The NGAL Test™

Control Kit

IFU-0065 v.09

REF ST003CA IVD CE

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

PRODUCT NAME	The NGAL Test™ Control Kit
PRODUCT CODE	ST003CA
INTENDED USE	The NGAL Test Control Kit contains control solutions to validate the calibration curve when using The NGAL Test Reagent Kit.
REAGENTS	The NGAL Test Control Kit contains 3 Low Controls and 3 High Controls. Each Control contains 1 mL of a ready-to-use solution of recombinant human NGAL in HEPES buffer containing preservative. The NGAL concentrations of The NGAL Test controls are lot-specific. Target values and target ranges are provided in the enclosed analytical value sheet.
VALUE ASSIGNMENT	Traceability: No international standard is currently available for NGAL. This method has been standardized against an internal BioPorto standard of recombinant human NGAL.
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 controls. • Use only clean containers if transferring controls. • Do not pour controls 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. • Controls 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 control containers as it may cause contamination or mix-up. • Do not use controls after the expiration date on the labels. • Controls with different lot numbers must not be mixed. • All solutions and samples must be handled carefully and disposed of in accordance with national and local regulations 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.

bioporto DIAGNOSTICS

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WARNINGS AND PRECAUTIONS *(continued)*

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.
- Stability after opening: 3 months at 2-8°C, tightly capped

MATERIALS PROVIDED

See “Reagents” section

MATERIALS REQUIRED BUT NOT PROVIDED

- The NGAL Test Reagent Kit REF ST001CA
- The NGAL Test Calibrator Kit REF ST002CA
- Clinical chemistry analyzer
- General laboratory equipment

QUALITY CONTROL PROCEDURE

The NGAL Test Control Kit includes two controls (Control Low and Control High). Controls are ready for use. No reconstitution is required.

To perform QC testing, add drops of each control into sample cups and analyze in accordance with the analyzer-specific application note. Application notes are based upon customers' experience and are not fully verified by BioPorto Diagnostics A/S. Please see the Instructions for Use for The NGAL Test Reagent Kit which also gives details of the test principle of The NGAL Test.

QC Frequency:

QC must be run

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

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QUALITY CONTROL PROCEDURE *(continued)*

The control intervals must be adapted to individual laboratory requirements. Each laboratory must establish quality control procedures following applicable government regulations and local guidelines for quality control including corrective measures to be taken if values fall outside the limits.

LIABILITY

This Control 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.

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.

SYMBOLS GLOSSARY

REF	Catalogue number	Caution	
IVD	In vitro diagnostic medical device	CONT	Contents of kit
LOT	Batch code		Use by date
	Consult instructions for use	2°C 8°C	Temperature limitation
CE	European Conformity	CONTROL L	Control Low
	Manufacturer	CONTROL H	Control High

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Signature Manifest

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ST003 CE EN

QA Approval

Name/Signature	Title	Date	Meaning/Reason
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Author Approval

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