Supporting IVD assay development for cardiac markers

Background

Cardiovascular disease (CVD) accounts for approximately one third of all deaths globally and is a major contributing factor toward rising healthcare cost. In vitro diagnostic (IVD) assays for detecting cardiac markers are essential tools to help treat or prevent CVD.

By enabling clinicians to monitor biomolecules that are released into the blood when the heart is damaged or stressed, IVD assays support diagnosis of conditions including coronary heart disease, cerebrovascular disease, and deep vein thrombosis to guide therapeutic intervention.

IVD assay performance and utility hinges on high quality reagents that are available in unlimited supply. Partnering with an experienced reagent manufacturer such as Medix Biochemica, with a proven track record in batch-to-batch consistency, delivery accuracy, scalability and formulation flexibility is essential to enable streamlined IVD development.

Some commonly used cardiac markers

ApoA1– a major component of the high-density lipoprotein (HDL) that has been suggested to be a better indicator of coronary artery disease than HDL

ApoB – the primary apolipoprotein of low-density lipoprotein (LDL), used as a marker for atherosclerosis

Copeptin – a cleavage product of pre-provasopressin (preproAVP), that has been proposed as a marker of myocardial infarction and heart failure

CK-MB – a dimeric enzyme used for diagnosis of myocardial infarction

CRP – an inflammation marker found in the blood; C-reactive protein can be used as an indicator of myocardial infarction

D-dimer – a degradation product of crosslinked fibrin, used to diagnose pulmonary embolism and deep vein thrombosis

FABP3 – a carrier protein for fatty acids and other lipophilic substances that is used as a diagnostic marker in the early phase of acute myocardial infarction

Galectin-3 – a lectin used in assessing the prognosis of patients diagnosed with chronic heart failure

GDF-15 – a stress-responsive cytokine used as a marker of heart failure and atherosclerosis

Lp-PLA2 – a secreted enzyme produced by inflammatory cells in blood vessels that can be used as a risk marker for CVD

Myeloperoxidase – an enzymatic mediator of inflammatory cascades, displaying elevated serum levels in CVD

Myoglobin – an intracellular protein that transports oxygen in cardiac and skeletal muscle cells, and one of the earliest markers of cardiac injury

proBNP / NT-proBNP – a prohormone and its N-terminal cleavage product that show increased plasma concentrations in patients with heart failure

Renin – a proteolytic enzyme secreted by the kidneys, used to diagnose hypertension

ST2 – a member of interleukin-1 receptor family, expressed as two isoforms; elevated blood levels of the soluble isoform indicate increased risk for heart failure progression

Troponin I / Troponin T – two components of a complex of regulatory proteins (comprising troponin I, T, and C) that are integral to muscle contraction in skeletal and cardiac muscles; serum cardiac troponin tests are often used to help diagnose myocardial infarction

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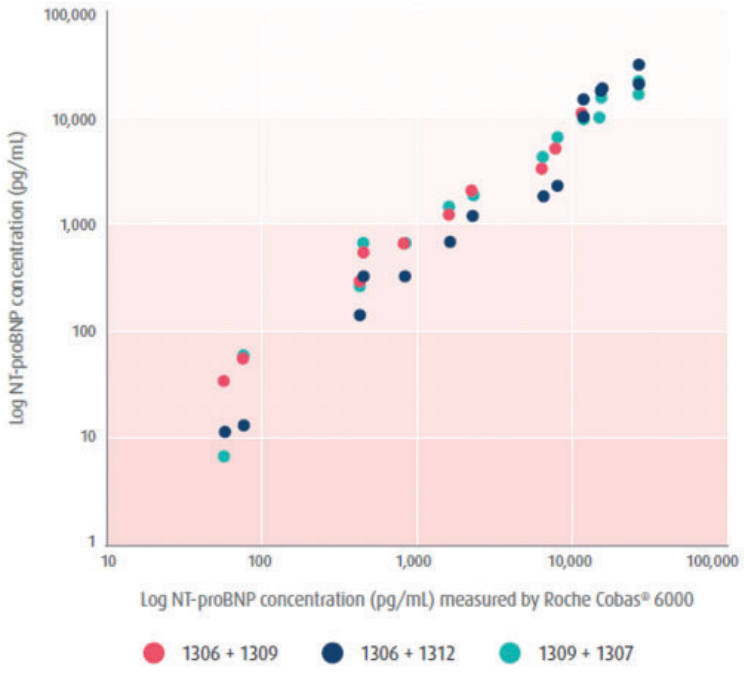
After marker selection, identifying suitable antibodies – especially matched antibody pairs - can be one of the most time-consuming steps of IVD assay development. For reliable results, Medix Biochemica's CVD marker antibodies are highly validated for a range of applications and often available as matched pair antibodies.

Analyte	IT	CLIA	LF	FIA
CK-MB				•
CRP	•		•	•
D-dimer	•			•
FABP3	•		•	•
Galectin-3		•		•
GDF-15		•		•
Lp-PLA2				•
Myeloperoxidase				•
Myoglobin	•		•	•
NT-proBNP		•	•	•
ST2		•		•
Troponin I (cTnI)				•



- Correlation of MedixMAB antibodies tested with Roche NT-proBNP assay.
- MedixMAB NT-proBNP antibodies demonstrate remarkable assay sensitivity that correlates very well with the reference IVD assay.
- Antibody pairs include both capture and detection antibodies.

Medix Biochemica Group is a global, market-leading supplier to the IVD industry. We develop, manufacture, and market critical raw materials including antibodies, antigens, and biologicals, many of which are used as components of IVD tests for cardiac marker detection.