RANDOX REAGENTS

DEVELOPMENT OF A NEW LATEX-ENHANCED IMMUNOTURBIDIMETRIC ASSAY FOR THE DETERMINATION OF TYPE IIA SECRETORY PHOSPHOLIPASE A2 (sPLA2), A BIOMARKER OF INCREASED CARDIOVASCULAR RISK

G. Shanbhag, P.Lowry, M.E. Benchikh, A. Chacko, R.I. McConnell, S.P. Fitzgerald.
Randox Laboratories Limited, 55 Diamond Road, Crumlin, Co Antrim BT29 4QY, United Kingdom

INTRODUCTION

Secretory phospholipase A2 (sPLA2) enzymes are biomarkers of increased cardiovascular risk and are targets of emerging therapeutic agents.[1,2] They are associated with incident coronary artherosclerosis in healthy men and women and with recurrent adverse cardiovascular events in patients with acute coronary syndromes.[3] sPLA2-IIA is a member of the phospholipase A2 family and is a potent biomarker for cardiovascular risk assessment. It is widely expressed in hepatocytes, macrophages, platelets and vascular smooth muscle cells and is up regulated in response to pro-inflammatory compounds such as interleukin-1β, interleukin-6, tumor necrosis factor-α, interferon-γ and oxidized low-density lipoprotein (LDL).[1]

The objective of this study was to develop a new quantitative, latex-enhanced immunoturbidimetric immunoassay to determine levels of sPLA2-IIA in human serum / plasma which have prognostic value in patients with Coronary Heart Disease (CHD) and can be employed to assess risk of future cardiovascular events. The assay is applicable to a variety of automated, clinical analyser systems, which ensures the reliability and accuracy of the measurements and facilitates the testing procedure.

METHODOLOGY

The assay is a latex-enhanced immunoturbidimetric assay based on the principle of measuring changes in scattered light. The latex particles are coated with anti-sPLA2-IIA antibodies, which in the presence of sPLA2-IIA rapidly agglutinate. When a sample containing sPLA2-IIA is introduced, the agglutination reaction is initiated and the change in scattered light is measured as a change in absorbance that is directly proportional to the concentration of sPLA2-IIA in the sample. The assay is applicable to a variety of automated systems. A correlation study was conducted using a commercially available enzyme immunoassay.

RESULTS

Sensitivity

sPLA2-IIA immunoturbidimetric assay	
Limit of detection	Assay range
<15 ng/ml	0-500 ng/ml

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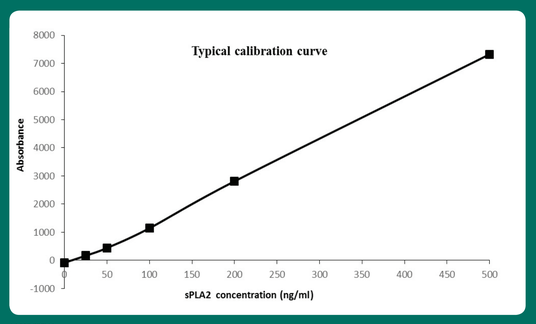

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Within-run precision

sPLA2-IIA immunoturbidimetric assay		
Sample	Mean concentration (ng/ml)	%CV
Level 1	31	0.0
Level 2	53	1.3
Level 3	97	2.2
Level 4	192	0.0
Level 5	399	3.2

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Total precision

sPLA2-IIA immunoturbidimetric assay		
Sample	Mean concentration (ng/ml)	%CV
Level 1	20	5.7
Level 2	46	2.9
Level 3	89	2.0
Level 4	186	7.0
Level 5	443	3.5

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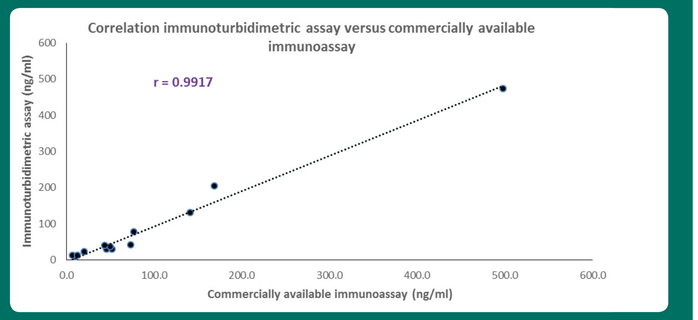
Correlation



y=0.9743x -3.9416
r=0.9917
n=13

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CONCLUSION

The data generated indicates that this latex-enhanced immunoturbidimetric assay is applicable to the detection of sPLA2-IIA in human plasma and serum. The assay is of value as a new analytical tool for assessment of cardiovascular risk in clinical settings. Its applicability to a variety of automated clinical analysers ensures the reliability and accuracy of the measurements and facilitates the testing procedure.

REFERENCES

1. Ryu S. K., Mallat Z., Benessiano J., *et al*. Phospholipase A2 enzymes, high-dose atorvastatin, and prediction of ischemic events after acute coronary syndromes. *Circulation* 2012, 125:757-766.
2. Mallatt, Z., Steg, G., Benessiano, J., *et al*. Circulating secretory phospholipase A2 activity predicts recurrent events in patients with severe acute coronary syndromes, J. *Am. Coll. Cardiology*, 2005, 46(7): 1249-1257.
3. Mallat Z, Simon T, Benessiano J., *et al*. Circulating secretory phospholipase A2 activity and risk of incident coronary events in healthy men and women: the EPIC-Norfolk study. *Arterioscler. Thromb .Vasc. Biol*. 2007, 27: 1177–1183.

RANDOX
Randox Laboratories Limited, 55 Diamond Road, Crumlin, County Antrim, BT29 4QY, United Kingdom
T +44 (0) 28 9442 2413 **F** +44 (0) 28 9445 2912 **E** marketing@randox.com **I** www.randox.com