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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

Immunoassay 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.[13]

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)[1,2]
- GDF-15 is the strongest predictor in the ABC bleeding risk score.[3] It provides physicians with an improved understanding of each patient's bleeding risk profile and can inform treatment decisions[3]

Better decisions in acute coronary syndrome

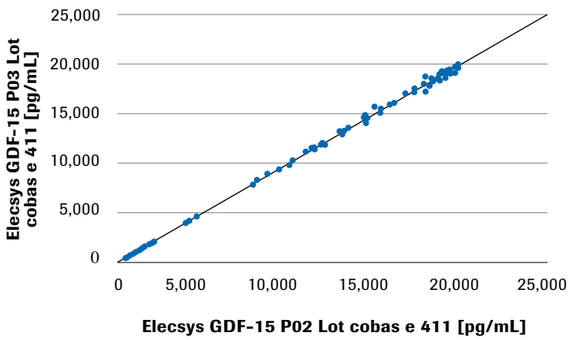
- GDF-15 is a strong independent prognostic marker to anticipate all-cause mortality and reinfarction in patients with acute coronary syndrome (ACS)[4-7]
- The addition of GDF-15 to TnT-hs can facilitate the selection of patients with non–ST elevation acute coronary syndrome (NSTE-ACS) who would benefit from early revascularization and more intensive medical therapies[5,8]

Get the full picture in heart failure

- Heart failure (HF) is a complex syndrome, affecting not only the heart but many extra-cardiac tissues[9,10]
- GDF-15 is independently associated with mortality and non-fatal events in HF with reduced (HFrEF) or preserved ejection fraction (HFpEF)[11]
- Together with NT-proBNP and TnT-hs it provides a comprehensive clinical picture and helps to identify high-risk patients who benefit from intensified management[11]

Elecsys® GDF-15 Assay – Technical features

Lot to Lot Method Comparison according to CLSI EP09-A3



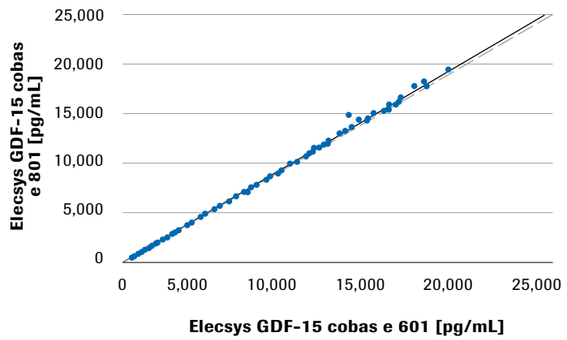
Lot to lot method comparison according to CLSI EP09-A3 between P02 and P03 lot on cobas e 411. Sample concentrations were between 450 and 19,944 pg/mL (P02 lot).[12,13]

Passing/Bablok
y = 0.996x + 1.22
t = 0.976

Linear regression
y = 0.995x + 18.3
r = 1.00

N = 138

Elecsys® platform comparison according to CLSI EP09-A3



Platform method comparison according to CLSI EP09-A3 between cobas e 601 and cobas e 801. Sample concentrations were between 403 and 18,876 pg/mL (cobas e 601).[12,13]

Passing/Bablok
y = 1.017x – 3.97
t = 0.989

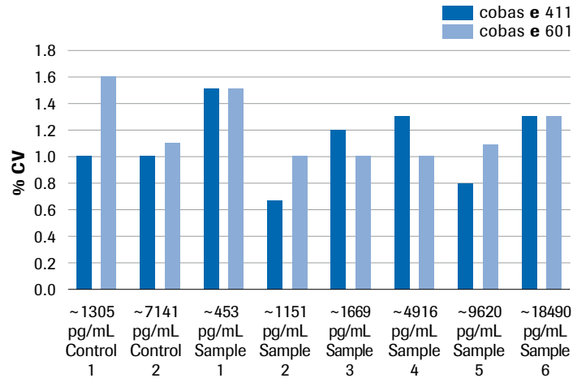
Linear regression
y = 1.021x -10.9
r = 1.00

N = 143

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



Intermediate/Within-Lab Precision of Elecsys® GDF-15 immunoassay according to CLSI-EP05-A3

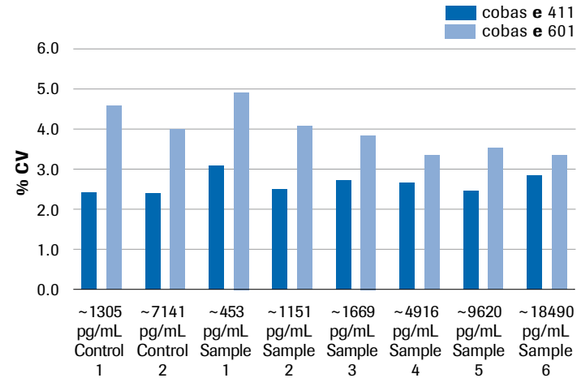


Fig. 3: Precision according to the EP5-A3 protocol of the Clinical and Laboratory Standards Institute (CLSI) on cobas e 411 and e 601.[12,13]

Elecsys® GDF-15 test characteristics[12,13]	
Testing time	18 min
Test principle	Sandwich principle
Calibration	2-point calibration
Traceability	The assay has been standardized by weighing recombinant GDF-15 into equine serum.
Sample material	Serum and Li heparin, K_2 EDTA and K_3 EDTA plasma
Sample stability	Stable for 8 days at 20 – 25 °C, 14 days at 2 – 8 °C, 12 months at -20 °C (±5 °C). Freeze only once.
Reagent stability	**cobas e** 411, **e** 601, **e** 602, E170: After opening at 2 – 8 °C: 12 weeks on the analyzers: 8 weeks; **cobas e** 801: on the analyzer: 16 weeks
Sample volume	**cobas e** 411, **e** 601, **e** 602, E170: 35 µL **cobas e** 801: 21 µL
LoB, LoD, LoQ* (Specification)	LoB: ≤ 350 pg/mL; LoD: ≤ 400 pg/mL; LoQ: ≤ 400 pg/mL
Measuring range	400 – 20,000 pg/mL
Dilution	1:5 (concentration of diluted sample must be >3500 pg/mL) using Diluent MultiAssay

** LoB = Limit of Blank; LoD = Limit of Detection; LoQ = Limit of Quantitation (20 % CV)*

Order information

Elecsys® GDF-15	07125933 190 (E170, **e** 411, **e** 601, **e** 602) 07028172 190 (**e** 801)	100 tests per rackpack 100 tests per rackpack
CalSet GDF-15	07125941 190 (E170, **e** 411, **e** 601, **e** 602, **e** 801)	4 × 1.0 mL each of CalSet GDF-15 Level 1 and 2
PreciControl Cardiac II	04917049 190 (E170, **e** 411, **e** 601, **e** 602, **e** 801)	4 × 2.0 mL each of PreciControl Cardiac II 1 and 2
Diluent MultiAssay	03609987 190 (E170, **e** 411, **e** 601, **e** 602) 07299010 190 (**e** 801)	2 × 16 mL sample diluent 45.2 mL sample diluent

Broad cardiac menue available on cobas e analyzers

- CK-MB
- Digitoxin
- Digoxin
- GDF-15
- Myoglobin
- NT-proBNP
- Troponin I
- Troponon T hs