

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.

OUR ADVANTAGES



Sensitive

Lower detection limits (e.g., KPC ≤ 600 pg/ml, NDM ≤ 150 pg/ml) and demonstrates 100% sensitivity and specificity in clinical studies.



Rapid

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



Easier

Simple operation, visible result, easy interpretation

Test Kit Contents

Test kit contains test cassettes, sampling tubes containing individual dilution buffer, droppers and instructions for use. The kits are different into type A/B, type A is the kit and type B contains the blood sample pretreatment kit.

Type A:

REF	Components		Test Cassette	Dilution Buffer and Dropper	Instructions For Use
	Specification				
211045-01-01	1 pc/Box		1	1	1
211045-20-01	20 pcs/Box		20	20	1

Type B:

REF	Components		Test Cassette	Dilution Buffer and Dropper	Lysis buffer	Washing buffer	Instructions For Use
	Specification						
211045-01-061	1 pc/Box		1	1	1.5ml	1.5ml	1
211045-20-061	20 pcs/Box		20	20	25ml	25ml	1

Test Procedure-Purified strain

1

Scrape one loop of bacteria with a 1ul inoculating loop, and the scraped bacteria should be full of inoculation loop hole as far as possible.

2

Dip the loop in the bottom of the tube containing the dilution buffer. Shake the inoculating loop in order to wash off the bacteria in the tube as much as possible. If the bacteria are sticky and difficult to wash off, a vortex mixer can be used to fully wash the bacteria off the inoculation loop. Repeat the above steps to scrape 2 loops of bacteria and wash them off in the dilution buffer.

3

Remove the inoculating loop, cover the tube with the dropper and mix well on the vortex mixer.
Attention: The normalization of sampling and the adequacy of processing samples into dilution buffer directly affect the test results.

4

Open the aluminum foil pouch, take out the test cassette and lay it on a clean flat surface. Add 4 drops (approximately 100 µL) processed sample extract into the sample well. The results should be observed 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.

Test Procedure-Blood culture

- Mix 1 mL of positive blood culture and 1 mL of lysis buffer in a EP tube. Vortex for 20 seconds and centrifuge 3min at 15000rpm Discard carefully the supernatant by pipetting.
 - Re-suspend the pellet in 1 mL of washing buffer solution. Vortex for 20 seconds, and then centrifuge at 15000rpm for 3 minutes to remove the supernatant to obtain bacterial sample.
 - Drop all the dilution buffer from one piece of dropper into the tube to re-suspend the pellet. Vortex for 20 seconds.
- Sample testing: Add 100µL processed sample extract into the sample well of test cassette. The results should be observed within 15-20 minutes. Result observed after 20 minutes is invalid.

1

Positive blood culture(1-5 days)

2

5-10min

1mL of Lysis Buffer

Centrifugation then discard the supernatant

1mL of Washing Buffer

Centrifugation then discard the supernatant

100 uL

3

MegOmic

15min

C
K
I
N
V
O

X 4

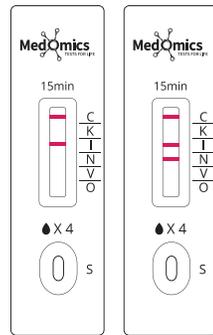
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Display of Results/Expected Values

Positive

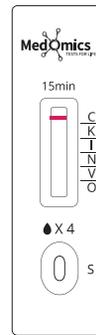
Positive result: If the quality control C line appears, and one or more red lines appear in the K, N, I, V, O detection line area, indicating that the sample contains one or more carbapenemases.

Note: The color intensity of the detection line is related to the concentration of carbapenemases in the sample, the result should be determined by whether the detection line is colored or not regardless of the color intensity.



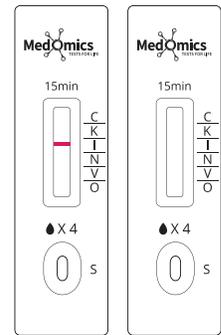
Negative

Negative result: If only the quality control C line appears, and the detection line is not visible, the sample contains no carbapenemases or the carbapenemase concentration is lower than the limit of detection, and the result is negative.



Invalid

Invalid result: If the C line does not appear, the result is invalid and a new test must be performed.



Clinical result-Purified strain

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:

Medomics NDM carbapenemase test result	NG Biotech 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	

Medomics VIM carbapenemase test result	NG Biotech 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	

Medomics OXA-48 carbapenemase test result	NG Biotech 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	

Medomics IMP carbapenemase test result	NG Biotech 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	

Medomics KPC carbapenemase test result	NG Biotech 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	

Clinical result-Blood Culture

Blood culture:

		NG Biotech NDM carbapenemase test result		
Medomics NDM carbapenemase test result		Positive	Negative	Total
Positive		17	0	17
Negative		0	165	165
Total		17	165	182
*95% Confidence interval				
Sensitivity: 100.00% (81.57% ~ 100.00%) Specificity: 100.00% (97.72% ~ 100.00%)		PPV: 100.00% (81.57% ~ 100.00%) NPV: 100.00% (97.72% ~ 100.00%)		Accuracy: 100%(182/182) Kappa value: 1.0000

		NG Biotech VIM carbapenemase test result		
Medomics VIM carbapenemase test result		Positive	Negative	Total
Positive		11	0	11
Negative		0	171	171
Total		11	171	182
*95% Confidence interval				
Sensitivity: 100.00% (74.12% ~ 100.00%) Specificity: 100.00% (97.80% ~ 100.00%)		PPV: 100.00% (74.12% ~ 100.00%) NPV: 100.00% (97.80% ~ 100.00%)		Accuracy: 100%(182/182) Kappa value: 1.0000

		NG Biotech OXA-48 carbapenemase test result		
Medomics OXA-48 carbapenemase test result		Positive	Negative	Total
Positive		16	0	16
Negative		0	166	166
Total		16	166	182
*95% Confidence interval				
Sensitivity: 100.00% (80.64% ~ 100.00%) Specificity: 100.00% (97.74% ~ 100.00%)		PPV: 100.00% (80.64% ~ 100.00%) NPV: 100.00% (97.74% ~ 100.00%)		Accuracy: 100%(182/182) Kappa value: 1.0000

		NG Biotech IMP carbapenemase test result		
Medomics IMP carbapenemase test result		Positive	Negative	Total
Positive		17	0	17
Negative		0	165	165
Total		17	165	182
*95% Confidence interval				
Sensitivity: 100.00% (81.57% ~ 100.00%) Specificity: 100.00% (97.72% ~ 100.00%)		PPV: 100.00% (81.57% ~ 100.00%) NPV: 100.00% (97.72% ~ 100.00%)		Accuracy: 100%(182/182) Kappa value: 1.0000

		NG Biotech KPC carbapenemase test result		
Medomics KPC carbapenemase test result		Positive	Negative	Total
Positive		46	0	46
Negative		0	136	136
Total		46	136	182
*95% Confidence interval				
Sensitivity: 100.00% (92.29% ~ 100.00%) Specificity: 100.00% (97.25% ~ 100.00%)		PPV: 100.00% (92.29% ~ 100.00%) NPV: 100.00% (97.25% ~ 100.00%)		Accuracy: 100%(182/182) Kappa value: 1.0000



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