

## The NGAL Test™ Calibrator Kit

[REF] ST002CA

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™ Calibrator Kit contains calibrator solutions for establishing the calibration curve. NGAL measurements are useful in the diagnosis of acute kidney injury which may lead to acute renal failure.

### REAGENTS

#### Composition

Each Calibrator (1-5) contains 1 mL of a ready-to-use solution of recombinant human NGAL in a HEPES buffer containing preservative.

### VALUE ASSIGNMENT

No internationally approved reference material for NGAL is currently available. The NGAL solutions in The NGAL Test™ Calibrator Kit have been value-assigned by turbidimetry using a precise transfer protocol ensuring traceability to the BioPorto Diagnostics 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.

### 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 calibrators.
- Do not pour calibrators back into their original containers once transferred.
- Do not leave liquid in the dropper tip when storing calibrators 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.
- Calibrators 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

- Calibrator 1 (50 ng/mL), 1 mL
- Calibrator 2 (150 ng/mL), 1 mL
- Calibrator 3 (600 ng/mL), 1 mL
- Calibrator 4 (1500 ng/mL), 1 mL
- Calibrator 5 (3000 ng/mL), 1 mL

### MATERIALS REQUIRED BUT NOT PROVIDED

- The NGAL Test™ Reagent Kit [REF] ST001CA.
- The NGAL Test™ Control Kit [REF] ST003CA.
- 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.

### CALIBRATION PROCEDURE

Use the Calibrators, with aqueous 0.9% w/v sodium chloride solution as the zero calibrator, to establish a 6-point calibration curve as described in the instrument manual. The assigned NGAL concentration values of the calibrators are given on the labels of the calibrator vials.

Each laboratory should determine the appropriate frequency of calibration. Calibration should be repeated at least once a month or when a new reagent lot is used.

Drip the required volume into a sample cup and analyze in the same way as for specimens.


Measurements should be carried out in accordance with the specific application note for the automated 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™.

[REF] Catalogue number

[IVD] In vitro diagnostic medical device

[LOT] Batch code


[IFU] Valid version of instructions

 Consult instructions for use

 European Conformity

 Use by

 Manufacturer

 Temperature limitation