The NGAL Test™ Reagent Kit
REF ST001RA

RUO

APPLICATION

The NGAL Test™ is 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.

TEST PRINCIPLE

The NGAL Test™ is a particle-enhanced turbidimetric immunoassay for the quantitative determination of NGAL in human urine or plasma. A sample of human urine or plasma is mixed with reaction buffer R1. After a short incubation, the reaction is started by the addition of anti-NGAL-coated immunoparticles R2. NGAL in the sample causes the immunoparticles to aggregate. The degree of aggregation is quantified by the amount of light scattering measured as absorption of light. The NGAL concentration in the sample is determined by interpolation on an established calibrationcurve.

ASSAY REAGENTS

Materials provided

R1 Reaction Buffer, 35 mL
R2 Immunoparticle Suspension, 7 mL

Composition

The Reaction Buffer R1 is a ready-to-use Tris buffer solution containing stabilizers andpreservative.

The Immunoparticle Suspension R2 is a ready-to-use suspension of polystyrene particles coated with anti-NGAL mouse monoclonal antibodies containingpreservative.

MATERIALS REQUIRED BUT NOT PROVIDED

- The NGAL Test™ Control Kit ST003RA
- 0.9% w/v sodium chloride as zero calibrator if required
- Automated chemistryanalyzer
- Analyzer-specific application note (available for a number of analyzers)
- Analyzer-specific reagent containers for R1 and R2

WARNINGS AND PRECAUTIONS

This test is for research use only

- This kit should only be used by qualified laboratory staff
- Do not shake the reagents.
- Use only clean containers if transferring reagents.
- Do not pour reagents back into their original containers once transferred.
- All specimens used in this test should be considered potentially infectious, and as such 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 containers as it may cause contamination ormix-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.

STORAGE AND STABILITY

Shelf life at 2-8°C: See expiry date on the label.
Stability after opening: 4 weeks at 2-8°C.

On-board stability: See relevant application note.

COLLECTION OF SPECIMENS

NGAL can be determined in human urine and plasma samples. Blood specimens should be collected aseptically into appropriate tubes by qualified staff using approved venepuncture techniques. Plasma should be prepared by standard techniques for laboratory testing. Urine should be centrifuged. The prepared specimens should be capped. If the assay cannot be performed within 24 hours or specimens are to be shipped, the specimens should be frozen at −70°C or below. Do not use hemolyzed, hyperlipemic, heat-treated or contaminated specimens.

SAMPLE STABILITY

Samples should be analyzed as soon as possible. However, both urine and plasma samples are stable for at least 1 day at room temperature (20-25°C) and for 3 days at 2-8°C. NGAL values are not significantly affected by 3 freeze/thaw cycles over 3 days.

ASSAY PROCEDURE

It is recommend to read the instructions before use. The assay should be carried out in accordance with the specific application note for the automated chemistry analyzer to be used. A general example of the assay procedure for an automated analyzer is given below:

1. Incubate 3 µL sample with 150 µL R1 at 37°C for 5 minutes
2. Add 50 µL R2
3. Read absorbance change at 570 nm for 5 minutes after the addition of R2
4. Calculate NGAL concentration from the absorbance change by interpolation on a calibration curve prepared with calibrators of known concentrations

APPLICATION PARAMETERS FOR THE HITACHI 917 ANALYZER

TEMPERATURE	37°C
ASSAYCODE	2point end-10
ASSAY POINT	18-34
SAMPLEVOLUME	3 (µL)
R1 VOLUME	150 (µL)
R2 VOLUME	50 (µL)
WAVELENGTH	800/570
CALIB.METHOD	SPLINE-6-6
UNITS	ng/mL

NUMBER OF DETERMINATIONS

On a Hitachi 917 1 mL of R2 Immunoparticle Suspension provides 20 cuvette readings of standards or samples. The dead volume of the analyzer and reagent container should be added when calculating the required amount of reagent.

LOADING OF REAGENTS

The NGAL Test™ Reagents are provided in containers that fit a number of commonly used analyzers. For use on other analyzers, transfer the contents of R1 and R2 into appropriate containers.

CALIBRATION

The NGAL Test™ Calibrator Kit REF ST002RA available from BioPorto Diagnostics should be used for calibration, with 0.9% w/v aqueous sodium chloride solution as zero calibrator.

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.

QUALITY CONTROL

For quality control, use The NGAL Test™ Control Kit REF ST003RA available from BioPorto Diagnostics. Quality control intervals and limits should be adapted to each laboratory's individual requirements. Each laboratory should establish corrective measures if values fall outside the limits.

MEASURING RANGE

The measuring range of The NGAL Test™ is 25 ng/mL to 3000 ng/mL on a Hitachi 917 analyzer. For information about measuring range on other analyzers please refer to the analyzer-specific application note.

LIABILITY

This Reagent Kit is only intended for the in vitro determination of NGAL in human urine or plasma. The Reagent Kit is only intended for use by qualified personnel and must only be used to carry out research activities. The Reagent Kit must not be used for diagnostic activities.

If the recipient of this test passes it on in any way to a third party, this instruction must be enclosed, and said recipient shall at recipient's own risk secure in favor of BioPorto Diagnostics A/S all limitations of liability herein.

R1	Reaction Buffer
R2	Immunoparticle Suspension
REF	Catalogue number
LOT	Batch code
	Consult instructionsfor use
	Use by
	Manufacturer
	Temperature limitation