Product Details

The NGAL Test Reagent Kit	
Catalog Number	ST001
Kit Contents	Reagent R1: Reaction buffer; ready to use (1 x 35 mL) Reagent R2: Immunoparticle suspension; ready to use (1 x 7 mL) Instructions for Use
Test Method	Particle-enhanced turbidimetric immunoassay (PETIA) for use on automated clinical chemistry analyzers
Sample Type	Human urine, EDTA plasma, and heparin plasma
Sample Stability	1 day at room temperature (20-25°C); 3 days at 2-8°C; 1 year frozen at -70°C or below, stable for 3 freeze/thaw cycles
Number of Tests per Kit*	85-100 determinants
Sample Analysis Time*	Approximately 10 minutes
Measuring Range*	50 to 3000 ng/mL
Precision*	Within run (repeatability): 1.1-4.7% in urine, 1.2-8.5% in plasma Between run: 0.9-2.3% in urine, 0.9-2.9% in plasma Between day: 0.8-2.3% in urine, 1.6-8.9% in plasma
Storage	Store at 2-8°C
Shelf Life	24 months from date of manufacture. See expiry date on the label.
Interferences	No interference was observed in plasma (EDTA, Heparin) or urine for hemoglobin up to 500 mg/dL, conjugated bilirubin up to 30 mg/dL, free bilirubin up to 15 mg/L, and triglycerides up to 375 mg/dL.
Confounding Factors	Do NOT use this test on urine samples from patients with a known urinary tract infection.
Regulatory Status	The NGAL Test is CE-Marked for IVD use in the EU; registered in Canada, Israel and Korea; available for Research Use Only in the US.
Available Separately	ST002-Calibrator Kit: 5 levels (1mL each), ready to use ST003-Control Kit: 2 levels (high & low, 3 x 1mL each), ready to use

* *varies by analyzer*

CE Marked Intended Use

The NGAL Test™ is a particle-enhanced turbidimetric immunoassay for the quantitative determination of neutrophil gelatinase-associated lipocalin (NGAL) in human urine, EDTA plasma and heparin plasma on automated clinical chemistry analyzers. NGAL measurements are useful in the diagnosis of acute kidney injury which may lead to acute renal failure.

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