

The NGAL Test™

For your clinical chemistry analyzer

The NGAL Test™ Calibrator Kit

REF ST002RA

Revision: TNT2011-10-RUO

APPLICATION

The NGAL Test™ Calibrator Kit is for calibration of The NGAL Test™, a particle-enhanced turbidimetric immunoassay for the quantitative determination of NGAL in human urine, EDTA plasma or heparin plasma.

For research use only. Not for use in diagnostic procedures.

REAGENTS

Composition

Each Calibrator contains 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

This test is for research use only

- 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 reagents
- Use only clean containers if transferring reagents
- Do not pour reagents back into their original containers once transferred
- Avoid direct skin contact. Powder-free gloves should be worn. Should reagents come into contact with the skin, eyes or mouth, flush with plenty of water. Seek medical advice if any symptom is observed or when it is considered necessary.
- Do not switch caps on reagent containers as it may cause contamination or mix-up
- Do not use reagents after the expiry date on the labels
- Reagents 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% w/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: 4 weeks at 2-8°C, capped. On the Hitachi 917 analyzer, the manufacturer obtains satisfactory performance for up to 8 weeks.

PROCEDURE

Materials provided

Calibrator 1 (150 ng/mL), 1 mL
Calibrator 2 (600 ng/mL), 1 mL
Calibrator 3 (1500 ng/mL), 1 mL
Calibrator 4 (3000 ng/mL), 1 mL
Calibrator 5 (5000 ng/mL), 1 mL

MATERIALS REQUIRED BUT NOT PROVIDED

- The NGAL Test™ Reagent Kit **REF** ST001RA
- The NGAL Test™ Control Kit **REF** ST003RA
- 0.9% w/v sodium chloride as zero calibrator
- Automated chemistry analyzer
- Analyzer-specific application note (available for a number of analyzers)
- Analyzer-specific reagent containers

CALIBRATION PROCEDURE

Use the Calibrators, with normal saline 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** ST001RA, which also give details of the test principle of The NGAL Test™.



Catalogue number



Batch code



Consult instructions for use



Use by



Manufacturer



Temperature limitation



BIOPORTO[®]
Diagnostics



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