Leading Technology in Fluid-Stable Reagents from DiaSys

- Global player in clinical chemistry tests with recognized R & D department
- Quality products made in Germany
- High quality raw materials from traceable origin
- Processes and resources certified according to ISO 13485, ISO 9001 and fulfilling highest internal quality standards
- Sustainable processes and products preserving the environment
- High performance ready-to-use reagents with minimized interferences, long shelf life, on-board stability and traceability to international references
- Perfectly matched fluid-stable reagents, calibrators and controls
- Premium service supply in technics, applications and after sales

CHOOSING QUALITY.
Lp-PLA$_2$
Lipoprotein-associated phospholipase A$_2$

Emerging Biomarker in Atherosclerotic Risk Assessment

- Liquid-stable, ready-to-use reagents
- Excellent precision
- No interference by hemolytic, icteric and lipemic samples
- Adaptable on any clinical chemistry analyzer
Clinical Relevance

Lp-PLA₂ – also known as platelet-activating factor acetylhydrolase (PAF-AH) – is a vascular-specific inflammatory enzyme, predominantly expressed by macrophages, lymphocytes and foam cells in atherosclerotic plaques. Circulating Lp-PLA₂ is mainly associated with apolipoprotein B-containing lipoproteins, hence closely associated with low-density lipoprotein (LDL). The enzyme hydrolyzes oxidized phospholipids on LDL particles within the arterial intima, generating two highly inflammatory mediators, lysophosphatidylcholine (Lyso-PC) and oxidized non-esterified fatty acids (oxNEFAs).

Many important studies confirm a strong association between Lp-PLA₂ levels and cardiovascular risk among different populations. These studies show that in individuals with normal LDL, elevated Lp-PLA₂ levels were strongly associated with heart disease and ischemic stroke, independent of traditional risk markers and high-sensitive CRP. Due to the fact that Lp-PLA₂ is involved in the causal pathway of plaque inflammation and plaque rupture, the testing for Lp-PLA₂ represents a valuable adjunctive tool which goes beyond traditional cardiovascular risk assessment.

The Importance of Lp-PLA₂ Testing

Studies provide strong evidence, that the presence of Lp-PLA₂ is associated with an increased risk of cardiac death, myocardial infarction, acute coronary syndrome and ischemic stroke. Increased Lp-PLA₂ concentrations can be found in vulnerable atherosclerotic plaques and allow discrimination between morphologically identical stable and unstable plaques. Lp-PLA₂ testing is an excellent complement to angiography because it detects very small plaques not visible by medical imaging. Unlike traditional atherosclerotic risk markers Lp-PLA₂ is highly specific for vascular inflammation, has low biological variability, and plays a causative role in atherosclerotic plaque inflammation.

The predictive value of traditional atherosclerotic risk markers is limited. Lp-PLA₂ is able to overcome these limitations and, therefore, represents a powerful tool to close the diagnostic gap.
DiaSys Lp-PLA₂ FS

Features and Benefits
- Enzymatic test determining the activity of Lp-PLA₂
- Liquid-stable, ready-to-use reagent
- Adaptable on any clinical chemistry analyzer
- For use in serum, EDTA and heparin plasma
- Wide measuring range up to 2000 U/L
- 2-point calibration with superior stability of 4 weeks
- No interferences by blood components like bilirubin, ascorbate, hemoglobin and others
- Excellent precision over the entire measuring range

Precision

<table>
<thead>
<tr>
<th>Sample</th>
<th>Intra-assay n = 20 Mean [U/L]</th>
<th>SD [U/L]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>319</td>
<td>2.02</td>
<td>0.63</td>
</tr>
<tr>
<td>Sample 2</td>
<td>633</td>
<td>4.40</td>
<td>0.69</td>
</tr>
<tr>
<td>Sample 3</td>
<td>1113</td>
<td>7.98</td>
<td>0.72</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Sample</th>
<th>Total precision CLSI n = 80 Mean [U/L]</th>
<th>SD [U/L]</th>
<th>CV [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sample 1</td>
<td>314</td>
<td>4.80</td>
<td>1.53</td>
</tr>
<tr>
<td>Sample 2</td>
<td>625</td>
<td>10.0</td>
<td>1.61</td>
</tr>
<tr>
<td>Sample 3</td>
<td>1105</td>
<td>13.3</td>
<td>1.20</td>
</tr>
</tbody>
</table>

Essential Role of Lp-PLA₂ in Risk Assessment

Since 2010, Lp-PLA₂ testing is recommended by four major guidelines for patients estimated to be at moderate or high cardiovascular disease risk by traditional risk assessment.

2012
- AACE Guideline for Management of Dyslipidemia and Prevention of Atherosclerosis
- European Guideline on cardiovascular disease prevention in clinical practice

2011
- AHA/ASA Guideline for the Primary Prevention of Stroke

2010
- ACCF/AHA Guideline for Assessment of Cardiovascular Risk in Asymptomatic Adults