

KPC/IMP/NDM/VIM/OXA-48 Combo Test Kit (LFIA)



Due to the emergence, spread, and persistence of multidrug-resistant (MDR) bacteria or “superbugs”, Antimicrobial resistance (AMR) poses a serious global threat of growing concern to human, animal, and environment.

Enterobacterales are conditionally pathogenic bacteria that cause serious hospital-acquired infections. The spread of carbapenemase-producing Enterobacterales has become a major global public health threat. Carbapenems have traditionally been used to treat infections caused by broad-spectrum beta-lactamase-producing *Escherichia coli* and *Klebsiella pneumoniae* and are still considered antibiotics to be used as antibiotic of choice. At present, the common carbapenemases mainly include KPC, IMP, NDM, VIM and OXA-48 like types.

Accurate and quick detection of CRE is of great significance for clinical prevention and treatment.

Test Contents: KPC/IMP/NDM/VIM/OXA-48



Instructions for use



Diluent & Dropper



Test Cassette



Specification:
1pc/box, 20pcs/box

Shelf life:
24 months

Stored at 2°C - 30°C

Test method comparison:

Medomics Immunochromatography test	Traditional culture method
Suspected CRE- infected patient	Suspected CRE- infected patient
sample collection	sample collection
Bacterial culture	Bacterial culture
Using Medomics Carbapenemases combo rapid test	Antibiotic sensitivity test
Result in 15 minutes.	Result in 3-5 days.

OUR ADVANTAGES



Evidence-based medicine for a more accurate anti-infective treatment as soon as possible



Result in 15 minutes, without 3-5 days from antibiotic sensitive test



Simple operation, visible result, easy interpretation

Test procedure:

1

Scrape one loop of bacteria with a 1ul inoculating loop.

2

Wash off the bacteria into the tube containing the dilution buffer, repeat the above steps two times.

3

Remove the inoculating loop, cover the tube with the dropper and mix well on the vortex mixer.

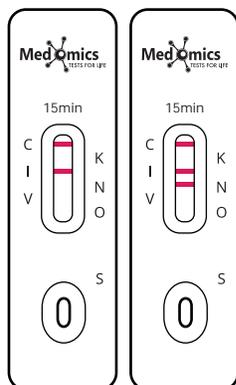
4

Add 4 drops processed sample extract into the sample well, observe the results within 15-20 minutes. Result observed after 20 minutes is invalid.

Remark: Additional required but not provided equipment: Timer, inoculating loop, culture dish and vortex mixer.

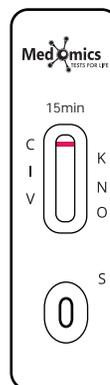
Result display:

Positive



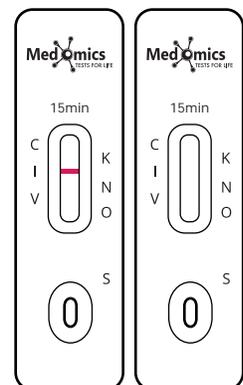
If the quality control C line appears, and one or more red lines appear on the K/N/I/V/O detection line area, indicating that the sample contains one or more Carbapenemase.

Negative



If only the quality control C line appears, and the detection K/N/I/V/O line is not visible, the sample contains no carbapenemase or its concentration is lower than the limit of detection, and the result is negative.

Invalid



If the C line doesn't appear, the result is invalid and a new test must be performed.



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Clinical result:

The clinical research was evaluated by comparing the KPC/IMP/NDM/VIM/OXA-48 Combo Test Kit (LFIA) manufactured by Jiangsu Medomics Medical Technology Co., Ltd with CARBA 5 manufactured by NG Biotech, to evaluate the clinical sensitivity and specificity of the Candidate Kit. The Clinical Test results of the test kit and the reference kit are summarized in the 2x2 table below:

		NG Biotech NDM carbapenemase test result		
Medomics NDM carbapenemase test result		Positive	Negative	Total
Positive		29	0	29
Negative		0	327	327
Total		29	327	356
*95% Confidence interval				
Sensitivity: 100.00% (88.30%~100.00%) Specificity: 100.00% (98.84%~100.00%)		PPV: 100.00% (88.30%~100.00%) NPV: 100.00% (98.84%~100.00%)		Accuracy: 100% (356/356) Kappa value: 1.0000

		NG Biotech VIM carbapenemase test result		
Medomics VIM carbapenemase test result		Positive	Negative	Total
Positive		24	0	24
Negative		0	332	332
Total		24	332	356
*95% Confidence interval				
Sensitivity: 100.00% (86.20%~100.00%) Specificity: 100.00% (98.86%~100.00%)		PPV: 100.00% (86.20%~100.00%) NPV: 100.00% (98.86%~100.00%)		Accuracy: 100%(356/356) Kappa value: 1.0000

		NG Biotech OXA-48 carbapenemase test result		
Medomics OXA-48 carbapenemase test result		Positive	Negative	Total
Positive		35	0	35
Negative		0	321	321
Total		35	321	356
*95% Confidence interval				
Sensitivity: 100.00% (90.11%~100.00%) Specificity: 100.00% (98.82%~100.00%)		PPV: 100.00% (90.11%~100.00%) NPV: 100.00% (98.82%~100.00%)		Accuracy: 100.00% (356/356) Kappa value: 1.0000

		NG Biotech IMP carbapenemase test result		
Medomics IMP carbapenemase test result		Positive	Negative	Total
Positive		21	0	21
Negative		0	335	335
Total		21	335	356
*95% Confidence interval				
Sensitivity: 100.00% (84.54%~100.00%) Specificity: 100.00% (98.87%~100.00%)		PPV: 100.00% (84.54%~100.00%) NPV: 100.00% (98.87%~100.00%)		Accuracy: 100.00% (356/356) Kappa value: 1.0000

		NG Biotech KPC carbapenemase test result		
Medomics KPC carbapenemase test result		Positive	Negative	Total
Positive		82	0	82
Negative		0	274	274
Total		82	274	356
*95% Confidence interval				
Sensitivity: 100.00% (95.52%~100.00%) Specificity: 100.00% (98.62%~100.00%)		PPV: 100.00% (95.52%~100.00%) NPV: 100.00% (98.62%~100.00%)		Accuracy: 100.00% (356/356) Kappa value: 1.0000



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