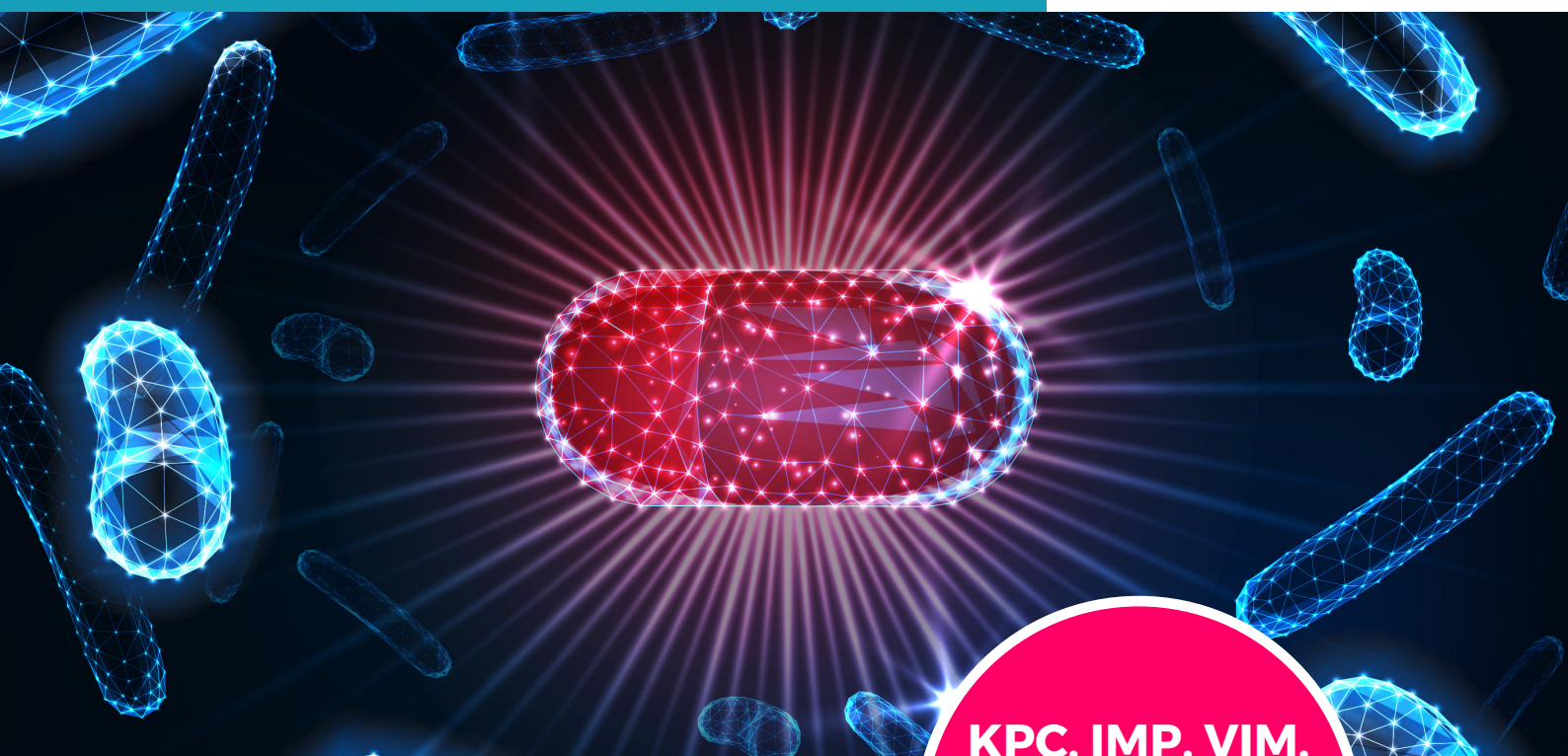# REALQUALITY Carba-Screen

Real time PCR kit for the screening and identification of genes encoding Ambler class A, B and D carbapenemases responsible for carbapenem antibiotic resistance, and colistin resistance genes.

KPC, IMP, VIM, NDM, OXA-48, AcOXA, MCR 1, 2 e 4

The test can be automated on the GENEQUALITY® X120 and GENEQUALITY® Max platforms which also allow sample tracking, integration with laboratory LIMS and minimal intervention by the operator.

For *in vitro* diagnostic use

AB
ANALITICA
ADVANCED BIOMEDICINE

ACTIVE SURVEILLANCE ANTIBIOTIC RESISTANCE

Carbapenemases are enzymes produced by microorganisms able to inactivate antibiotics that have a beta-lactam ring, including carbapenems, broad spectrum antibiotics used in the last line.

Invasive infections from **CRE** (Carbapeneme-resistant Enterobacterales) and, in particular, from **CPE** (Carbapenemase-Producing Enterobacterales) are under surveillance by the Ministry of Health in 2013, subsequently updated on 6 December 2019 (Ministerial Circular 0035470-06/12/2019-DGPRE-MDS-P of the Ministry of Health).

It is particularly important to promptly identify patients carrying pathogens with resistance genes in order to isolate them from other patients and limit the spread of associated resistances.

Colistin is used as a "last-resort" antibiotic to treat severe infections, when other antibiotics are no longer effective. In recent years, genes associated with colistin resistance, called mcr (mobile colistine resistance), have been identified. These genes are carried by plasmids and thus transmissible between different bacterial species.

It is therefore extremely important to identify the potential presence of colistin resistance genes as well.

DESCRIPTION:

REALQUALITY Carba-Screen is a kit for the detection of carbapenem resistance genes at two levels of identification, and of colistin. The kit can be used both for patient screening and as a confirmation molecular test following the phenotypic characterization of the pathogen responsible for the infection.

The kit includes a first **screening step** (Mix Carba-Screen) to identify the samples positive for class A, B, and D carbapenemases and for AcOXA genes, and a subsequent **step to identify resistance genes** (Mix Carba B and Mix Carba A + D) only in the samples resulted positive in the previous step.

1° level: Screening
Mix Carba-Screen
Class B carbapenemases
Class A+D carbapenemases
Acinetobacter OXA (OXA-23-like, OXA-24-like, OXA-51-like with promoter ISAba1, OXA-58 like)
IC

2° level: Identification				
Mix Carba B	IMP	VIM	NDM	IC
Mix Carba A+D	KPC	OXA-48	MCR 1, 2, 4	IC

PRODUCT CHARACTERISTICS:

- Validated on rectal swabs and bacterial colonies.
- Internal control (IC) based on amplification of the bacterial 16s rRNA gene.
- Includes dUTP/UNG system for contamination prevention.
- Validated instruments:
  - CFX96 Dx System/CFX96 Real-Time PCR Detection System-IVD (Bio-Rad)
  - AriaDx Real Time PCR System (Agilent Technologies)
  - Mic qPCR Cycler (Bio Molecular System)
- Available also in automatic format for GENEQUALITY® X120 and GENEQUALITY® Max platforms.

CODE	VERSION	PRODUCT	FORMAT
RQ-170-6M	C1	REALQUALITY Carba-Screen (Screening Mix)	100 tests
	C3	*REALQUALITY Carba-Screen (Identification mix)*	50 tests
RQ-170-6A	C1	REALQUALITY Carba-Screen (Screening Mix)	100 tests
	C3	*REALQUALITY Carba-Screen (Identification mix)*	50 tests

CE IVD