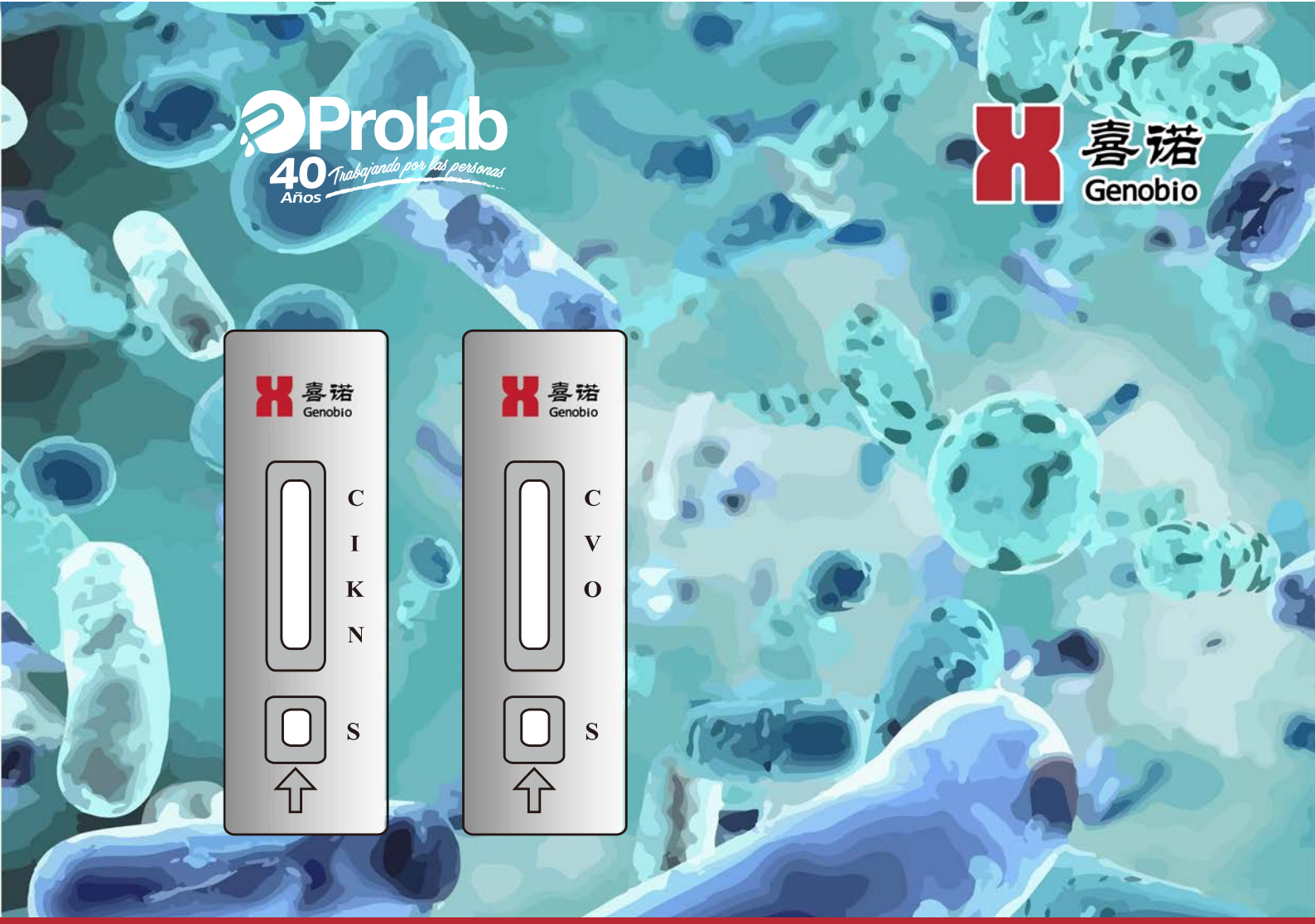


Obtain result within 15min

Carbapenem-resistant K.N.I.O.V. Detection K-Set (Lateral Flow Assay)

Product code: CP5-01

Multiple genotypes

KPC, NDM, IMP, VIM and OXA-48 in one

- Rapid
- Comprehensive
- Economic
- Simple
- Intuitive result

Overview

Carbapenem antibiotics are one of the most effective drugs to control clinical pathogenic infections. Carbapenem-resistant Enterobacter (CRE) has become a global public problem due to its broad-spectrum drug resistance, resulting in very limited treatment options for patients. In addition, the irrational use of antibiotics has continuously improved the resistance of bacteria, which has brought great troubles to clinicians in choosing antibiotics.

Carbapenemase-resistant K.N.I.O.V. Detection K-Set (Lateral Flow Assay), a rapid diagnostic product, uses sandwich immunochromatography technology to detect carbapenem-resistant genes and accurately identify genotypes, including NDM, KPC, IMP-4, VIM and OXA-48 in one product. It is of great significance for the early typing of drug-resistant strains, the guidance of medication, and the improvement of human's medical and health.

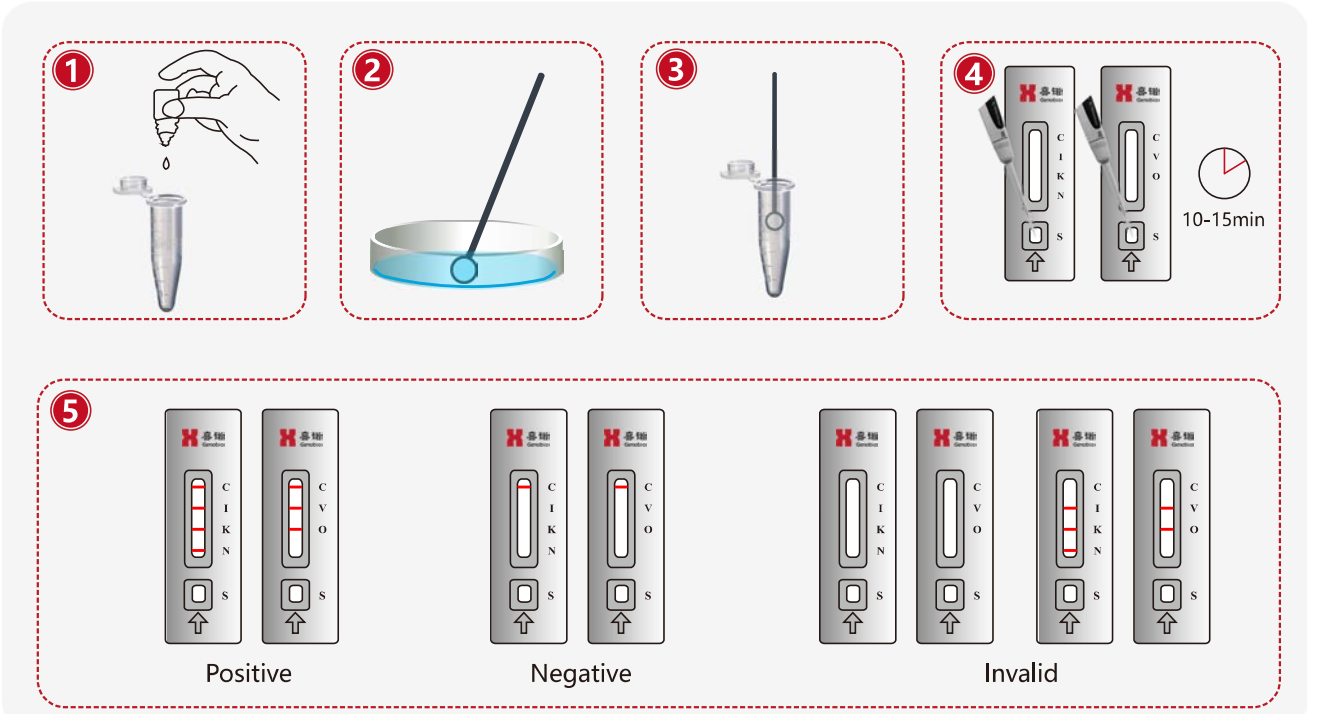
Product Types

- KPC
- NDM
- IMP-4
- VIM
- OXA-48

Product Characteristics

Basic parameters	Carbapenem-resistant K.N.I.O.V. Detection K-Set (Lateral Flow Assay)
Method	Lateral Flow Assay
Sample type	Bacterial colony
Specification	25 tests/kit
Detection time	10-15 min
Detection objects	Carbapenemase
Detection type	***KPC, NDM, VIM, IMP, OXA-48***
Stability	The K-Set is stable for 2 years at 2℃-30℃

Operation Method



- 1. Add 5 drops of sample treatment solution
- 2. Dip bacterial colonies with a disposable inoculation loop
- 3. Insert the loop into the tube
- 4. Add 50 μL to the S well of each cassette, wait for 10-15 minutes
- 5. Read the result

Features

Rapid

Obtain result within 15 min, 3 days earlier than traditional detection methods

Simple

Easy to use, ordinary laboratory staff can operate without training

Flexible

Combines KPC, NDM, IMP, VIM and OXA-48 tests together, gives a comprehensive detection of the gene types of carbapenem-resistant bacteria infected

Intuitive result

There is no need for calculation, visual reading result

Economic

Product can be transported and stored at room temperature, reducing costs

Innovation for Better Health

CONTACTO

Teléfono: 2 2661 3700
Email: prolab@prolab.cl
Web: www.prolab.cl

Health Canada ISO CE MDSAP

喜诺 Genobio Genobio Pharmaceutical Co., Ltd.
Add: 2-1,2,3-101, No.2 Zone, Binlv Industrial Park, Binhai Tourism Area, Binhai New Area, Tianjin 300480, P. R. China

Tianjin Era Biology Technology Co., Ltd.
Add: 8-1, East District, Datang Headquarters Base, Binhai-Zhongguancun Science Park,TEDA, Tianjin, China

Genobio is wholly-owned subsidiary of Era Biology Group

Carbapenem-resistant K.N.I.V.O. Detection K-Set

(Lateral Flow Assay)

Instruction for Use

(XN-CE-CP5-010 VER 1.0)

[Name]

Carbapenem-resistant K.N.I.V.O. Detection K-Set (Lateral Flow Assay)

[Specifications]

CP5-01: 25 tests/kit（Cassette format）

[Intended Use]

The Carbapenem-resistant K.N.I.V.O. Detection K-Set (Lateral Flow Assay) is an immunochromatographic test system intended for the qualitative detection of KPC-type, NDM-type, IMP-type, VIM-type and OXA-48-type carbapenems in bacterial colonies. The assay is a rapid test which can be used as an aid in the diagnosis of KPC-type, NDM-type, IMP-type, VIM-type and OXA-48-type carbapenem-resistant strains.

[Summary and Explanation]

Carbapenem antibiotics are one of the most effective drugs for the clinical control of pathogenic infections. Carbapenemase-producing organisms (CPO) and carbapenem-resistant Enterobacter (CRE) have become a global public health issue due to their broad-spectrum drug resistance, and treatment options for patients are very limited. Carbapenemase refers to a type of β-lactamase that can at least significantly hydrolyze imipenem or meropenem, including A, B, D three types of enzymes classified by Ambler molecular structure. Among them, Class B are metallo-β-lactamases (MBLs), including carbapenemases such as IMP, VIM and NDM, referred to as metalloenzyme, which were mainly found in Pseudomonas aeruginosa, Acinetobacteria and Enterobacteriaceae bacteria. Class A and D are serinase. Class A, such as KPC-type carbapenemase, have been detected primarily in Enterobacteriaceae bacteria, and Class D, such as OXA-type carbapenemase, were frequently detected in Acinetobacteria. KPC has become one of the most important contemporary pathogens, while the optimal treatment remains undefined. Infections due to KPCs are associated with high therapeutic failure and mortality rates of at least 50%. To develop rapid carbapenemase diagnostic products is of great significance for the early typing of drug-resistant strains, the guidance of medication, and the improvement of human's medical and health standards.

[Detection Principle]

The Goldstream® Carbapenem-resistant K.N.I.V.O. Detection K-Set (Lateral Flow Assay) is a sandwich immunochromatographic assay. If KPC-type, NDM-type, IMP-type, VIM-type or OXA-48-type carbapenemase are present in the specimen, then it binds to the gold-conjugated anti-KPC, anti-NDM, anti-IMP, anti-VIM or anti-OXA-48 antibodies, respectively. The gold-conjugated antibody-antigen complex continues to wick up the membrane where it will interact with the test lines, which have immobilized anti-KPC, anti-NDM, anti-IMP, anti-VIM or anti-OXA-48 monoclonal antibodies. The gold-conjugated antibody-antigen complex forms a sandwich at the test line causing a visible line to form. With proper flow and reagent reactivity, the wicking of any specimen, positive or negative, will cause the gold-conjugated antibodies to move to the control line. Immobilized goat anti-chicken IgY antibodies at the control line will bind to the gold-conjugated chicken IgY antibodies and form a visible control line. Positive test results create one or more red lines in test area. Negative test results form only control line (C line). The quality control line (C line) is an internal quality control. If the control line does not appear, the result is invalid.

[Main Components]

a: Carbapenem-resistant K.N.I.V.O Detection Cassette: 25 tests/kit
KPC/NDM/IMP Detection Cassette A: 25 cassettes
VIM/OXA-48 Detection Cassette B: 25 cassettes
b: Sample treatment solution: Phosphate buffer (containing surfactant and preservatives), 10.0 mL.
c: Positive control A: Mixed-lyophilized powder of KPC/NDM/IMP carbapenemase, 1.0 mL.
d: Positive control B: Mixed-lyophilized powder of VIM/OXA-48 carbapenemase, 1.0 mL.
Package insert: 1
Note: don't use any other components of kits from different batch number.

[Materials Required but Not Supplied]

1. Pipettes and sterile tips
2. Timer
3. Disposable sterile micro-centrifuge tubes
4. Disposable inoculation loop

[Storage Conditions and Validity]

1. Store at 2-30 ℃ in a dry and cool place for 24 months.
2. The test card should be used within 1 hour after opening the aluminum pouch.
3. The Sample treatment solution can be stored for 1 month after opening.
4. Divide reconstituted quality control into aliquots and store at -20℃.

[Sample Requirements]

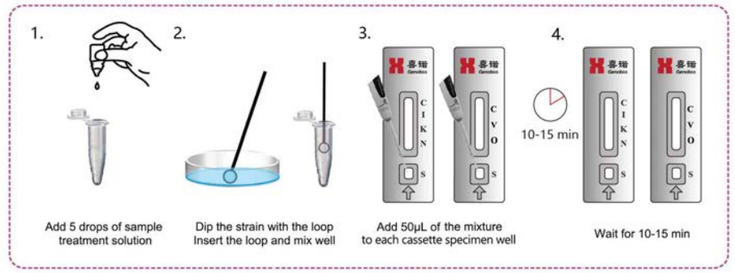
Bacterial samples should be obtained and handled by standard microbiological method before testing.

[Detection Method]

Allow the test kit and samples to reach room temperature (15-30℃) before testing. Open the pouch and take out the test cards A and B.

Qualitative Procedure

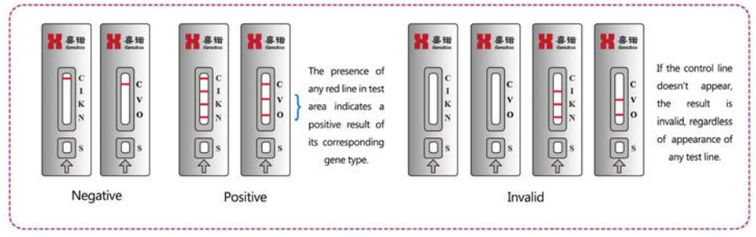
1. Add 5 drops of Sample treatment solution into an appropriate container (for example: disposable micro-centrifuge tube).
2. Take the colony with a disposable inoculation loop, dip the loop into the container.
3. Vortex to homogenise the mixture.



4. Place the Cassette A and B horizontally and add 50 μL of mixture into the sample hole, respectively.
5. Read and record the results after 10-15 minutes. (See **Reading the Test**).
6. Do not read the results after 30 minutes.

[Reading the Test]

Read the results.
Negative results: if a single red line appears in the control line region (C), it indicates a negative result.
Positive results: in addition to a red line appears in the control line region (C), the presence of one or more red lines in test area, regardless of the intensity of the test line, indicates a positive result of its corresponding gene type carbapenemase.
Invalid results: if the control line does not appear, the result is invalid and the test should be repeated.



[Quality Control]

The quality control line (C line) is internal quality control, if the quality control line does not appear, the result is invalid.
The Quality Control needs to be reconstituted before using. Open the Quality Control bottle, add 1 mL of Sample treatment solution, mix until it is completely dissolved, then test immediately. Please carry out Quality Control according to the laboratory quality control plan.

[Interpretation of Results]

1. The control line must be present for a valid test.
2. The presence of one or more red lines in test area, regardless of the intensity of the test line, indicates a positive result of its corresponding gene type.
3. Negative results do not rule out carbapenem antibiotic resistance. The sample may adopt other drug resistance pathways other than carbapenemase production.

4. This product is a qualitative detection reagent, and the color intensity of the test result cannot be used as a basis for predicting the quantity of carbapenemase in the sample.
5. Hook effect: The kit does not have a hook effect in the range of 0-1μg/mL.

[Limitations]

1. The product is only used to detect carbapenemases in bacterial culture. The assay performance characteristics have not been established for non-bacteria colony samples. The presence or absence of carbapenemase is related to bacteria, not to patients.
2. The test results of this product are for reference only and should not be used as the only basis for clinical diagnosis and treatment. The clinical management of patients should be comprehensively considered in conjunction with their symptoms or signs, medical history, other laboratory tests and treatment responses.
3. There are no known interfering substances and cross-reactive substances related to this detection reagent.

[Performance]

1. Detection limit

The Limit of Detections (LoDs) of KPC, NDM, IMP, VIM and OXA-48 are 0.50 ng/mL, 0.15 ng/mL, 0.20 ng/mL, 0.30 ng/mL and 0.10 ng/mL, respectively.

2. Clinical Study

The performance of the Carbapenem-resistant K.N.I.V.O. Detection K-Set (Lateral Flow Assay) were evaluated by comparison with a reference molecular method (a validated commercial multiplex PCR test) and a total of 1055 samples were involved in the study.

KPC-type		PCR		Total
		Positive	Negative	
Assessment reagent	Positive	69	0	69
	Negative	0	141	141
Total		69	141	210

Sensitivity=100%; (95%CI: 93.43-100%)
Specificity=100%; (95%CI: 96.70-100%)

NDM-type		PCR		Total
		Positive	Negative	
Assessment reagent	Positive	71	0	71
	Negative	0	145	145
Total		71	145	216

Sensitivity=100%; (95%CI: 93.60-100%)
Specificity=100%; (95%CI: 96.78-100%)

IMP-type		PCR		Total
		Positive	Negative	
Assessment reagent	Positive	55	0	55
	Negative	0	145	145
Total		55	145	200

Sensitivity=100%; (95%CI: 91.87-100%)
Specificity=100%; (95%CI: 96.78-100%)

VIM-type		PCR		Total
		Positive	Negative	
Assessment reagent	Positive	24	0	24
	Negative	0	185	185
Total		24	185	209

Sensitivity=100%; (95%CI: 82.83-100%)
Specificity=100%; (95%CI: 97.46-100%)

KPC-OXA-48		PCR		Total
		Positive	Negative	
Assessment reagent	Positive	25	0	25
	Negative	0	195	195
Total		25	195	220

Sensitivity=100%; (95%CI: 83.42-100%)
Specificity=100%; (95%CI: 97.59-100%)

[Warning and Precautions]

1. Carefully and completely read the instructions before performing the test.
2. Pick a single colony for detection to avoid contamination by other colonies.
3. This product is only used for in vitro diagnosis, one-time use.
4. Please read the test results within 30 minutes to avoid wrong medical interpretation.
5. Use the test card within 1 hour after opening the aluminum bag.
6. Do not use the reagent if expired.
7. Do not use the components from different batches or different types of reagents.
8. Quality control products should be used as required to avoid affecting the test results.
9. Properly dispose the specimen and used materials following the local biohazardous disposal regulation.

[Reference]

1. Cohen Stuart J, Leverstein-Van Hall MA. Guideline for phenotypic screening and confirmation of carbapenemases in Enterobacteriaceae.Int J Antimicrob Agents 2010;36:205–210.
2. Nordmann P, Poirel L. The difficult-to-control spread of carbapenemase producers among Enterobacteriaceae worldwide. Clin Microbiol Infect 2014; 20:821–830.
3. Pfaller MA, Huband MD, Mendes RE, Flamm RK, Castanheira M.2018.Invitro activity of meropenem/Vaborbactam and characterisation of carbapenem resistance mechanisms among carbapenem-resistant Entero-bacteriaceae from the 2015 meropenem/vaborbactam surveillance programme. Int J Antimicrob Agents 52:144–150.
4. Tijet N, Patel SN, Melano RG. 2016. Detection of carba-penemase activity in Enterobacteriaceae:comparison of the carbapenem inactivation method versus the Carba NP test. J Antimicrob Chemoth.

[Symbols Legend]

CE	CE MARK		KEEP DRY
⚠	CAUTION		BIOLOGICAL RISKS
	CONSULT INSTRUCTIONS FOR USE	LOT	BATCH CODE
	DO NOT REUSE	IVD	IN VITRO DIAGNOSTIC MEDICAL DEVICE
	TEMPERATURE LIMITATION		DATE OF MANUFACTURE
	MANUFACTURER	Σ	SUFFICIENT FOR
	KEEP AWAY FROM SUNLIGHT		USE BY
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		

[Manufacturer]

Genobio Pharmaceutical Co., Ltd.
Address: 2-1, 2, 3-101, No.2 Zone, Binlv Industrial Park, Binhai Tourism Area, Binhai New Area, Tianjin 300480, P. R. China
Telephone: +86 (022) 60978665
Fax: +86(022) 60978661-802
Email: marketing@era-bio.com

[Preparation and Revision Date]

2021.08.19

EC REP **Caretechion GmbH**
Niederrheinstr. 71, 40474
Duesseldorf, Germany