QUANTITATIVE DETERMINATION OF HUMAN GDF-15/MIC-1

IVD CE

Human GDF-15/MIC-1 ELISA

- High sensitivity (22 pg/ml)
- Very good analytical characteristics
- Validated for human serum, plasma (EDTA, citrate, heparin)

CARDIOLOGY
PREGNANCY
ONCOLOGY
HEMATOLOGY

BioVendor
Research
and Diagnostic Products

HUMAN GDF-15/MIC-1 ELISA

Introduction

Growth differentiation factor 15 (GDF-15) is a member of the transforming growth factor b (TGF- b) cytokine superfamily and was originally cloned as macrophage-inhibitory cytokine 1 (MIC-1).

Circulating GDF-15 concentrations are increased across a wide spectrum of cardiovascular diseases, including acute and chronic coronary artery disease, congestive heart failure, and ischemic stroke. GDF-15 is also upregulated by other cardiovascular events triggering oxidative stress, including pressure overload, and atherosclerosis.

Moreover, increased circulating GDF-15 concentrations have been linked to an enhanced risk of future adverse cardiovascular events in elderly women and it was describe as a new biomarker of the risk of death in patients with non-ST-elevation acute coronary syndrome.

Serum GDF-15 concentrations increase in maternal serum with advancing gestation in normal pregnancy. Low GDF-15 concentrations reportedly are associated with an increased risk of preterm labor or miscarriage.

Increased GDF-15 expression has been documented in a variety of epithelial cell lines, including breast, pancreas, colorectal, and prostate cancers. Microarray studies have revealed increased expression of GDF-15 in patients with breast cancer, and serum GDF-15 levels are the best single predictor of the presence of pancreatic carcinoma. In the case of prostate cancer, serum GDF-15 levels increase with progression of disease to metastasis. In colon cancer, increasing GDF-15 expression is associated with the progression of colonic adenomas to invasive cancer and subsequent metastasis, with serum levels at presentation being an independent predictor of subsequent disease-free status and overall survival.

GDF-15 levels in blood plasma have been found to be dramatically elevated in beta-thalassemia patients compared to healthy donors and patients with hereditary hemochromatosis, another from of iron overload disease. In addition, the role of GDF-15 in other disorders characterized by ineffective erythropoiesis, as well as the role of GDF-15 in regulation of iron metabolism is under investigation. There are some hypotheses for treatment of thalassemia by administration of GDF-15 antagonist, and to reduce hepcidin levels by administration of GDF-15, a GDF-15 substitute, or GDF-15 agonist.

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BioVendor Human GDF-15/MIC-1 ELISA (RD191135200R)

Intended use

The RD191135200R Human GDF-15 ELISA is a sandwich enzyme immunoassay for the quantitative measurement of human GDF-15/MIC-1 (growth differentiation factor 15 / macrophage-inhibitory cytokine 1).

- The total assay time is less than 3.5 hours
- The kit measures human GDF-15 in serum and plasma (EDTA, citrate, heparin)
- Assay format is 96 wells
- Quality Controls are human serum based
- Standard is recombinant protein based
- Components of the kit are provided ready to use, concentrated or lyophilized

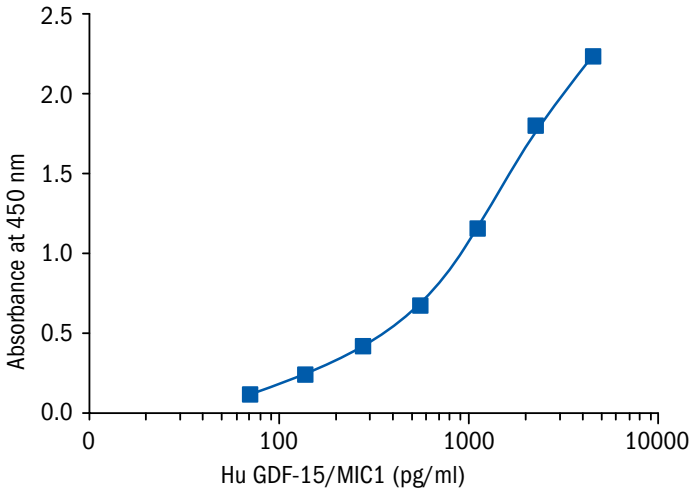
Clinical application

- Cardiology
- Pregnancy
- Oncology
- Hematology

HUMAN GDF-15/MIC-1 ELISA CAT. NO.: RD191135200R	
Assay format	Sandwich ELISA, Biotin-labelled antibody, 96 wells/kit
Samples	Plasma, Serum
Standards	70 to 4480 pg/ml
Limit of detection	22 pg/ml

Test principle

In the BioVendor Human GDF-15/MIC-1 ELISA, the standards, quality controls and samples are incubated in microtitrate wells pre-coated with polyclonal anti-human GDF-15 antibody. After 60 min incubation and a washing, biotin labelled polyclonal anti-human GDF-15 antibody is added and incubated with captured GDF-15 for 60 min. After another washing, the streptavidin-HRP conjugate is added. After 30 min incubation and the last washing step, the remaining conjugate is allowed to react with the substrate solution (TMB). The reaction is stopped by addition of acidic solution and absorbance of the resulting yellow product is measured. The absorbance is proportional to the concentration of GDF-15. A standard curve is constructed by plotting absorbance values against concentrations of standards, and concentrations of unknown samples are determined using this standard curve.



Precision

Intra-assay (Within-Run) (n=8)

Sample	Mean (pg/ml)	SD (pg/ml)	CV (%)
1	7279.7	456.9	6.3
2	870.9	62.9	7.2

Inter-assay (Run-to-Run) (n=8)

Sample	Mean (pg/ml)	SD (pg/ml)	CV (%)
1	1771.0	150.6	8.5
2	397.8	37.6	9.5

Spiking recovery

Serum samples were spiked with different amounts of human GDF-15 and assayed.

Sample	Observed (pg/ml)	Expected (pg/ml)	Recovery O/E (%)
1	1650.2	-	-
	4520.9	4450.2	101.6
	3070.6	3050.2	100.7
	2136.9	2350.2	90.9
2	1051.95	-	-
	3666.6	3851.9	95.2
	2316.7	2451.9	94.5
	1661.6	1751.9	94.8

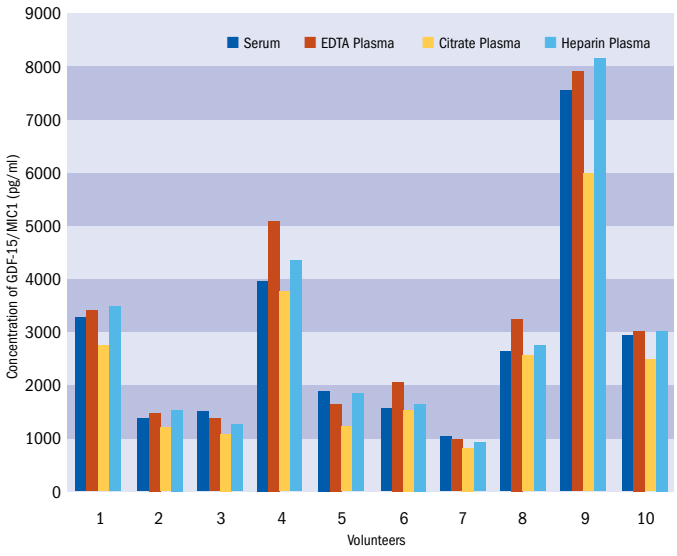
Linearity

Serum samples were serially diluted with Dilution Buffer and assayed.

Sample	Dilution	Observed (pg/ml)	Expected (pg/ml)	Recovery O/E (%)
1	-	8719.2	-	-
	2x	4053.5	4359.6	93.0
	4x	1949.1	2179.8	89.4
	8x	873.1	1089.9	80.1
2	-	7694.1	-	-
	2x	3888.9	3847.0	101.1
	4x	1897.7	1923.5	98.7
	8x	943.0	961.8	98.0

Effect of sample matrix

Heparin, citrate and EDTA plasmas were compared to respective serum samples from the same 10 individuals. Results are shown below:



Summary of protocol

- Reconstitute QCs and Master Standard and prepare set of Standards
- Dilute samples 5x
- Add 100 µl Standards, QCs and samples
- Incubate at RT for 1 hour/300 rpm
- Prepare Wash Solution
- Wash plate 3 times
- Prepare Biotin Labelled Antibody Solution
- Add 100 µl Biotin Labelled Antibody Solution
- Incubate at RT for 1 hour/300 rpm
- Wash plate 3 times
- Add Streptavidin-HRP Conjugate
- Incubate at RT for 30 min
- Wash plate 3 times
- Add 100 µl Substrate Solution
- Incubate at RT for 30 min
- Add 100 µl Stop Solution
- Read absorbance and calculate results

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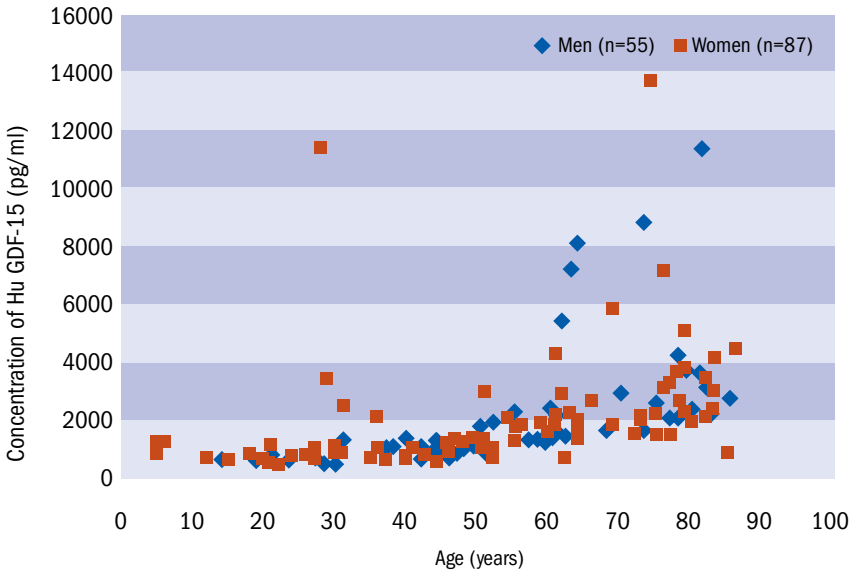
Preliminary Population Data

The following results were obtained when serum samples from 142 unselected donors (87 women + 55 men) 6-86 years old were assayed with the BioVendor Human GDF-15/MIC-1 ELISA in our laboratory:

Age and Sex Dependent Distribution of GDF-15/MIC1

Sex	Age (years)	n	Mean GDF-15 (pg/ml)	Median GDF-15 (pg/ml)	SD GDF-15 (pg/ml)	Min. GDF-15 (pg/ml)	Max. GDF-15 (pg/ml)
	14 - 19	2	573.5	573.5	20.3	553.2	593.7
Men	21 - 49	20	840.8	814.9	272.9	386.6	1344.3
	50 - 85	33	2972.5	2162.0	2437.0	758.0	11340.0
	6 - 18	6	852.1	743.3	251.0	581.3	1204.7
Women	20 - 49	32	980.0	798.9	586.2	402.8	3307.8
	50 - 86	49	2584.4	1986.5	2067.5	658.5	13652.8



Related products

· RBG10164005 GDF-15/MIC-1 Human Cell Culture

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