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

FOR ***IN VITRO*** DIAGNOSTIC USE ONLY.
FOR PROFESSIONAL USE ONLY.

Test cassette: 1pc/bag

REF	Specification
211045-01-01	1 pc/Box
211045-20-01	20 pcs/Box

Instruction for Use

Product Name

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

Intended Use

KPC/IMP/NDM/VIM/OXA-48 Combo Test Kit (LFIA) is a colloidal gold immunochromatography for the rapid qualitative detection of KPC, IMP, NDM, VIM and OXA-48 carbapenemases in bacterial samples obtained after culture.

Summary

Antimicrobial resistance (AMR) poses a serious global threat of growing concern to human, animal, and environment health. This is due to the emergence, spread, and persistence of multidrug-resistant (MDR) bacteria or "superbugs."
Several fields of modern medicine depend on the availability of effective antibiotic drugs; chemotherapy for cancer treatment, organ transplantation, hip replacement surgery, intensive care for pre-term newborns and many other activities could not be performed without effective antibiotics. In fact, infections caused by multidrug-resistant bacterial strains are among the main factors influencing morbidity and mortality in patients undergoing these procedures.
Enterobacterales are conditionally pathogenic bacteria that cause serious hospital-acquired infections. The spread of carbapenemase-producing Enterobacterales (CPE) 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 a last resor. Carbapenemase-producing enzymes in these bacteria, which are capable of hydrolyzing all carbapenems, cephalosporins, and beta-lactams are the main cause of resistance to carbapenem antibiotics. Most carbapenemase genes are located on the metastable genetic elements, such as plasmids and integrons; thus, carbapenem resistance is easily transferred horizontally leading to rapid spread wordwide.
At present, the common carbapenemases mainly include KPC type, IMP type, NDM type, VIM type and OXA-48 type.

Test Principle

KPC/IMP/NDM/VIM/OXA-48 Combo Test Kit (LFIA) detects the five most common carbapenemase families (KPC, IMP, NDM, VIM and OXA-48) with colloidal gold immunochromatography using a double antibody sandwich assay.
When the appropriate amount of test samples treated with dilution buffer is added to the sample well of the test cassette, the sample will move forward along the test strip by capillary action. If the sample contains KPC, IMP, NDM, VIM and OXA-48 carbapenemases and the concentration is higher than the limit of detection, the antigen will form immune complexes with corresponding carbapenemase antibody labeled with colloidal gold respectively, which are captured by K line, I line, N line, V line and O line. If test sample contains KPC carbapenemase, forming a red K line, indicating a positive result for KPC carbapenemase. If test sample contains IMP carbapenemase, forming a red I line, indicating a positive result for IMP carbapenemase. If test sample contains NDM carbapenemase, forming a red N line, indicating a positive result for NDM carbapenemase. If test sample contains VIM carbapenemase, forming a red V line, indicating a positive result for VIM carbapenemase. If test sample contains OXA-48 carbapenemase, forming a red O line, indicating a positive result for OXA-48 carbapenemase.
Additionally, the test strip also contains a control line (C line). The C line should be formed to indicate that the sample has been transported properly through the membrane regardless of whether sample contains carbapenemases or not. If the C line does not appear, it indicates that the test result is invalid and the sample need to retest.

Test Kit Contents

Test kit contains test cassettes, sampling tubes containing individual dilution buffer, droppers and instructions for use.

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

• Test cassette contains test strip, plastic cassette, desiccant. The test strip contains colloidal gold-labeled anti-carbapenemase antibody, nitrocellulose membrane (C line fixed with goat-anti-mouse IgG polyclonal antibody, and T line fixed with five antibodies for KPC, IMP, NDM, VIM and OXA-48 carbapenemases.)

Storage Instructions

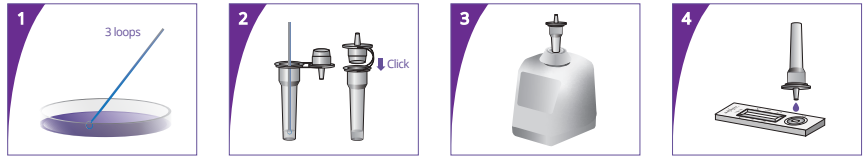
The test kit should be stored away from direct sunlight at 2℃ to 30℃ with a shelf-life of 24 months. Do not freeze.

Sample Requirements

For bacterial samples obtained after culture.

Test Procedure

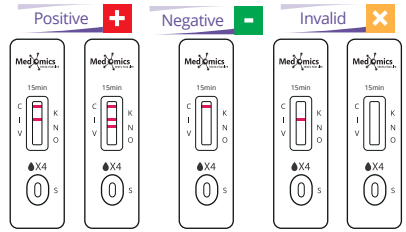
1.Scrape one loop of bacteria with a 1ul inoculating loop, and the scraped bacteria should be full of inoculation loop hole as far as possible.
2.Dip the loop in the bottom of the tube containing the dilution buffer. Shake the inoculating loop in order to wash off the bacteria in the tube as much as 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.

Display of Results/Expected Values

1. 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.
2. 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.
3. Invalid result: If the C line does not appear, the result is invalid and a new test must be performed.



Test Method Limitations

1. This product is only for qualitative testing and the specific concentration of each indicator must be measured using other quantitative methodologies.
2. This test is used to qualitatively detect KPC, IMP, NDM, VIM and OXA-48 carbapenemases in bacterial samples. A positive or negative result does not rule out the existence of other antibiotic resistance mechanisms.
3. Improper handling and use will affect the test results of the samples.

Product Performance

• Limit of Detection-LoD
Limit of Detection (LoD) studies determined the lowest detectable concentration of the five carbapenemases which ≥95% of all (true positive) replicates test positive.
The LoD of KPC type is not more than 600pg/ml; the LoD of IMP type is not more than 200pg/ml; the LoD of NDM type is not more than 150pg/ml; the LoD of VIM type is not more than 150pg/ml; the LoD of OXA-48 type is not more than 300pg/ml.
• Cross Reactivity
Cross reactivity and potential interference of KPC/IMP/NDM/VIM/OXA-48 Combo Test Kit (LFIA) were evaluated by testing microorganisms in the absence or presence of Carbapenemase-producing bacteria. The listed items in the following table may be present in the clinical samples. Each of the bacteria was tested in triplicate with no false positive results.

Potential Cross-Reactant	Concentration Tested	Cross-Reactivity (Yes/No)
E.coli	1.0×10^6CFU/mL	No
Klebsiella pneumoniae	1.0×10^6CFU/mL	No
Enterobacter cloacae	1.0×10^6CFU/mL	No
Pseudomonas aeruginosa	1.0×10^6CFU/mL	No
Acinetobacter baumannii	1.0×10^6CFU/mL	No
Staphylococcus aureus	1.0×10^5CFU/mL	No

• Interfering Substances Effect
A study was performed to evaluate and demonstrate that the endogenous substances naturally present or drugs that may be artificially introduced into clinical samples do not inference with the detection of carbapenemases in the Medomics KPC/IMP/NDM/VIM/OXA-48 Combo Test Kit (LFIA) at the concentrations listed below. Test the listed items in the absence or presence of Carbapenemase-producing bacteria.

Potential Interfering Substances	Concentration	Cross-Reactivity (Yes/No)
Culture medium	100mg/mL	No
Whole Blood	50μL/mL	No
Saliva	50μL/mL	No
Urine	50μL/mL	No
Meropenem	10μg/mL	No
Imipenem	10μg/mL	No
Doripenem	10μg/mL	No
Ertapenem	10μg/mL	No
Ceftriaxone	500μg/mL	No

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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 2×2 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	

Warnings and Precautions

1. Please read the manual carefully before operation, and please test in strict accordance with the requirements of the manual.
2. This test kit is used for in vitro diagnosis only.
3. This test kit should be used within 1 hour after opening the foil pouch.
4. When preparing the bacterial solution, pay attention to selecting a single colony to avoid contamination by miscellaneous bacteria.
5. The test results of this kit are for clinical reference only and are not the sole basis for clinical diagnosis. The clinical diagnosis and treatment of patients should be comprehensively considered in combination with their symptoms/signs, medical history, other laboratory tests and treatment response.
6. This product is for one-time use, please do not reuse.
7. Do not use if damaged.
8. After the test, the used test cards, etc. should be disposed of as medical waste.

Reference

1. Jose M. Munita and Cesar A. Arias. Mechanisms of Antibiotic Resistance. Microbiol Spectrum. 2016 April ; 4(2).
2. Yu-LinLee, et al. Carbapenemase-producing Enterobacterales infections: recent advances in diagnosis and treatment. International Journal of Antimicrobial Agents. Volume 59, Issue 2, February 2022, 106528

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IVD *In Vitro* Diagnostic Medical Device | LOT Batch code | REF Catalogue Number | STERILE EO Sterilized using ethylene oxide | EC REP Authorized representative in the European Community | Do Not Re-use | Do not use if package is damaged | Caution | Contains sufficient for <n> tests | Consult instructions for use | Use-by date | Date of manufacture | Manufacturer | Temperature limit | This way up | Fragile, handle with care | Stacking Limit By number | Keep away from sunlight | Keep dry