


# ANTIMICROBIAL RESISTANCE

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



**NG-Test CTX-M**

**NG-Test CTX-M MULTI**

**NG-Test CARBA 5**

**NG-Test MCR-1**

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

Rapid detection of **mobilized colistin resistance**

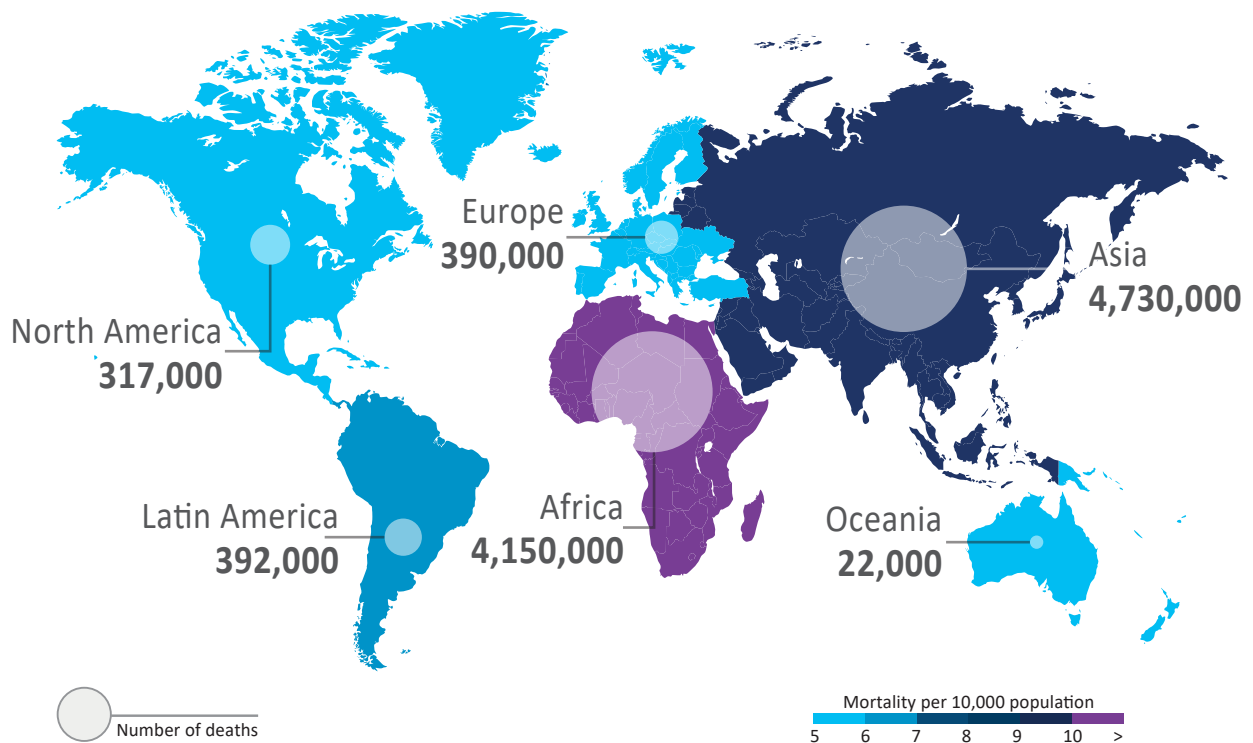
Rapid detection of **Carbapenemases**



# 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, 25.000 in the EU & 23.000 in the US\*
- AMR – a major European and Global challenge (European Commission)

## Deaths attributable to antimicrobial resistance every year by 2050



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 - <https://amr-review.org>

\* [www.oecd.org](http://www.oecd.org)

| 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 |
| NG-Test CTX-M MULTI | Culture  | Cassette | 20 tests  | 4-30°C  | 24 months  | NGB-CTM-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 NRC (AMR French National Reference Centre) of CHU Kremlin Bicêtre Paris-France. LFIA validation with 175 isolates (characterized  $\beta$ -lactamase by PCR).

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

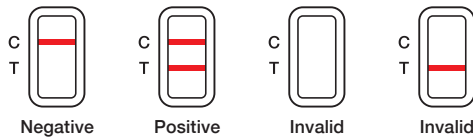
Sensitivity : 100% Confidence interval : 94,8% to 100%  
Specificity : 100% Confidence interval : 96,5% to 100%

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 -182.

NG-Test CTX-M



## Interpretation



## Performance Characteristics

### Detection limit

The detection limit was determined using purified recombinant enzymes.

Group 1 / CTX-M-15 250 pg/mL  
Group 2 / CTX-M-2 600 pg/mL  
Group 9 / CTX-M-14 100 pg/mL

### Validation on a reference strain bank

NG-Test CTX-M MULTI was evaluated on 165 isolates (PCR characterized ESBL content) at the NRC (AMR French National Reference Centre) of CHU Kremlin Bicêtre Paris-France.

| Status \ NG-Test | Positive NG-Test CTX-M MULTI | Negative NG-Test CTX-M MULTI | Total |
|------------------|------------------------------|------------------------------|-------|
| Positive result  | 149                          | 0                            | 149   |
| Negative result  | 0                            | 16                           | 16    |
| Total            | 149                          | 16                           | 165   |

Sensitivity : 100% 95% confidence interval : 97,5% to 100%  
Specificity : 100% 95% confidence interval : 80,6% to 100%

NG-Test CTX-M MULTI detects the following variants:

- Group 1: CTX-M-1, -3, -10, -15, -32, -37, -55, -57, -71, -82, -101, -182
- Group 2: CTX-M-2
- Group 8: CTX-M-8
- Group 9: CTX-M-9, -13, -14, -17, -18, -19, -24, -27, -65, -93
- Group 25: CTX-M-94, -100

NG-Test CTX-M MULTI



| 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:

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

### Clinical Evaluation

NG-Test CARBA 5 was evaluated at the NRC (AMR French National Reference Centre) of CHU Kremlin Bicêtre Paris-France during a prospective study.

116 strains were blind-tested and the results were compared to the PCR sequencing test. One IMI-producing isolate was excluded from the result analysis because this type is not in the device intended use.

| NG-test CARBA 5 | PCR      |          |       |
|-----------------|----------|----------|-------|
|                 | Positive | Negative | Total |
| Positive        | 70       | 0        | 70    |
| Negative        | 0        | 45       | 45    |
| Total           | 70       | 45       | 115   |

Sensitivity : 100% CI 95% = 93,5% - 100%  
Specificity : 100% CI 95% = 90,4% - 100%

A retrospective evaluation performed at the NRC on 180 isolates characterised by PCR permitted to identify variants detected by NG-Test CARBA 5:

Type NDM : NDM-1 -4 -5 -6 -7 -9

Type KPC : KPC-2 -3

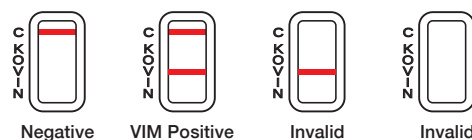
Type IMP : IMP-1 -8 -11

Type VIM : VIM-1 -2 -4 -19

OXA-48-like : OXA-48 -162 -181 -204 -232 -244 -517 -519 -535

Non-carbapenemases (cross-reactivity) : OXA-163 and OXA-405 (OXA-48-like extended spectrum oxacillinases with very weak carbapenemase activity).

## Interpretation



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

NG-Test CARBA 5



| 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 |



NG-Test MCR-1  
CE

### 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

#### Detection limit

The detection limit was determined using purified recombinant enzymes MCR detection threshold: 300 pg/mL.

#### Validation on a reference strain bank

NG-Test MCR-1 was evaluated on 44 clinical strains at NRC Kremlin Bicêtre-Paris (AMR French Reference Center), 117 clinical strains at ANSES-Lyon (National Health Security Agency) and 123 clinical strains at CNR-Clermont Ferrand. (Reference National Center).

A total of 284 strains were evaluated.

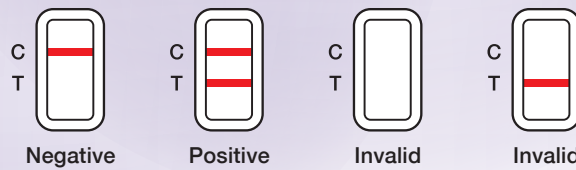
| NG-Test MCR-1 \ PCR | Positive           | Negative | Total |
|---------------------|--------------------|----------|-------|
| Positive            | 101                | 0        | 101   |
| Negative            | 3 ( <i>mcr-2</i> ) | 180      | 183   |
| Total               | 104                | 180      | 284   |

Sensitivity : 100% Confidence interval 95% : 96,3% to 100%  
Specificity : 98,3% Confidence interval 95% : 95,3% to 99,4%

Considering targeted MCR-1 enzyme, all results were correlated to the genotype of strains determined by PCR analysis.

NG-Test MCR-1 detects some MCR-2 variants.

### 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

