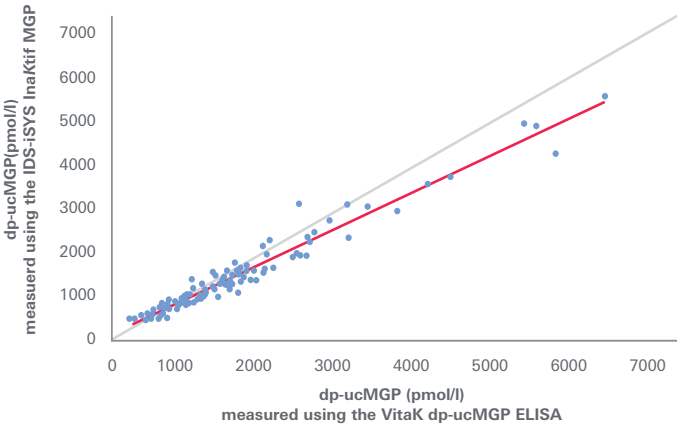
Format	Automated chemiluminescence sandwich immunoassay
Calibrators	Lyophilised, calibrator A and B (2 × 1.0 ml of each, included in the kit)
Controls	Lyophilised, control 1 – 3 (4 × 1 ml of each, not included in the kit)
Limit of quantitation	300 pmol/l
Dynamic range	300 – 12,000 pmol/l
Minimum sample volume	50 µl (plus dead volume)
Sample type	Human plasma, collected in potassium EDTA tube
Reagent stability	After opening, the IDS-iSYS Ina*K*tif MGP reagent cartridge may be stored on the IDS system ("on-board") for up to 14 days or at 2 – 8 °C for up to 28 days
Calibration stability	The calibration of the IDS-iSYS InaKtif MGP assay is stable for up to 14 days
Time to first result	64 minutes
Precision	

Sample ID	Mean (pmol/ml)	Within run (% CV)	Total (% CV)
1	591	4.5	7.9
2	870	6.2	8.2
3	2,558	0.8	3.5
4	4,067	1.1	3.4
5	6,488	0.8	3.3

Method comparison

The IDS-iSYS Ina*K*tif MGP assay was compared against the VitaK lab-developed dp-ucMGP ELISA method in accordance with CLSI EP-9A2 "Method Comparison and Bias Estimation Using Patient Samples". A total of 122 samples, selected to represent a wide range of dp-ucMGP concentrations (311 – 5,376 pmol/l), were tested with each method. Linear regression analysis was performed on the comparative data:

Slope 95% CI		Intercept (pmol/l) 95% CI		Correlation coef. (r)
0.83	0.80 to 0.86	93.1	40.4 to 145.8	0.98



Ordering information

Product name	Description	Code
IDS-iSYS Ina*K*tif MGP (dp-ucMGP)	Kit for 100 determinations	IS-4700
IDS-iSYS Ina*K*tif MGP (dp-ucMGP) Control Set	Control set: 3 different dp-ucMGP concentrations	IS-4730

References

1. Price PA et al. Matrix Gla protein, a new gammacarboxyglutamic acid-containing protein which is associated with the organic matrix of bone. Biochem Biophys Res Commun 117:765 – 771 (1983).
2. Cranenburg EC et al. Characterisation and potential diagnostic value of circulating matrix Gla protein (MGP) species. Thromb Haemost 104:811 – 822 (2010).
3. Schurgers LJ et al. Post-translational modifications regulate matrix Gla protein function: importance for inhibition of vascular smooth muscle cell calcification. J Thromb Haemost 5:2503 – 2511 (2007).
4. Murshed M et al. Extracellular matrix mineralization is regulated locally; different roles of two gla-containing proteins. J Cell Biol 165:625 – 630 (2004).
5. Schurgers LJ et al. Matrix Gla-protein: the calcification inhibitor in need of vitamin K. Thromb Haemost 100: 593 – 603 (2008).

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