Rapid, mobile, connected diagnostics

NG-Test CARBA 5

KPC, OXA-48-like, VIM, IMP, NDM Carbapenemases

Detection & Characterisation

Rapid

- Results in 15 minutes
- ***From bacterial culture***
  From direct blood culture*
- Minimal hands on time

Accurate

- Excellent correlation with PCR
- Numerous studies available

User friendly

- Minimal training needs
- No equipment needed
- No maintenance costs
- Stable at room temperature

In use Worldwide in Microbiology labs and National Reference Centers

*Using NG-Test Blood Culture Prep kit

NG biotech
Next Generation

Rapid, mobile, connected diagnostics

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
NG-Test Blood Culture Prep	Culture	Vials	20 tests	20-30°C	24 months	NGP-CAR-S73-002

NG-Test CARBA 5

CE

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 Referent Center, Kremlin-Bicêtre Hospital, 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.

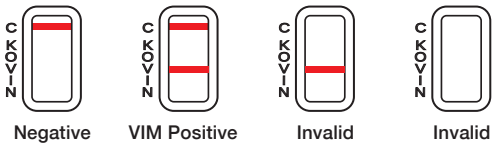
		PCR		
		Positive	Negative	Total
NG-test CARBA 5	Positive	70	0	70
	Negative	0	45	45
	Total	70	45	115

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).

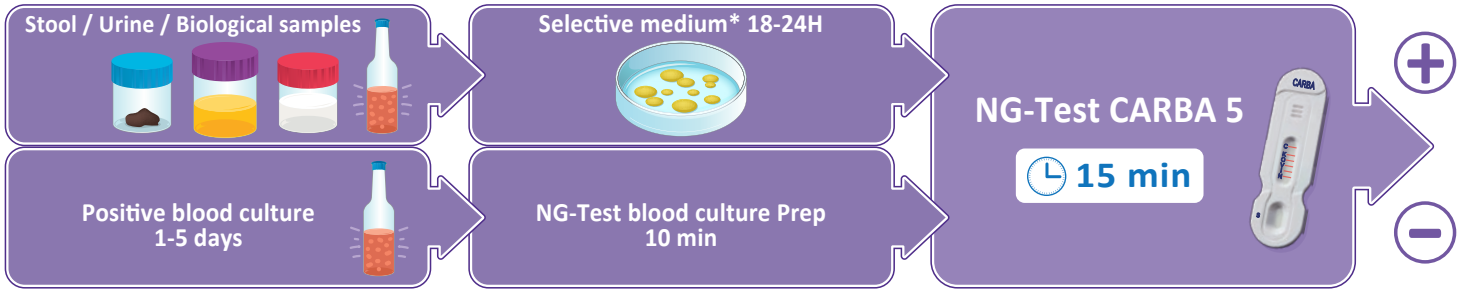
Interpretation



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

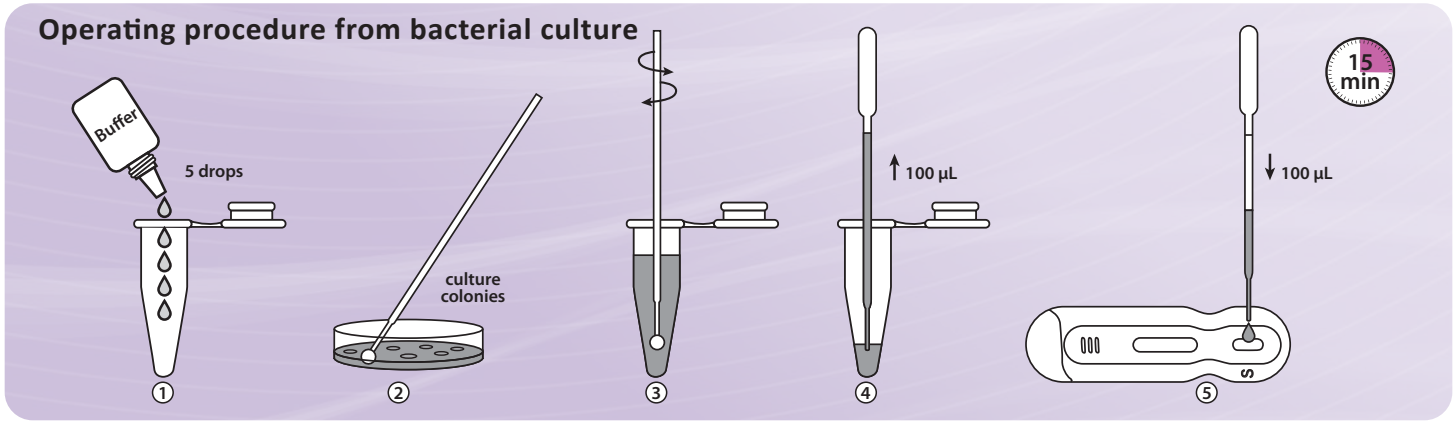
These tests were developed in collaboration with the CEA*.
*The French Alternative Energies and Atomic Energy Commission (CEA) is a key player in research, development and innovation.

IDENTIFICATION PROCESS FROM BACTERIAL CULTURE OR DIRECT BLOOD CULTURE



*Validated on: TSA, Mueller Hinton, ChromID® CARBA SMART, Drigalski (DRIG) CHROMagar™ mSuperCARBA™...etc

Operating procedure from bacterial culture



For professional in vitro diagnostic use only

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