The NGAL Test™ CE IVD

The NGAL Test™ Control Kit
REF ST003CA

Revision: TNT2014-11-EN

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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. The NGAL Test™ Control Kit contains control solutions to validate the calibration curve. NGAL measurements are useful in the diagnosis of acute kidney injury which may lead to acute renal failure.

REAGENTS
Composition
Each Control (Low CONTROL L and High CONTROL H) contains 1 mL of a ready-to-use solution of recombinant human NGAL in a HEPES buffer containing preservative.

VALUE ASSIGNMENT
No internationally approved NGAL reference material is currently available. The NGAL Test™ Control kit has been value-assigned with The NGAL Test™ from BioPorto Diagnostics A/S using calibrators that have been value-assigned using a precise transfer protocol ensuring traceability to the BioPorto master calibrator. The reference material was value-assigned by measurement of light absorbance at 280 nm using a theoretically calculated extinction coefficient based on the amino acid composition. The assigned values are given on the vial label or on the Certificate of Analysis.

WARNINGS AND PRECAUTIONS
For In Vitro Diagnostic Use IVD
- Read all instructions before starting this test.
- This kit should only be used by qualified laboratory staff.
- Do not pipette by mouth.
- Do not shake the controls.
- Do not pour controls back into their original containers once transferred.
- Do not leave liquid in the dropper tip when storing controls after opening. This increases the likelihood of evaporation during storage.
- Do not switch caps on containers as it may cause contamination or mix-up.
- Do not use after the expiry date on the labels.
- Controls with different lot numbers should not be mixed.
- All solutions supplied should be handled carefully and disposed of in accordance with national and local regulations.
- All equipment used in this test should be sterilized by one of the following methods:
  - Soak in 3.5% v/v glutaraldehyde for 30 minutes or longer.
  - Soak in 0.5% w/v sodium hypochlorite for 1 hour or longer.
  - Autoclave at 121°C for 20 minutes or longer.

STORAGE AND STABILITY
Shelf life at 2-8°C: See expiry date on the label.
Stability after opening: 3 months at 2-8°C, capped.

PROCEDURE
Materials provided
Control Low, 3 x 1 mL CONTROL L
Control High, 3 x 1 mL CONTROL H
Please refer to the vial labels or the Certificate of Analysis for lot-specific values.

MATERIALS REQUIRED BUT NOT PROVIDED
- The NGAL Test™ Reagent Kit REF ST001CA.
- The NGAL Test™ Calibrator Kit REF ST002CA.
- 0.9% w/v aqueous sodium chloride solution as zero calibrator.
- Clinical chemistry analyzer.
- Analyzer-specific application note (available for a number of analyzers).
- Analyzer-specific reagent containers.

ASSAY PROCEDURE
Drip the required volume into a sample cup and analyze in the same way as for patient samples.

Measurements should be carried out in accordance with the specific application note for the chemistry analyzer used. Please see the Instructions for Use for The NGAL Test™ Reagent Kit REF ST001CA, which also give details of test principle and performance characteristics of The NGAL Test™.

INTERNAL QUALITY CONTROL
The controls should be run the same day as each run of samples and after every calibration. Each laboratory should establish quality control procedures and acceptance limits that are adapted to its requirements and conform to pertinent regulations or accreditation requirements, including the corrective measures that should be taken if values fall outside the limits.

CONTROL L	Control Low
CONTROL H	Control High
REF	Catalogue number
IVD	In vitro diagnostic medical device
LOT	Batch code
IFU	Valid version of instructions
	Consult instructions for use
CE	European Conformity
	Use by
	Manufacturer
8°C 2°C	Temperature limitation

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