References:
12. Internal data (2016); data on file.

Illuminating the hidden severity of cardiovascular disease with GDF-15
A valuable biomarker to improve risk stratification and optimize patient management
Elecsys® GDF-15 Assay

Elecsys® GDF-15 Assay – Intended Use
Immunosassay for the in vitro quantitative determination of Growth Differentiation Factor-15 (GDF-15) in human serum and plasma. The Elecsys GDF-15 assay is intended as an aid in risk stratification of patients with Acute Coronary Syndrome (ACS) or Chronic Heart Failure (CHF). The Elecsys GDF-15 assay is intended as an aid in risk prediction of major bleeding events of patients with Atrial Fibrillation (AF). The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers. 

Elecsys® GDF-15 Assay – Value Propositions
Predicting bleeding risk in atrial fibrillation patients with more confidence
• Bleeding risk is a leading concern when selecting oral anticoagulation (OAC) therapy for stroke prevention in patients with atrial fibrillation (AF)13
• GDF-15 is the strongest predictor in the ABC bleeding risk score.13 It provides physicians with an improved understanding of each patient’s bleeding risk profile and can inform treatment decisions7

Elecsys® GDF-15 Assay – Technical features
Lot to Lot Method Comparison according to CLSI EP09-A3

Elecsys® GDF-15 test characteristics16,33

<table>
<thead>
<tr>
<th>Order information</th>
<th>Elecsys® GDF-15</th>
<th>Cobas e 411</th>
<th>Cobas e 601</th>
<th>Cobas e 801</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test time</td>
<td>16 min</td>
<td>16 min</td>
<td>16 min</td>
<td>16 min</td>
</tr>
<tr>
<td>Test principle</td>
<td>Sandwich principle</td>
<td>Sandwich principle</td>
<td>Sandwich principle</td>
<td>Sandwich principle</td>
</tr>
<tr>
<td>Calibration</td>
<td>2-point calibration</td>
<td>2-point calibration</td>
<td>2-point calibration</td>
<td>2-point calibration</td>
</tr>
<tr>
<td>Traceability</td>
<td>The assay has been standardized by weighing recombinant GDF-15 into equine serum.</td>
<td>Serum and Li heparin, K3 EDTA and K2 EDTA plasma.</td>
<td>Serum and Li heparin, K3 EDTA and K2 EDTA plasma.</td>
<td>Serum and Li heparin, K3 EDTA and K2 EDTA plasma.</td>
</tr>
<tr>
<td>Sample material</td>
<td>Stable for 8 days at 20–25°C, 14 days at 2–8°C, 12 months at −20°C (±5°C). Freeze only once.</td>
<td>Stable for 8 days at 20–25°C, 14 days at 2–8°C, 12 months at −20°C (±5°C). Freeze only once.</td>
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</tr>
<tr>
<td>Sample stability</td>
<td>Reagent stability</td>
<td>Reagent stability</td>
<td>Reagent stability</td>
<td>Reagent stability</td>
</tr>
<tr>
<td>Sample volume</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measuring range</td>
<td>400–20,000 pg/mL</td>
<td>400–20,000 pg/mL</td>
<td>400–20,000 pg/mL</td>
<td>400–20,000 pg/mL</td>
</tr>
<tr>
<td>Dilution</td>
<td>1:5 (concentration of diluted sample must be &gt;3500 pg/mL) using Diluent MultiAssay</td>
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</tr>
</tbody>
</table>

Proven Elecsys® assay performance – confidence in results
• Advanced ECL assay design and low inherent system variability
• High precision at across measure range

Repeatability/Within-Run-Precision of Elecsys® GDF-15 immunoassay according to CLSI EP05-A3

Elecsys GDF-15 P03 Lot cobas e 411 [pg/mL]

Elecsys GDF-15 P02 Lot cobas e 411 [pg/mL]

Elecsys GDF-15 P03 Lot cobas e 411 [pg/mL]

Elecsys GDF-15 P02 Lot cobas e 411 [pg/mL]

Fig. 3: Precision according to the EP5-A3 protocol of the Clinical and Laboratory Standards Institute (CLSI) on cobas e 411 and e 601.16,33