The NGAL Test™

For your clinical chemistry analyzer

The NGAL Test™ Control Kit
REF ST003RA

Revision: TNT2011-10-RUO

APPLICATION

The NGAL Test™ Control Kit is for monitoring the analytical performance of The NGAL Test™, a particle-enhanced turbidimetric immunoassay for the quantitative determination of NGAL in human urine, EDTA plasma and heparin plasma.

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

REAGENTS

Composition

Each Control contains 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 or on the Certificate of Analysis.

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 or controls back into their original containers once transferred
- All specimens used in the test run should be considered to be potentially infectious, and as such should be treated with standard precautions. Powder-free gloves should be worn. Avoid direct skin contact. 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 or control 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% 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: 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

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 ST001RA
- The NGAL Test™ Calibrator Kit REF ST002RA
- 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

ASSAY PROCEDURE

The NGAL Test™ Control Kit is ready to use.

Dispense the required volume into a sample cup and analyze in the same way as for unknown samples.

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™.

INTERNAL QUALITY CONTROL

The controls should be run daily 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

LOT — Batch code


Consult instructions for use


Use by


Manufacturer


Temperature limitation

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