

NG-Test Blood Culture Prep

Sample Preparation kit from a positive blood culture
For professional in vitro diagnostic use only



ENO002BCU / Rev: 200225 / EN

INTENDED USE

NG-Test Blood Culture Prep is intended for preparing a bacterial extract from positive blood culture samples. It is an *in vitro* diagnostic kit for professional use only. **NG-Test Blood Culture Prep** should be used in conjunction with NG-Test CARBA 5.

PRINCIPLE

In clinical practice, blood cultures are performed when there is a clinical reason to suspect a septicaemia. Blood is collected and analyzed before administration of antibiotics. The blood culture bottles are incubated in an automatic detection system that signals the presence of bacteria, yeasts, or fungi in a sample.

The **NG-Test Blood Culture Prep** kit lyses red blood cells and washes the bacterial pellet from a positive blood culture sample. The resulting bacterial extract is suitable for analysis using the NG-Test CARBA 5 kit.

REAGENTS AND MATERIALS SUPPLIED

Each kit contains:

- 1 lysis buffer solution in a plastic bottle identified **R1** with red cap (25 mL, volume sufficient for 20 tests)
- 1 washing buffer solution in a plastic bottle identified **R2** with white cap (25 mL, volume sufficient for 20 tests)
- 1 instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Individual protective equipment (Single use gloves, eye protection, protective clothing)
- Pipette
- Vortex
- Centrifuge with rotor for Eppendorf tubes, speed 15 000 r.p.m. (around 20 000 g)
- Kit NG-Test CARBA 5 (Ref: NGB-CAR-S23-XXX)

PRECAUTIONS

- All operations must be carried out according to good laboratory practices.
- Do not use after the expiry date.
- Handle the samples as if they were potentially infectious.
- After use, discard the device in an infectious waste container.

Lysis buffer **R1** is classified as hazardous chemical: DANGER (H315, H318)*



STORAGE AND STABILITY

Store the kit between 20 and 25°C. Do not freeze.

Do not use the kit beyond the expiry date indicated on each kit.

Note: If a precipitation occurs in the lysis buffer **R1**, incubate at 30-37°C and shake the vial regularly for 1 hour. If the precipitate is still visible, do not use the vial and contact your distributor.

CULTURE AND SAMPLING

The samples to be tested shall be obtained and handled according to the standardized microbiological procedures.

OPERATING PROCEDURE

NOTE: Microtubes are provided in the NG-Test CARBA 5 kit.

1. Wear individual protective equipment.
2. Mix 1 mL of positive blood culture with 1 mL of lysis buffer solution (**bottle identified R1 with red cap**) in a micro tube. Vortex for 20 seconds or mix by returning the tube at least 5 times.
3. Centrifuge 1 minute at 15 000 r.p.m. (~20 000 g). Discard carefully the supernatant by pipetting. **Make sure you have removed completely the supernatant.**
4. Re-suspend the pellet in 1 mL of washing buffer solution (**bottle identified R2 with white cap**). Vortex for 20 seconds. Centrifuge 1 minute at 15 000 r.p.m. (~20 000 g). **Discard completely the supernatant by pipetting.**
5. Re-suspend the pellet in 5 drops (150 µL) of extraction buffer (provided in the NG-Test CARBA 5 kit).
6. Perform the NG-Test CARBA 5 test according to the manufacturer's instructions (Operating procedure – Carrying out the test).

NG-Test Blood Culture Prep

Sample Preparation kit from a positive blood culture

For professional in vitro diagnostic use only



ENO002BCU / Rev: 200225 / EN

LIMITATIONS

This kit should be used as an aid for the rapid identification of bacterial resistance to carbapenem antibiotics, from patient positive blood culture sample.

Clinical data and other test results must be taken into consideration to establish diagnosis.

A positive or negative test does not rule out the presence of other mechanisms of antibiotic resistance.

In the case of mixed cultures, it is common practice to sub cultivate each blood culture sample on an agar plate individually and use the NG-Test CARBA 5 kit on bacterial colony (see NG-Test CARBA 5 Instructions for use).

PERFORMANCES

NG-Test Blood Culture Prep was evaluated followed by NG-Test CARBA 5 at the institute of microbiology, Zurich university, Switzerland. 178 blood cultures were blind-tested with Whole Genom Sequencing (WGS) characterized beta-lactamase content.

		Genotype (WGS)		
		Positive	Negative	Total
NG-Test Blood Culture Prep + NG-Test CARBA 5	Positive	143	0	143
	Negative	0	35	35
	Total	143	35	178

Sensitivity	100%	CI 95%: 97.4 – 100%
Specificity	100%	CI 95%: 90.1 – 100%

SYMBOLS

	Content for 20 assays		Expiry date
	in vitro diagnostic medical device		Catalogue reference
	Batch number		Temperature limit
	Consult instructions for use		Corrosive
	Manufacturer		



NG Biotech

Z.A. Courbouton, Secteur 1,
35480 Guipry France
Phone: +33 (0) 2 23 30 17 83
Fax: +33 (0) 9 71 70 53 10
Email: info@ngbiotech.com



*H315: Causes skin irritation; P264: Wash hands thoroughly after handling; P280: Wear protective gloves/protective clothing/eye protection/face protection; P302+P352: IF ON SKIN: Wash with soap and water; P321: Specific treatment (see First aid measures in the Material Safety Data Sheet); P332+P313 If skin irritation occurs: Get medical advice/attention; P362+P364: Take off contaminated clothing and wash it before reuse.

H318: Causes serious eye damage; P280: Wear protective gloves/protective clothing/eye protection/face protection; P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. continue rinsing; P310: Immediately call a POISON CENTER or doctor/physician.