The NGAL Test™

Reagent Kit

IFU-0010 v.14

REF ST001CA IVD CE

Language-specific IFU available at:
https://www.bioporto.com/edocs

PRODUCT NAME	The NGAL Test™ Reagent Kit
PRODUCT CODE	ST001CA
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. NGAL measurements are useful in the diagnosis of acute kidney injury (AKI) which may lead to acute renal failure.
SUMMARY AND EXPLANATION	Renal expression of NGAL increases dramatically in kidney injury from a variety of causes and NGAL is released into both urine and plasma. A large variety of renal disorders are associated with elevated urinary and plasma levels of NGAL. Urinary NGAL serves as an early marker of acute kidney injury after cardiopulmonary bypass surgery[1,2] and both urinary and plasma levels of NGAL provide an early indication of acute renal injury in unselected patients in intensive care[3]. Elevated urinary and plasma NGAL levels have also been observed in patients with chronic kidney diseases[4], and raised urinary levels after renal transplantation are associated with poor graft function[5].
TEST PRINCIPLE	The NGAL Test is a particle-enhanced turbidimetric immunoassay for the quantitative determination of NGAL in human urine, EDTA plasma and heparin plasma. A sample of human urine or plasma is mixed with reaction buffer REAG R1. After a short incubation, the reaction is started by the addition of an immunoparticle suspension REAG R2 (polystyrene microparticles coated with mouse monoclonal antibodies to NGAL). 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 calibration curve.
REAGENTS	REAG R1 Reaction Buffer, 35 mL, ready-to-use buffer solution containing murine protein and preservative. REAG R2 Immunoparticle Suspension, 7 mL, ready-to-use suspension of polystyrene microparticles coated with mouse monoclonal antibodies to NGAL and contains preservative.
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 shake the reagents. • Use only clean containers if transferring reagents. • Do not pour reagents back into the 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. • Reagents contain preservatives with 2-methyl-2H isothiazol-3-one (MIT) which may cause an allergic skin reaction. For more information, please refer to the safety data sheet. • Do not switch caps on reagent containers as it may cause contamination or mix-up. • Do not use reagents after the expiration date on the labels. • Reagents with different lot numbers should not be mixed. • All solutions and samples must be handled carefully and disposed of in accordance with national and local regulations

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WARNNGS AND PRECAUTIONS
(continued)

For in vitro diagnostic use for laboratory professionals. Exercise the normal precautions required for handling all laboratory reagents.

Infectious or microbial waste:
Warning: handle waste as potentially biohazardous material. Dispose of waste according to accepted laboratory instructions and procedures.

Environmental hazards:
Apply all relevant local disposal regulations to determine the safe disposal.

Safety data sheet available for professional user on request and at https://www.bioporto.com/edocs.

This kit contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Warning

H317	May cause an allergic skin reaction.

Prevention:

P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P272	Contaminated work clothing should not be allowed out of the workplace.
P280	Wear protective gloves.

Response:

P333 + P313	If skin irritation or rash occurs: Get medical advice/attention.
P362 + P364	Take off contaminated clothing and wash it before reuse.

Disposal:

P501	Dispose of contents/container to an approved waste disposal plant.

Hazardous components:

- 2-methyl-2H-isothiazol-3-one

Product safety labeling follows EU GHS guidance.
Contact phone:

- Emergency: 112
- BioPorto: +44 4529 0000

STORAGE AND STABILITY

- Shelf life at 2-8°C: see stated expiration date on the label.
- Reagent on-board stability is specific to the analyzer. For more information, please refer to the analyzer-specific application note. Application notes are based upon customers' experience and are not fully verified by BioPorto Diagnostics A/S.

SPECIMEN COLLECTION, HANDLING AND STORAGE

NGAL can be determined in human urine and plasma samples

Blood specimens should be collected aseptically into appropriate (K2 EDTA, K3 EDTA and heparin) tubes by qualified staff using approved venipuncture techniques. Plasma should be prepared using standard techniques for laboratory testing. Plasma and urine samples must be vortexed and centrifuged (1500 x g for 15 min) prior to use. The prepared specimens should be capped. If the assay cannot be performed within 24 hours or specimens are to be shipped, the specimens must be frozen at −70°C or below. Do not use hemolyzed, hyperlipidemic, heat-treated or contaminated specimens.

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SPECIMEN COLLECTION, HANDLING AND STORAGE *(continued)*	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) • 3 days at 2-8°C • NGAL values are not significantly affected by 3 freeze/thaw cycles over 3 days at −70°C or below
MATERIALS PROVIDED	• The NGAL Test™ Reagent Kit REF ST001CA (see "Reagents" section)
MATERIALS REQUIRED BUT NOT PROVIDED	• The NGAL Test™ Calibrator Kit REF ST002CA • The NGAL Test™ Control Kit REF ST003CA • Clinical chemistry analyzer • Analyzer-specific reagent container(s) • General laboratory equipment
NUMBER OF DETERMINATIONS	The number of determinations is specific to the analyzer. For more information, please refer to the analyzer-specific application note. Application notes are based upon customers' experience and are not fully verified by BioPorto Diagnostics A/S.
ASSAY PROCEDURE	Measurements should be carried out in accordance with the specific application note and operator's manual for the chemistry analyzer used. Application notes are based upon customers' experience and are not fully verified by BioPorto Diagnostics A/S.
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 REAG R1 and REAG R2 into appropriate containers. For more information, please refer to the analyzer-specific application note. Application notes are based upon customers' experience and are not fully verified by BioPorto Diagnostics A/S.
CALIBRATION	Calibrators: Use The NGAL Test™ Calibrator Kit REF ST002CA, which includes five calibrators with set points throughout the measuring range. Use all five calibrators in ascending order. Calibration frequency: Calibration must be performed: • After installing new application parameters • After reagent lot change • As required following quality control procedures Calibration should at least be repeated according to the calibration stability specific to the analyzer. The calibration interval may be extended based on acceptable verification of calibration by the laboratory. For more information, please refer to the analyzer-specific application note. Application notes are based upon customers' experience and are not fully verified by BioPorto Diagnostics A/S. Traceability: No international standard is currently available for NGAL. This method has been standardized against an internal BioPorto standard of recombinant human NGAL.

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QUALITY CONTROL

For quality control, use The NGAL Test™ Control Kit REF ST003CA, which includes two levels of controls.

Quality control should be performed:

- After every calibration
- Daily, in parallel with patient samples

The control intervals should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures if values fall outside the limits. Follow the applicable government regulations and local guidelines for quality control.

RESULT CALCULATION

The analyzer automatically calculates the analyte concentration of each sample in ng/mL.

LIMITATIONS

The finding of an elevated urinary or plasma NGAL level cannot be independently diagnostic of any single pathology. A variety of pathologies other than renal disorders are associated with elevated levels of urinary and/or plasma NGAL. Clinicians must interpret the significance of any elevated NGAL level in conjunction with the patient's clinical features.

Urinary NGAL concentrations are variable in subjects with urinary tract infection and should be assessed in consideration of NGAL values typically observed in acute kidney injury and in consideration of other clinical assessments when urinary tract infections are suspected.

Endogenous substances and commonly used pharaceuticals[6] specific to the analyzer. For more information, please refer to the analyzer-specific application note. Application notes are based upon customers' experience and are not fully verified by BioPorto Diagnostics A/S.

TROUBLESHOOTING

If performance is unacceptable, try to recalibrate. Check reagents and procedure. If the problem persists, please contact reagent supplier.

REFERENCE RANGE

NGAL concentrations of self-declared healthy subjects were measured in duplicate, and the following results were obtained:

Sample type	Population	N	NGAL Median (ng/mL)	NGAL Reference Limits (ng/mL); central 95 %
Urine	***Total***	*239*	*< 25*	*< 25-158*
	Female	116	28	< 25-208
	Male	123	< 25	< 25-105
EDTA plasma	***Total***	*250*	*57*	*< 25-142*
	Female	125	56	< 25-122
	Male	125	59	<25-154
Heparin plasma	***Total***	*250*	*57*	*< 25-116*
	Female	125	57	< 25-104
	Male	125	58	26-120

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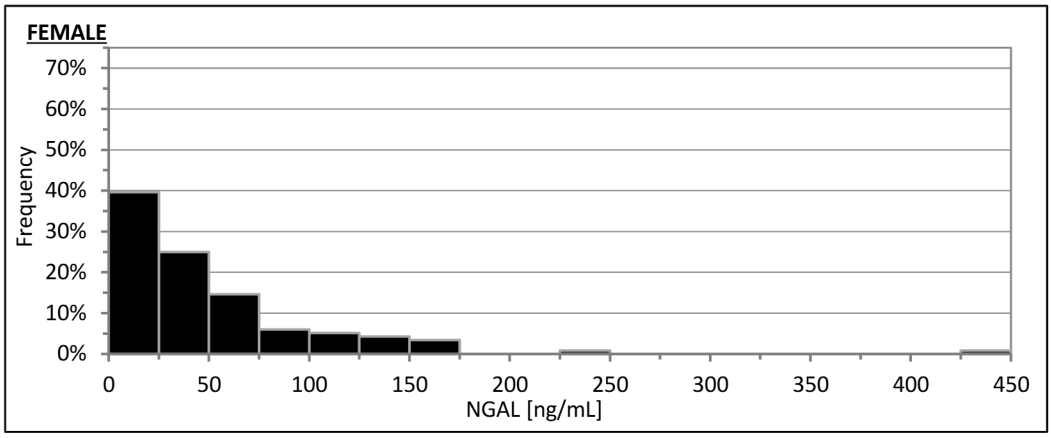
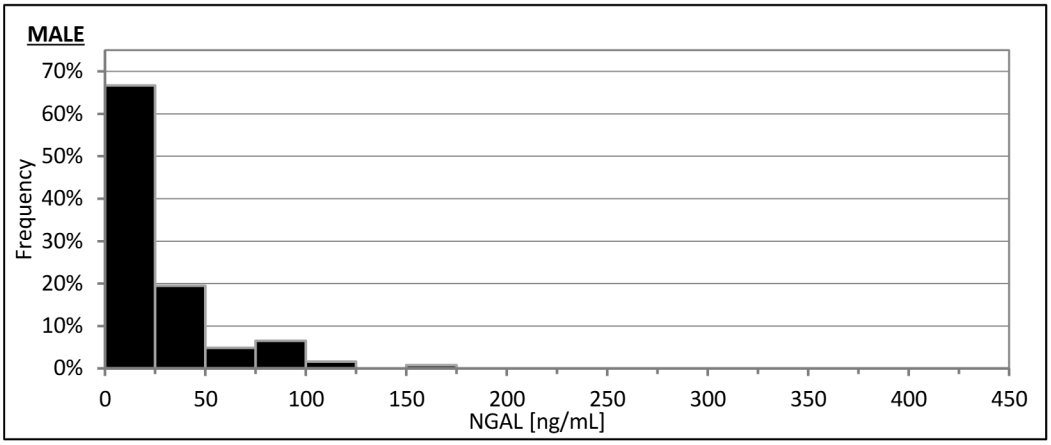
REFERENCE RANGE

In urine, normal NGAL concentrations are significantly lower in males than in females (Wilcoxon-Mann-Whitney test, p<0.0001). See the following graphs.





INTERPRETATION OF RESULTS

Urinary and/or plasma concentrations of NGAL may be elevated in conditions that show no apparent relation to change in kidney function, including bacterial infections, other inflammatory disorders, and certain carcinomas. BioPorto Diagnostics A/S has determined that the NGAL concentration in an isolated sample of urine and/or EDTA plasma should exceed 250 ng/mL in order to indicate the presence of renal disorder, including acute kidney injury, without incurring the risk of an unacceptably high proportion of false positive diagnoses of renal disorder. The NGAL Test result cannot be used as a stand-alone result. Clinicians must interpret the significance of an NGAL result in conjunction with the patient's full clinical assessment.

LIABILITY

This Reagent Kit ("Product") is only intended for assisting in the in vitro determination of NGAL in human urine or plasma. The Product is only intended for use by qualified personnel carrying out research and diagnostic activities. The recipient of this Product shall use the Product solely for the purpose described in the Instructions for Use ("IFU") and it is not intended for any use beyond the IFU and before the expiration of the Product. If the recipient of this Product transfers the Product in any way to a third party, this IFU must be enclosed and said recipient shall at recipient's own risk secure in favor of BioPorto Diagnostics A/S and its subsidiaries ("BioPorto") all limitations of liability herein.

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LIABILITY
(continued)

BioPorto discard any liability after expiration date of the Product and is under no circumstances, for any reason, liable for any indirect or consequential loss / damage, as well as "punitive damages" including but not limited to consequential loss and loss of revenue and legal fees, regardless of whether the loss or damage may be suffered by the recipient of this Product. It is emphasized that this limitation of liability shall apply regardless of the basis on which the loss or damage is based, including but not limited to delays, defects, product liability, professional liability, contract, warranty, and tort.

To the extent permitted by applicable law, BioPorto shall not for any reason be responsible for any damage caused to the recipient of this Product or any third party or any losses in connection therewith.

In no event shall BioPorto's liability exceed the price actually paid to BioPorto for this Product.

The limitations of liability apply to any breach or liability by BioPorto; including but not limited to defects, product liability, intellectual property rights etc., and shall apply to the extent permitted by applicable law. BioPorto shall not in any way be responsible for the acts, defaults, or omissions of the recipient of this Product, its employees or representatives.

REFERENCES

1. Xin C, Yulong X, Yu C, Changchun C, Feng Z, Xinwei M (2008) Urine neutrophil gelatinase-associated lipocalin and interleukin-18 predict acute kidney injury after cardiac surgery. Renal Fail 30:904-913.
2. Tuladhar SM, Püntmann VO, Soni M, Punjabi PP, Bogle RG (2009) Rapid detection of acute kidney injury by plasma and urinary neutrophil gelatinase-associated lipocalin after cardiopulmonary bypass. J Cardiovasc Pharmacol 53:261-266.
3. Bangert K, Heslet L, Ghiglione M, Uttenthal LO (2006) NGAL is significantly increased in urine and plasma in acute renal failure. Intensive Care Med 32(Suppl 1):S10.
4. Bolignano D, Donato V, Coppolino G, Campo S, Buemi A, Lacquaniti A, Buemi M (2008) Neutrophil gelatinase-associated lipocalin (NGAL) as a marker of kidney damage. Am J Kidney Dis 52:595-605.
5. Hollmen ME, Kyllönen LE, Inkinen KA, Lalla ML, Salmela KT (2011) Urine neutrophil gelatinase-associated lipocalin is a marker of graft recovery after kidney transplantation. Kidney Int 79:89-98.
6. Sonntag O, Scholer A (2001) Drug interference in clinical chemistry: Recommendation of drugs and their concentrations to be used in drug interference studies. Ann Clin Biochem 38:376-385.

SYMBOLS GLOSSARY

REF	Catalogue number	Caution	
IVD	In vitro diagnostic medical device	Σ n	Contains sufficient for <n> tests
LOT	Batch code		Use by date
	Consult instructions for use	2°C 8°C	Temperature limitation
CE	European Conformity	REAG R1	Reaction Buffer
	Manufacturer	REAG R2	Immunoparticle Suspension
CONT	Contents of kit		

bioporto DIAGNOSTICS

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Signature Manifest

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ST001 CE EN

QA Approval

Name/Signature	Title	Date	Meaning/Reason
Aydin Mataji (AMA)	Senior QA Specialist	31 Mar 2025, 09:26:21 AM	Approved

Author Approval

Name/Signature	Title	Date	Meaning/Reason
Janie Hendrix (JHE)	Technical Application Specialist	31 Mar 2025, 06:27:23 PM	Approved