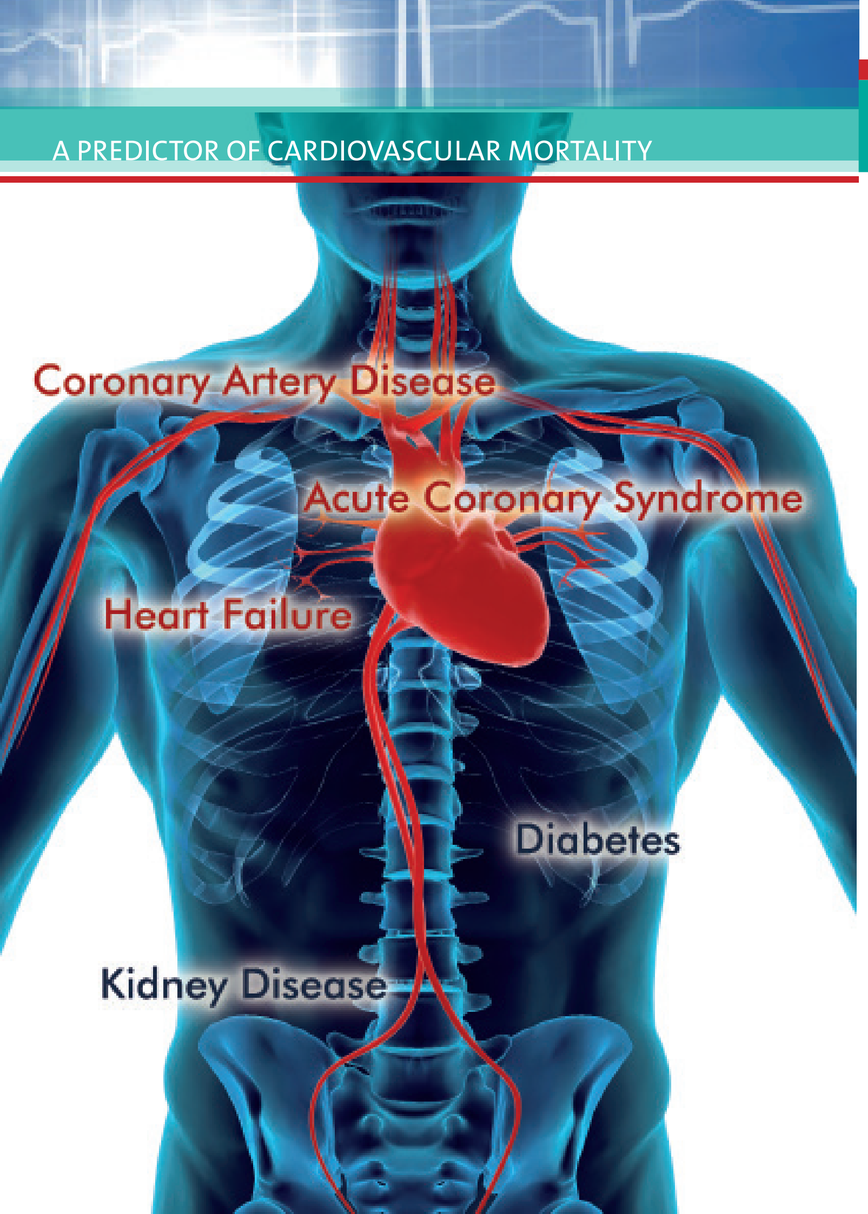
A PREDICTOR OF CARDIOVASCULAR MORTALITY



Setting the **standard** for **clinical** research.

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IMMUNOASSAYS

Divischgasse 4 · 1210 Vienna · Austria
T +43 1 291 07 45 · F +43 1 291 07 6389
info@bmgrp.com · www.bmgrp.com

OSTEOPROTEGERIN ELISA

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OSTEOPROTEGERIN ELISA BI-20403

ELISA for the quantitative determination of Osteoprotegerin in human serum and plasma samples.

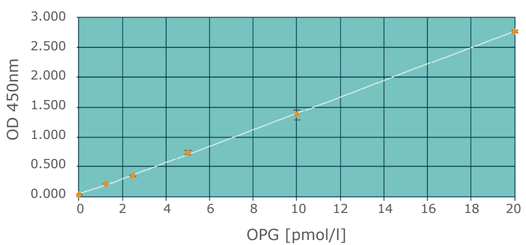
Features and benefits

- Optimized for clinical samples
- Fully validated for use with human serum and plasma
- Low sample volume: 20µl/well
- 6 standards + 1 control in human serum matrix
- Day test: 4 h / 1 h / 30 min
- Convenient ready to use protocol
- CE marked in EU

Assay characteristics & performance

Method	Sandwich ELISA, HRP/TMB
Sample type	Serum, plasma (Citrate, EDTA, Heparin)
Standard range	0 – 20 pmol/l (0 / 1.25 / 2.5 / 5 / 10 / 20 pmol/l)
Conversion factor	1 pg/ml = 0.05 pmol/l (MW: 20 kDa)
Sample volume	20 µl
Detection limit / LLOQ	0.07 pmol/l (0 pmol/l + 3 SD) / < 0.08pmol/l
Incubation time, temperature	4 h / 1 h / 30 min, room temperature
Precision	Intra-assay (n=5) ≤ 3%. Inter-assay (n=12) ≤ 5%.

Typical standard curve



Effect of sample matrix

Measurement of OPG in serum, EDTA-, heparin-, and citrate-plasma (n=7) showed comparable results: all 4 matrices can be tested by the assay.

Values from apparently healthy individuals

Sample type	Serum (n=60)	EDTA-plasma (n=6)	Heparin-plasma (n=7)	Citrate-plasma (n=5)
Median (pmol/l)	2.7	2.2	2.3	2.3

Spike recovery (n=4 resp. 3 OPG concentrations)

The mean recovery of recombinant OPG in serum and EDTA-plasma is between 93-108%.
The mean recovery of recombinant OPG in heparin- and citrate-plasma is between 82-109%.

Linearity (dilutions: 1+1, 1+3, 1+7)

The dilution linearity of endogenous OPG in serum samples (n=3) is between 79-102%.
The dilution linearity of recombinant OPG in serum samples (n=8) is between 80-116%.

STUDIES EVALUATING THE ASSOCIATION BETWEEN OSTEOPROTEGERIN (OPG) AND CARDIOVASCULAR DISEASE

	First Author and Reference	Target Population / Study Design	Main Findings / Conclusion
Diabetes	Anand DV et al., J Amer Coll Cardiol, 2006; 47: 1850-1857	Asymptomatic patients with type 2 diabetes, Prospective, n=510*	"Only OPG predicted both subclinical disease and near-term cardiovascular events."
	Reinhard H et al., Diabetes Care, 2010; 33: 2561-2566	Type 2 diabetic patients, Prospective observational follow-up study, n=283	"... OPG is a strong predictor of all-cause mortality in type 2 diabetic patients. The effect of OPG on all-cause mortality was independent of conventional cardiovascular risk factors, UAER, and NT-proBNP levels."
Kidney Disease / Kidney Transplantation	Scialla J et al., Clin J Am Soc Nephrol, 2011; 6: 2612-2619	Patients with CKD, Prospective, n=351*	"These data support a strong relationship between serum OPG and arterial stiffness independent of many potential confounders including traditional cardiovascular risk factors..."
	Kurnatowska I et al., Nephron Clin Pract, 2011; 117(4): c297-304	Hemodialysis patients, Prospective, n=47*	"The plasma level of OPG could serve as a surrogate marker of progression of atherosclerosis and calcification in patients with end-stage renal disease."
	Svensson M et al., Nephrol Dial Transplant, 2012; 27: 2571-2575	Renal transplant recipients, Prospective, n=1,889*	"In a large cohort of kidney transplant patients with long-term follow-up, OPG was independently associated with renal events, CV events and mortality."
CAD / ACS / HF	Schoppet M et al., J Clin Endo & Metab, 2003; 83 (3): 1024-1028	Patients undergoing diagnostic coronary angiography for suspected CAD, Prospective, n=552*	"OPG serum levels are associated with the severity of CAD and are increased in elderly men and patients with diabetes mellitus."
	Røysland R et al., Heart, 2012; 98: 786-791	Patients with NSTE-ACS, Prospective, n=4,463	"OPG is independently associated with 30 day and 1 year risk of CV mortality and HF development after NSTE-ACS."
	Omland T et al., Circulating J Am Coll Cardiol, 2008; 51: 627-633	Patients with ACS, Prospective, n=897	"Serum OPG is strongly predictive of long-term mortality and HF development in patients with ACS. Higher baseline OPG levels were associated with mortality and HF hospitalization."
General Population	Lieb W et al., Arterioscler Thromb Vasc Biol, 2010; 30: 1849-1854	Framingham study participants, n=3,250*	"Data reinforce OPG as marker for CVD risk factor burden and predictor of CVD and mortality in the community."
	Kiechl S et al., Circulation, 2004; 109: 2175-2180	General population, Prospective, n=915	"OPG is an independent risk factor for the progression of atherosclerosis and onset of CVD."
	Abedin et al., Am J Cardiol, 2007; 99(4): 513-518	General population (unselected), Cross-sectional, n=3,386	"OPG is independently associated with CAC and aortic plaque in an unselected population, suggesting it may be a novel biomarker for atherosclerosis in humans."
	Omland T et al., Hypertension, 2007; 49: 1392-1398	General population, Cross-sectional, n=2,715	"OPG is independently associated with indices of LV function in both sexes and with indices of LV hypertrophy in male but not female subjects."

Abbrevations:
CV: Cardiovascular
ACS: Acute Coronary Syndrome
CVD: Cardiovascular Disease
CAC: Coronary Artery Calcification
HF: Heart Failure
CAD: Coronary Artery Disease
LV: Left Ventricular
CKD: Chronic Kidney Disease
NSTE: non ST-Elevation

* Osteoprotegerin measured with Biomedica OPG ELISA

OPG-201911