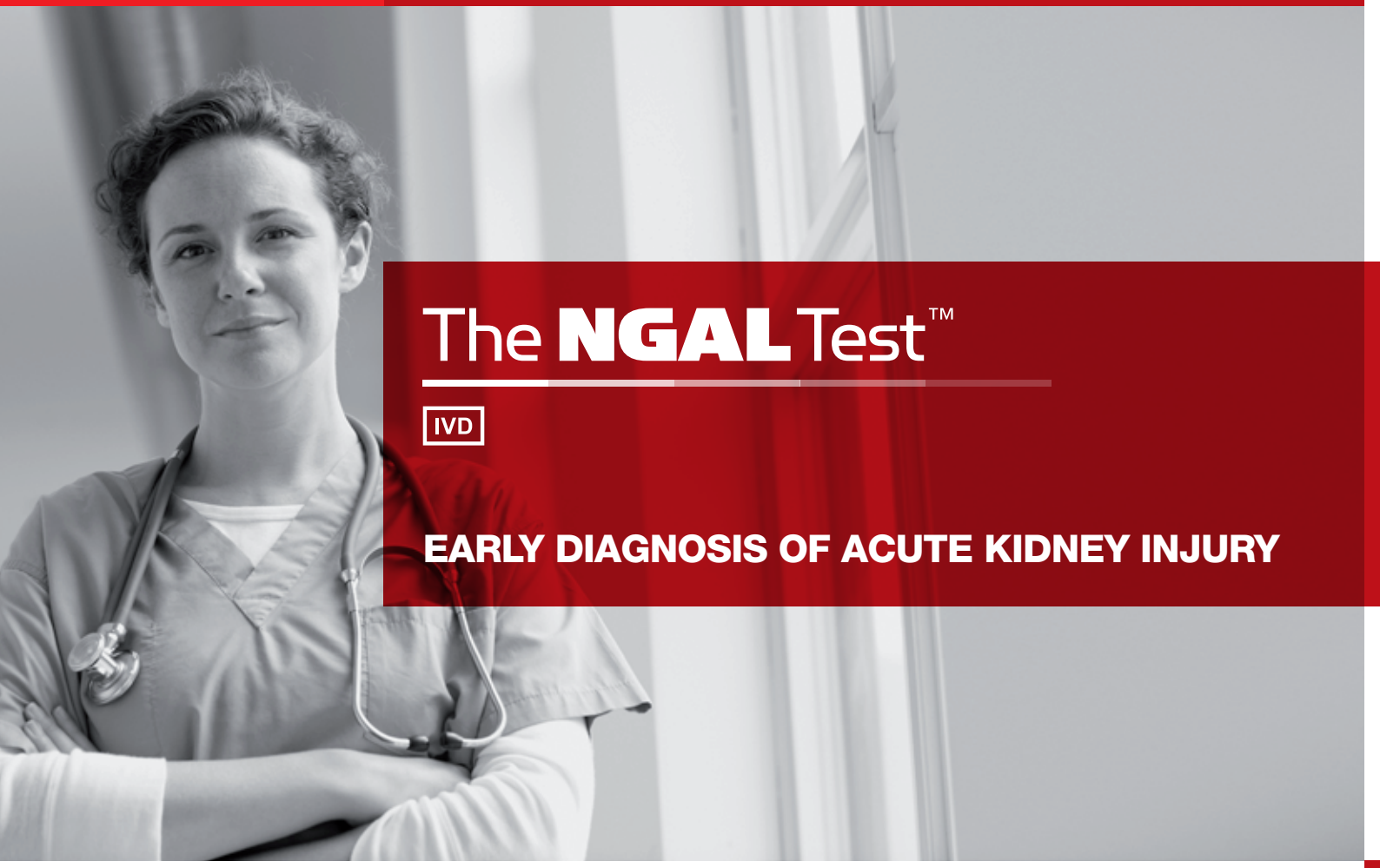

The NGAL Test™

IVD

EARLY DIAGNOSIS OF ACUTE KIDNEY INJURY

NGAL is a biomarker for diagnosing acute kidney injury (AKI). Its key advantage is that it responds earlier than other renal status markers like serum creatinine and shows a proportionate response to injury. NGAL determination thus permits the early diagnosis and prognostic stratification of patients with AKI.

Clinical application

Measuring NGAL in urine or plasma gives you information on AKI status that you need for rapid decision making e.g. in the following settings:

- Intensive care - monitoring
- Emergency room - triage tool
- Renal transplantation - predictive evaluation
- Intravenous contrast agents - assesing nephrotoxicity

"Evidence suggests that 15–20% of patients who do not fulfill current serum-creatinine-based consensus criteria for AKI are nevertheless likely to have acute tubular damage, which is associated with adverse outcomes"

Haase M et al, Nat. Rev. Nephrol 2012

"The use of urinary NGAL after cardiac surgery appears to be cost-effective in the early diagnosis of AKI"

Shaw A et al, Clin Ther 2011

BioPorto® Diagnostics

The NGAL Test™

– a new rapid NGAL assay for clinical chemistry platforms

The NGAL Test™ is a particle-enhanced turbidimetric immunoassay for the quantitative determination of NGAL in human urine, EDTA plasma and heparin plasma. The test can be run on most automated clinical chemistry analyzers.

Using only a few drops of plasma or urine The NGAL Test™ gives you results in just 10 minutes and thus addresses the widespread demand for fast NGAL results.

Assay specifications

Method	Particle-enhanced turbidimetric immunoassay
Sample	Urine, EDTA plasma and heparin plasma
Sample stability	If the assay cannot be performed within 24 hours or specimens are to be shipped, freeze the specimens at –20°C or below. For long-term storage of specimens, –70°C or below is recommended.
Calibrators	5 vials: 150, 600, 1500, 3000 and 5000 ng/mL Liquid ready-to-use
Controls	Low (200 ng/mL) and High (500 ng/mL) controls Liquid ready-to-use
Assay time	10 minutes
Shelf life	24 months
Open vial stability	30 days
On board stability	30 days (when refrigerated)
Measuring range	25 to 5000 ng/mL

Application notes

Application notes are available for*

Roche	Siemens	Abbott	Beckman Coulter
Cobas® Modular P®	ADVIA®	AEROSET® ARCHITECT®	Olympus AU®

*Application notes for other analyzers are in development.

Product information

Cat. no.	Product name	Contents
ST001CA	The NGAL Test™ Reagent Kit CE IVD	Immunoparticle Suspension, 7 mL Reaction Buffer, 35 mL
ST002CA	The NGAL Test™ Calibrator Kit CE IVD	5 vials of 1 mL Prediluted calibrators
ST003CA	The NGAL Test™ Control Kit CE IVD	6 vials of 1 mL Control Low, 3 x1 mL Control High, 3 x1 mL

BioPorto® Diagnostics

To learn more please visit NGAL.com

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www.ngal.com

LIMITATION
The NGAL Test™ is meant to aid the diagnosis of kidney injury which may lead to acute renal failure. However, The NGAL Test™ is not a stand-alone test as a variety of independent pathologies are associated with raised levels of urinary or plasma NGAL. Physicians must interpret the significance of any raised NGAL level in the light of the patient's clinical features.

For *in vitro* diagnostic use in selected countries only. See www.bioporto.com for availability in your country.

Diagnostic use patented/patent pending in selected countries, WO2006066587. See www.bioporto.com for an updated list of issued and pending patents.

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