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MAST® CARBA PAcE

PACE-ID

Intended Use

For the rapid detection of carbapenemase producing Enterobacteriales, *Pseudomonas*, OXA 48 and 23-like enzyme production in *Acinetobacter*.

FOR IN VITRO DIAGNOSTIC USE ONLY

Contents

- **Vial PEL.** Freeze dried pellet* - 4 vials containing inhibitors and lysis components, each designed for 12 tests.
- **Vial RB.** Reconstitution buffer* - 4 vials containing chromogenic indicator resuspension buffer, each sufficient for 12 tests.
- Plastic 0.5 mL tubes, sufficient for 48 tests.

Storage and shelf life

Store at 2 to 8°C in the containers provided until the expiry date shown on the pack label. Allow to equilibrate to room temperature before opening. Once reconstituted, test solution stored at 2 to 8°C, must be used within 4 weeks.

Precautions

For *in vitro* diagnostic use only. Observe approved biohazard and aseptic techniques. To be used by only trained and qualified laboratory personnel. Sterilise all biohazard waste before disposal. Refer to product safety data sheets.

Materials required but not provided

Standard microbiological supplies and equipment such as loops, MAST Group Ltd. culture media, table top vortexes, pipettes, incinerators and incubators, etc.

Procedure

1. Reconstitute the pellet by tipping the entire contents of vial RB into vial PEL.
2. Allow the pellet to fully dissolve at room temperature for 1 minute and mix contents by gently vortexing for 10 seconds. Reconstituted solution should be yellow, if the solution is any other colour do not use.
3. Dispense 250 µL of reconstituted solution into the tubes provided. One tube per test.
4. Using a pure, fresh culture of the test organism, take an approximate 1 to 5 µL loopful of organism, and add to the tube containing test solution. Mix well by vortexing for 20 seconds.

Note: to obtain distinct results, ensure that the bacterial resuspension is similar to the turbidity of a 3.0 to 3.5 McFarland standard; Approx. 10⁹ CFU/mL.

5. Incubate at 35±1°C for 10 minutes.
6. Record the colour of the test solution immediately or up to 20 minutes after incubation.

Please refer to corresponding steps on the image page.

Interpretation of results

If a colour change is recorded; from yellow to orange/red, record the organism as demonstrating carbapenemase activity.

If no colour change is recorded; solution remains yellow, record the organism as negative for carbapenemase activity.

Quality control

Check for signs of deterioration. Quality control must be performed with at least one organism to demonstrate a positive reaction and another to demonstrate a negative reaction. Do not use the product if the reactions with the control organisms are incorrect. The list below illustrates a range of performance control strains which the end user can easily obtain.

Test Organism	Result
<i>Acinetobacter baumannii</i> NCTC 13301	Orange/Red Carbapenemase positive
<i>Pseudomonas aeruginosa</i> NCTC 13437	Orange/Red Carbapenemase positive
<i>Acinetobacter lwoffii</i> ATCC® 15309	Remains Yellow Carbapenemase negative
<i>Pseudomonas aeruginosa</i> ATCC® 25668	Remains Yellow Carbapenemase negative
<i>Klebsiella pneumoniae</i> NCTC 13438	Orange/Red Carbapenemase positive

Limitations

1. Colonies isolated from indicator media are not recommended.
2. This product only detects the presence of a carbapenemase, differentiation can be carried out by using a suitable genotypic or phenotypic test (for example MASTDISCS® *Combi Carba Plus*; D73C).
3. Some GES-type carbapenemases might be difficult to detect.
4. To avoid potentially erroneous results, ensure that equipment used for testing is free of contamination.
5. Test results must be recorded within 20 minutes following the initial 10 minute incubation.
6. Results obtained with this kit must be considered alongside other clinically relevant data when diagnosing an infection.

References

Bibliography available on request.

Acknowledgement

HMRZ compound used in this product was developed by Dr. Hideaki Hanaki of Kitasato, Institute, Japan.



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