

ANTIMICROBIAL RESISTANCE

New range of rapid tests for Antimicrobial Resistance detection from cultured colonies

NG-Test CTX-M



Rapid detection of
**Extended Spectrum
Beta-Lactamase (ESBL)
Producing enterobacteriaceae**

NG-Test CARBA 5



Rapid detection of
**Carbapenemase
Producing
enterobacteriaceae**

NG-Test MCR-1

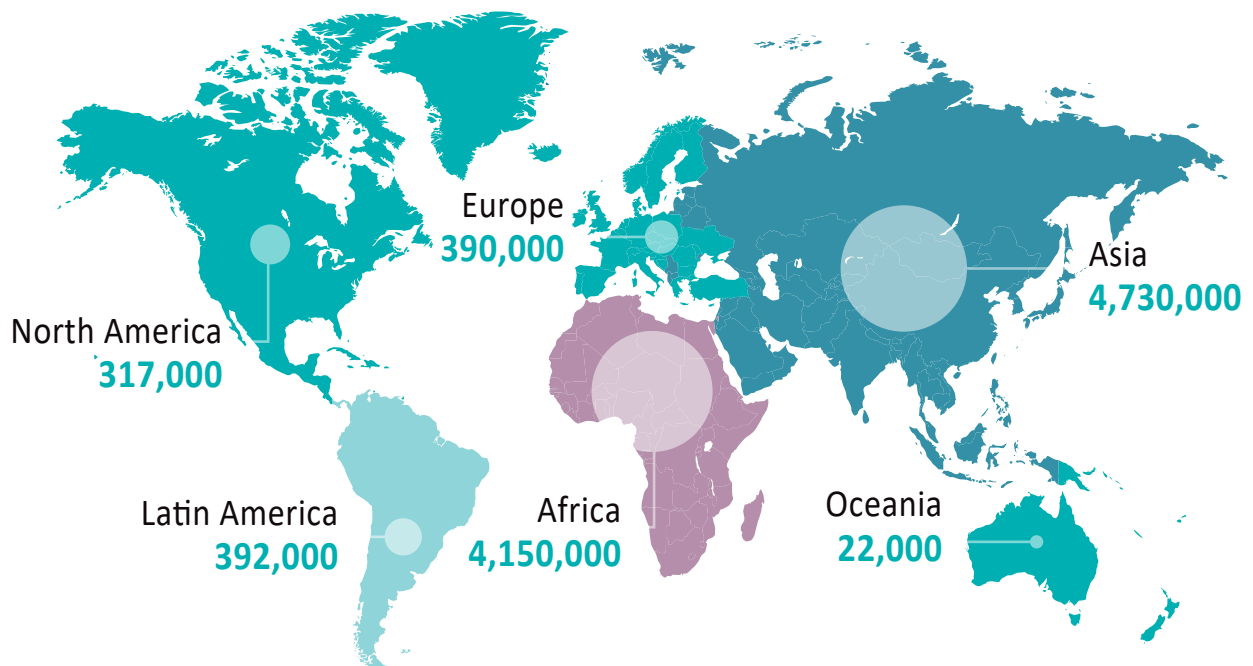


Rapid detection of
**mobilized colistin
resistance**

AMR is a Global Health Issue

- Antimicrobial Resistance (AMR) infections are increasing
- Antibiotic resistance can affect anyone, of any age, in any country.
- 700.000 people die each year globally and 25.000 in the EU & 23.000 in the US
- AMR – a major European and Global challenge (DG Santé)

Deaths attributable to antimicrobial resistance every year by 2050



Source: Review on Antimicrobial Resistance 2014

Without action, by 2050 someone could die every three seconds as a result of AMR, says the Review on Antimicrobial Resistance. That's 10 million people a year.

The majority of deaths will occur in Africa and Asia – over 4 million in each region. The estimated death toll for the rest of the world is lower, but could still reach nearly 400,000 in both Latin America and Europe.

(Source: Review on Antimicrobial Resistance 2014)

Product	Specimen	Format	Packaging	Storage	Shelf-life	Cat. Ref.
NG-Test CTX-M	Culture	Cassette	20 tests	4-30°C	24 months	NGB-CTX-S23-002

Performance Characteristics

Detection limit

The detection limit was determined using purified recombinant CTX-M-15 enzyme and evaluated at 200 pg/mL.

Validation on a reference strain bank

NG-Test CTX-M was evaluated on 175 clinical strains at the CNR of CHU Kremlin Bicêtre - Paris - France (AMR French Referent Center). LFIA validation with 175 isolates (characterized β -lactamase by PCR).

NG-Test CTX-M \ Status	Positive	Negative	Total
	Positive	70	0
Negative	0	105	105
Total	70	105	175

Sensitivity : 100%
Specificity : 100%

Confidence interval : 94,8% to 100%
Confidence interval : 96,5% to 100%

NG-Test CTX-M detects at least the following variants of group 1: CTX-M-1 / 3 / 15 / 32 / 37 / 55 / 57 / 71 / 82 / 101 and 182.

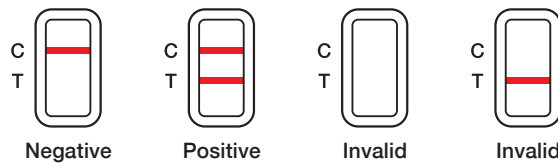
175 strains	70 strains tested positive with NG-Test CTX-M	66 strains carrying CTX-M-15 4 strains carrying variants of CTX-M (CTX-M-1 et CTX-M-3)
	105 tested negative with NG-Test CTX-M	98 strains carrying carbapenemases (SHV-11, DHA-1, ACC-1, DHA-2, ACC-1, VEB-1, OXA-163, OXA-405, OXA-9, KPC-2, KPC-3, TEM-1, IMI-1, IMI-2, etc)
		7 strains carrying variants of CTX-M (CTX-M-14, CTX-M-2, CTX-M-9, CTX-M-24)



NG-Test CTX-M



Interpretation



Product	Specimen	Format	Packaging	Storage	Shelf-life	Cat. Ref.
NG-Test CARBA 5	Culture	Cassette	20 tests	4-30°C	24 months	NGB-CAR-S23-002

Performance Characteristics

Detection limit

The detection limits were determined using purified recombinant enzymes:

NDM 150pg/mL
IMP 200pg/mL
VIM 300pg/mL
OXA 300pg/mL
KPC 600pg/mL

Validation on a reference strain bank

NG-Test CARBA 5 was evaluated on 167 clinical strains at the CNR of CHU Kremlin Bicêtre - Paris - France (AMR French Referent Center). Considering the carbapenemases targeted all the results were correlated with the genotype of the strains determined by PCR analysis.

Status \ Status	Positive	Negative	Total
Positive	116	0	116
Negative	0	51	51
Total	116	51	167

Sensitivity : 100%
Specificity : 100%

Confidence interval : 94,8% to 100%
Confidence interval : 96,5% to 100%

The NG test CARBA 5 detects at least the following variants: NDM-1 / 4 / 5 / 6 / 7 and 9

KPC-2 and 3

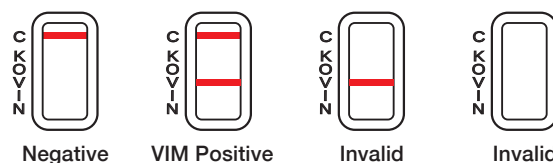
IMP-1 / 8 and 11

VIM-1 / 2 / 4 and 19

OXA-48 / 181 / 204 / 232 / 244 / 517 / 519 and 535

But also OXA-163 and OXA-405 (OXA-48-like extended spectrum oxacillinases)

Interpretation



NG-Test CARBA 5



NOTE: Multiple lines or one line on K, O, V, I, N position must be considered as a positive result

Product	Specimen	Format	Packaging	Storage	Shelf-life	Cat. Ref.
NG-Test MCR-1	Culture	Cassette	20 tests	4-30°C	24 months	NGB-MCR-S23-002



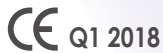
About MCR Genes, an Emerging Threat

The *mcr-1*, *mcr-2* and *mcr-3* genes cause resistance to colistin, a last-resort antibiotic used for treating resistant infections. Colistin is considered a last-resort antibiotic because while it can be used to treat patients with infections that have already developed resistance to other antibiotics it can have serious side effects. (Source: CDC).

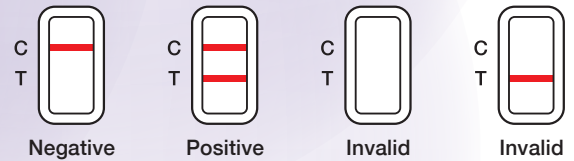
Performance Characteristics

The detection limit was determined using purified recombinant enzymes MCR detection threshold: 350 pg/mL.

NG-Test MCR-1



Interpretation



These tests were developed in collaboration with the CEA*.
*The French Alternative Energies and Atomic Energy Commission (CEA) is a key player in research, development and innovation.

General procedure for the AMR tests

