Read this Instructions for Use carefully before use

For Research Use Only

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MIZUHO MEDY Co., Ltd.

Carbapenemase Detection Reagent

Quick Chaser CARBA RESIST-6 RUO

[Introduction]

Carbapenemases are enzymes produced by certain Gram-negative bacteria that hydrolyze a broad range of *β*-lactam antimicrobial agents, including carbapenems. Carbapenemase genes may be horizontally transferred across bacterial species via plasmids, raising concerns regarding the spread of infection both within and outside healthcare facilities. Therefore, prevention of the dissemination of carbapenemase-producing organisms is an important issue in antimicrobial therapy and infection control.

Carbapenemase-producing organisms are primarily associated with Enterobacterales, *Pseudomonas aeruginosa*, and *Acinetobacter* species. Among these, carbapenemase-producing Enterobacterales (CPE) are recognized as one of the causative agents of carbapenem-resistant Enterobacterales (CRE) infections. In Japan, CRE infections have been designated as Category V Infectious Diseases since 2014. Currently, the IMP type is the predominant CPE genotype in Japan; however, the prevalence of KPC and NDM types, which are more common in Europe and North America, has also been increasing[1]). While these organisms may exhibit high-level resistance to multiple antimicrobial agents, including carbapenems, some "stealth-type" strains (e.g., IMP-6, OXA-48-like, and GES-5) may show relatively low minimum inhibitory concentration (MIC) values, necessitating careful interpretation and differentiation.

"Quick Chaser CARBA RESIST-6 RUO" is a research-use-only reagent based on the principle of immunochromatography that enables rapid and specific detection of six major carbapenemase types (IMP, KPC, OXA-48-like, VIM, NDM, and GES) using cultured isolates as test specimens through a simple testing procedure.

[General precautions]

1) This product is intended for research use only and must not be used for any other purpose.
2) Performance of this product is not guaranteed for any use other than those described in the Instructions for Use.

[Contents]

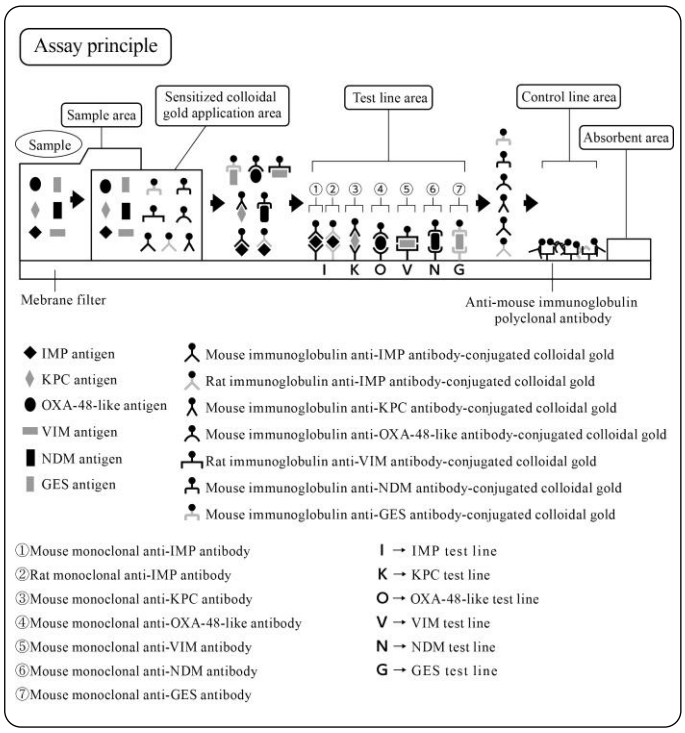
1) Test plate – 5 tests/kit
   - Mouse monoclonal anti-IMP antibody
   - Rat monoclonal anti-IMP antibody
   - Mouse monoclonal anti-KPC antibody
   - Mouse monoclonal anti-OXA-48-like antibody
   - Mouse monoclonal anti-VIM antibody
   - Mouse monoclonal anti-NDM antibody
   - Mouse monoclonal anti-GES antibody
   - Colloidal gold-conjugated mouse monoclonal anti-IMP antibody
   - Colloidal gold-conjugated rat monoclonal anti-IMP antibody
   - Colloidal gold-conjugated mouse monoclonal anti-KPC antibody
   - Colloidal gold-conjugated mouse monoclonal anti-OXA-48-like antibody
   - Colloidal gold-conjugated rat monoclonal anti-VIM antibody
   - Colloidal gold-conjugated mouse monoclonal anti-NDM antibody
   - Colloidal gold-conjugated mouse monoclonal anti-GES antibody
2) Extraction reagent solution – 7 mL×1 bottle
   Extraction reagent solution is buffer containing detergent.
3) Sample preparation tube – 5 pieces
4) Swab – 5 pieces

[Intended use]

Detection of carbapenemases (IMP, KPC, OXA-48-like, VIM, NDM, and GES types) in cultured isolates.

[Principle of the test]

"Quick Chaser CARBA RESIST-6 RUO" is a research-use-only reagent for the detection of six types of carbapenemases (IMP, KPC, OXA-48-like, VIM, NDM, and GES) in cultured isolates based on the principle of immunochromatographic assay.
Within the test plate, each sensitized colloidal gold application zone on the membrane filter is coated with monoclonal antibody-conjugated colloidal gold that specifically recognizes each of the six carbapenemases. In addition, the test (detection) lines on the membrane are immobilized with monoclonal antibodies specific to each carbapenemase type, while the control line is immobilized with anti-mouse immunoglobulin antibodies for control purposes. When one or more carbapenemases are present in the specimen, the carbapenemase antigens in the sample migrate from the sample application area and react with their corresponding monoclonal antibody-conjugated colloidal gold. The resulting complexes are captured at the respective test lines, leading to the appearance of red-purple lines due to colloidal gold labeling. Colloidal gold-conjugated antibodies that are not captured at the test lines are subsequently bound by anti-mouse immunoglobulin antibodies at the control line. As a result, the control line changes from blue to red-purple regardless of the presence or absence of carbapenemases in the specimen.



[Operational precautions]

1) Colonies collected for testing should be prepared according to the specified sample preparation procedure and used as soon as possible after preparation.
2) The specified sample volume (100 µL) must be applied. Use of volumes other than the specified amount may result in inaccurate test results or interpretation.
3) Allow the test plate and extraction solution to equilibrate to 15–30°C before use.
4) Strictly observe the specified interpretation time, as failure to do so may result in false-positive or false-negative results.
5) Interfering substances and interfering agents
   The following substances were tested at the concentrations indicated below, and no effect on the test results of this product was observed.
   Culture Media
   Sheep Blood Agar Medium (214mg/mL)
   Mueller-Hinton Agar Medium (214mg/mL)
   Tryptic Soy Agar (TSA) Medium (214mg/mL)
   BTB Agar Medium (214mg/mL)
   MacConkey Agar Medium (214mg/mL)
   β-Lactamase Inhibitors
   Boronic Acid Solution (14.3µL/mL)

Sodium Mercaptoacetate (SMA) (0.143mg/mL)

Antimicrobial Agents

Meropenem (MEPM) (14.3μg/mL)

Cefmetazole (CMZ) (42.6μg/mL)

Ceftazidime (CAZ) (42.9μg/mL)

6) Cross-reactivity

No cross-reactivity was observed with the following β-lactamases other than the target β-lactamases, or with bacterial species exhibiting intrinsic resistance to β-lactam antimicrobial agents.

β-Lactamases (non-target)

Ambler Class

Class A: SHV-1 type, CTX-M-55 type

Class B: DIM-1 type

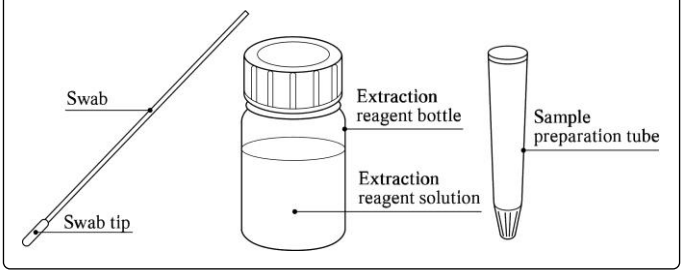
Class C: AmpC type

Bacteria

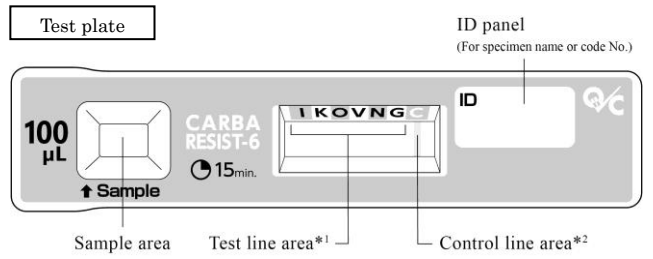
Aeromonas hydrophila, Stentrophomonas maltophilia

[Sample preparation and test procedure]

●Details of accessories



●Details of test plate

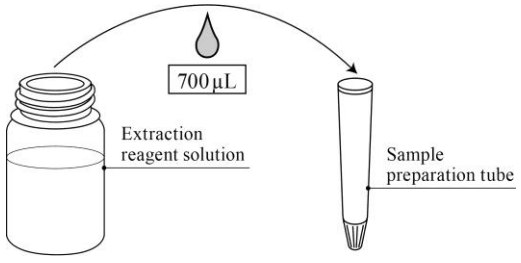


※1 I (IMP), K (KPC), O (OXA), V (VIM), N (NDM), G (GES)

※2 A blue line appears at the control line area before testing and turns reddish-purple as the sample flows through the membrane.

●Sample preparation

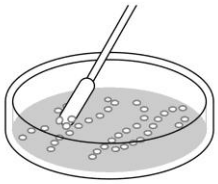
1. Dispense 700 μL of the extraction solution from the extraction solution bottle into the sample preparation tube.

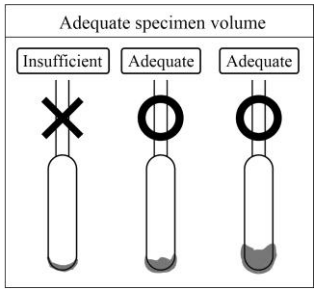


2. Collect several colonies grown on the culture medium using the swab tip.

* To minimize interference from the culture medium, avoid transferring agar into the extraction solution when collecting colonies.

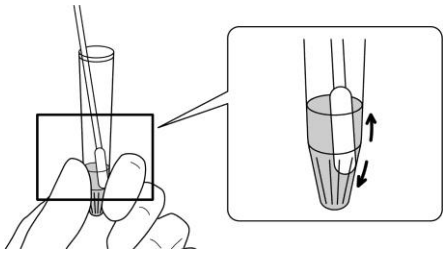
* Collect an appropriate amount of colonies as shown in "Adequate specimen volume" below. Insufficient sample volume may result in false-negative results.





3. Insert the swab tip containing the collected colonies to the bottom of the sample preparation tube. While gently pressing the swab tip from outside the tube, rotate the swab approximately 5 times and rub it against the side and bottom of the tube. Squeeze the liquid from the swab tip before removing the swab.

*When an appropriate amount of colonies is collected and suspended in the extraction solution, the turbidity of the suspension will be approximately McFarland standard 4–5.



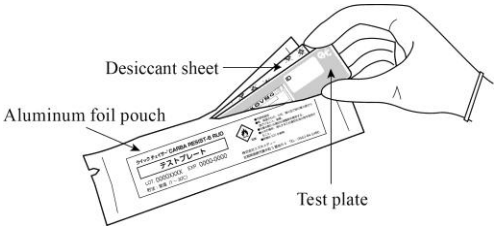
●Test procedure

1) Preparation of reagent

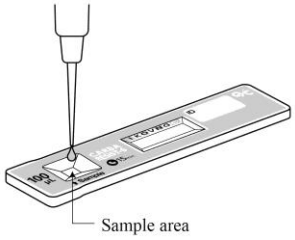
Test plate: No prior preparation required.

2) Test procedure

1.Remove the test plate from the aluminum foil pouch. Discard the desiccant sheet included in the aluminum foil pouch.



2.Using a pipette, apply 100 μL of the prepared sample from the sample preparation tube to the sample area of the test plate, taking care not to touch the pipette tip to the sample port.



3) Leave to react at 15 to 30 ℃

After 15 minutes, visually interpret the results based on the appearance of lines in each test line area and the color change of the control line (blue to reddish-purple).

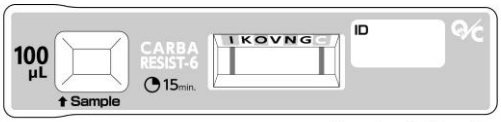
[Interpretation]

Interpret the results based on the appearance of reddish-purple lines in each test line area and the color change of the control line from blue to reddish-purple.

〈Positive〉

Interpret as positive when a reddish-purple line appears in one or more test line areas and the control line changes from blue to reddish-purple.

Positive



*Example of IMP positive

〈Negative〉

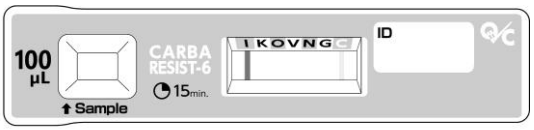
Interpret as negative when no line appears in the test line areas and the control line changes from blue to reddish-purple.

Negative

〈Retest〉

If the control line does not change from blue to reddish-purple, procedural errors such as insufficient sample volume may have occurred. Review the procedure and repeat the test using a new test plate. If the same result is obtained upon retesting, use an alternative method for testing.

Retest



Retest

●Limitations

1) Read results exactly at 15 minutes. Before this time, transient streak-like lines may appear due to colloidal gold migration; such lines should not be interpreted as test lines. After the specified reading time, drying of the test plate may cause line-like artifacts; therefore, strictly observe the recommended interpretation time.
2) A negative result does not rule out the presence of carbapenemase-producing organisms.
3) Results should be interpreted comprehensively in conjunction with other test findings.
4) Multiple subcultures of isolated strains may lead to false-negative results.

[Performance characteristics]

Seventy-four cultured and isolated strains were evaluated using this product, a commercially available immunochromatographic assay, and PCR.

Comparison with the commercial immunochromatographic assay

All results were consistent for 60 strains, excluding GES-type–positive strains.

Quick Chaser CARBA RESIST-6 RUO

Other product	Positive	Negative	Total	
Positive	51	0	51	Positive agreement rate: 100%(51/51)
Negative	14*1	9	23	Negative agreement rate: 39.1%(9/23)
Total	65	9	74	Total agreement rate: 81.1%(60/74)

*1 Of the 14 specimens that were positive with this product and negative with the other product, all were confirmed as GES-type positive by PCR.

Comparison with the PCR method

The types of carbapenemases identified as positive by this product were fully consistent with those determined by PCR.

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PCR method	Positive	Negative	Total	
Positive	62	0	62	Positive agreement rate: 100%(62/62)
Negative	3*2	9	12	Negative agreement rate: 75.0%(9/12)
Total	65	9	74	Total agreement rate: 95.9%(71/74)

*2 Of the three specimens that were positive with this product and negative by PCR, all were positive using a commercial immunochromatographic assay, and next-generation sequencing confirmed the presence of IMP-type carbapenemase genes (IMP-7, IMP-44, and IMP-49).

The following carbapenemase types and subtypes have been confirmed to be detectable using actual bacterial strains.

IMP	IMP-1,6,7,10,11,34,43,44,49
KPC	KPC-2,3,18
OXA-48-like	OXA-48,163,181
VIM	VIM-1,2,6,60
NDM	NDM-1,3,4,5,8,9,12
GES	GES-4,5,15,24,26

[Precautions for use and handling]

1) Precautions for handling (prevention of danger)
   1. Clinical specimens may contain infectious agents. Handle all specimens as potentially biohazardous materials and exercise appropriate caution during testing.
   2. When handling this product, wear appropriate personal protective equipment (PPE), including protective eyewear, disposable gloves, and masks. Avoid direct contact of specimens or extraction reagents with skin and eyes.
   3. If specimens or extraction reagents accidentally come into contact with the eyes or mouth, immediately rinse thoroughly with water and seek medical attention if necessary.
   4. Specimen collection should be performed under the guidance of adequately trained personnel.
   5. The membrane used in the test plate is made of nitrocellulose. As nitrocellulose is highly flammable, do not perform the procedure near open flames or other ignition sources.
   6. If specimens are spilled, wipe the affected area thoroughly using disinfectant alcohol or an equivalent disinfectant solution.
   7. Specimens and any materials or instruments that come into contact with specimens should be handled with appropriate caution due to the risk of secondary infection.
2) Precautions for use
   1. This product is intended for research use only (RUO). It must not be used for the diagnosis, treatment, or prevention of disease.
   2. GES-type β-lactamases include both carbapenemase-type and ESBL-type variants. This product detects these variants on the same test line without differentiation. Identification of carbapenemase-type GES genes requires genetic analysis methods such as PCR. In this Instructions for Use, GES variants containing the G170N or G170S mutation are defined as carbapenemase-type GES, whereas all other variants are defined as ESBL-type GES.
   3. Store the reagents according to the specified storage conditions and do not freeze. Frozen reagents may undergo quality deterioration and may not yield accurate results.
   4. Do not use reagents beyond their expiration date.
   5. Use only the extraction reagent supplied with this kit. Do not use extraction reagents from other kits.
   6. Use the test plate immediately after opening the aluminum pouch. Prolonged exposure to ambient conditions may cause moisture absorption and lead to improper test performance.

7. Do not touch the sample area, test line area, or control line area of the test plate directly.
8. To avoid interference with specimen flow, do not perform the assay in areas exposed to direct airflow, such as beneath air conditioning vents or fans.
9. Reagents and accessories provided with this product are intended solely for use with this assay and must not be used for any other purpose.
10. The test plate, swab, and sample preparation tube are for single use only. Do not reuse.
11. Use only the swabs supplied with this kit.
12. Do not touch the tip of the swab prior to use.
13. When removing the swab after specimen preparation, take care to avoid splashing of the sample.
14. Excessive specimen volume or highly viscous specimens may cause clogging, resulting in improper sample flow and potentially causing false-positive or false-negative results. In such cases, collect a new specimen and repeat the test. If clogging still occurs, prepare a new extract and dilute the specimen approximately 2- to 3-fold with the extraction reagent before testing. When using diluted specimens, follow the assay procedure as described in this Instructions for Use.

3) Precautions for waste disposal
1. Handle liquid waste and used utensils by any of the following disinfection and sterilization methods as sample (specimen) may contain infectious material such as HIV, HBV, and HCV, etc.
   a) Immerse in sodium hypochlorite solution (effective chlorine concentration of 1,000 ppm) for 1 hour or longer
   b) Immerse in 2% glutaraldehyde solution for 1 hour or longer
   c) Autoclave at 121°C for 20 minutes or longer
2. When disposing of reagents, consumables, and related materials, handle and dispose of them in accordance with applicable laws and regulations concerning waste management, public sanitation, and water pollution control.

[Storage·Expiry]

・Storage : 1-30℃
・Expiry : 12months from the date of manufacture
(As indicated on the product box and packaging)

[Reference]

1) Infectious Agents Surveillance Report (IASR), Vol. 45, pp. 129–130, July 2024 Issue

Technical information
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