

EZER™ OXA-23 Carbapenemase Rapid Test

INTENDED USE

The EZER™ OXA-23 Carbapenemase Rapid Test is an immunochromatographic assay (ICA) for the qualitative detection of OXA-23 carbapenemases in bacterial culture. It's an *in vitro* diagnostic test for professional use only.

BACKGROUND

Acinetobacter spp. are important opportunistic pathogens, and *Acinetobacter baumannii* is the species predominantly found in infections. Virtually any body site can be affected in compromised patients, but the organism is particularly associated with nosocomial invasion of burn wounds, pneumonia, bacteremia, postneurosurgical meningitis, and infections of the urinary tract. Treatment is often complicated by multiresistance¹. Carbapenem resistance in *Acinetobacter spp.* is mostly mediated by carbapenemases belonging to Amber class D. The carbapenem-hydrolyzing class D β -lactamases (CHDLs), also called oxacillinases (OXAs), are the most commonly reported carbapenem resistance determinants in *Acinetobacter spp.*, particularly in *A. baumannii*^{2,3}. Among the OXAs, OXA-23 stands as the predominant carbapenem resistance determinant in isolates of *A. baumannii*⁴.

Currently, definitive identification of OXA-23 depends on molecular amplification assays and DNA sequencing, which are costly procedures that can only be carried out in specialized settings by skilled personnel, thereby restricting their broader application.

OXA-23 Carbapenemase Rapid Test is an *in vitro* rapid and visual multiplex immunochromatographic assay that detects OXA-23 carbapenemase in bacterial colonies, ensures effective treatment of patients and prevention of spread of OXA-23 *Acinetobacter spp.*, especially in hospitals.

PRINCIPLE

The test is ready to use and is based on a membrane technology with colloidal gold nanoparticles. Our kit is aimed to the detection of OXA-23 carbapenemases in bacterial culture.

Nitrocellulose membrane is sensitised with OXA-23 monoclonal antibody ("T" line) and control capture reagent ("C" line).

Monoclonal antibody that individually recognize OXA-23

carbapenemases label with colloidal gold and dried on a membrane.

When the provided buffer containing the resuspended bacteria comes into contact with the strip, the solubilized antibody-colloidal gold conjugates migrate with the sample by passive diffusion, while conjugates and sample material come into contact with the immobilized OXA-23 antibody that are adsorbed onto the nitrocellulose strip. If the sample contains an OXA-23 carbapenemase, the complexes made of the conjugates and OXA-23 will remain bound to their "T" lines. The migration continues by passive diffusion and both conjugates and sample material come into contact with the (upper) line control reagent that binds a control conjugate ("C" line), thereby producing a red line. The result is visible within 15 minutes in the form of red lines on the strip.

CONTENTS

Test Device (20 Pcs)

Extraction Tube with Buffer (20 Pcs)

Package Insert (1 Pc)

Warnings and Precautions

1. For *in vitro* Diagnostic Use.
2. All the operations must be carried out according to good laboratory practices.
3. Do not use kit components beyond the expiration date.
4. The test plate should be used immediately after opening the packaging. When it absorbs moisture, the quality deteriorates and an accurate result cannot be obtained.
5. Please do not touch the sample drop and the judgment part of the test board directly by hand.
6. Do not reuse the device.
7. The color tone of the line may vary depending on the color tone and specimen properties. However, the test result is valid as long as a red line is present.
8. If the test is invalid, one should consider the possible improper handling, inaccurate operation procedure, or device quality. Repeat the test with a new device ensuring that the test procedure has been followed accurately.
9. After use, discard the device in an infectious waste container.

STORAGE CONDITIONS

Test devices must be stored at 2~30°C. **DO NOT FREEZE.**

CULTURE AND SAMPLING

Samples to be tested should be obtained and handled by standard microbiological procedures.

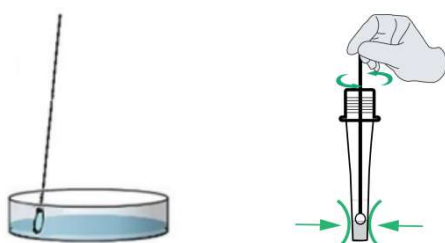
PROCEDURE

Bring the kit components to room temperature.

With bacterial colonies, we recommend the use of fresh bacterial colonies for optimal test performance.

1. Sample Extraction

(1) From the agar culture, touch 3 colonies with a 1 µL loop, and then suspend it in the extraction tube containing the buffer. The entire bacterial colony must be suspended into the buffer.



(2) Screw the cap on the extraction tube.

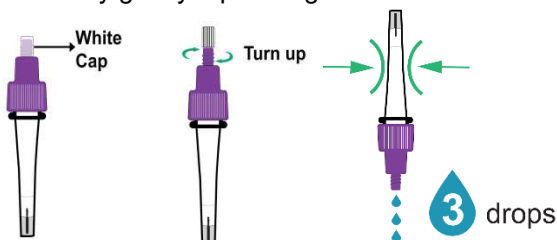
(3) Vortex to homogenize the mixture before use.



2. Test Reaction

(1) Open the pouch, and take out the device. Once opened, use the test immediately.

(2) Open the top cap of the extraction tube, invert extraction tube and add 3 drops (80µL) of test sample into sample well by gently squeezing extraction tube.

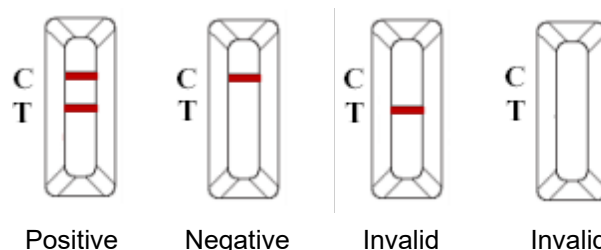


(3) Read results at 15 minutes and disregard after 30 minutes. A positive result may be visible at 3 minutes. However, the complete reaction time of 15 minutes is required to confirm a negative result.

INTERPRETATION OF RESULTS

Allow the samples to react according to the procedure and read the red lines that appear in the reading area.

The results are to be interpreted as follows :



Negative test result: If a red line appears at the quality control line (C) on the plate. No other line is present.

Positive test result: If a red line appears at the quality control line on the plate and a visible red line appears in the Test line position (T), the sample contains OXA-23 carbapenemase and must be interpreted as a positive result.

Invalid test result: The absence of a Control line indicates a failure in the test procedure. Repeat the test with a new test device.

QUALITY CONTROL

Each *EZER*TM OXA-23 Carbapenemase Rapid Test contains internal/procedural controls. The appearance of a control line at the Control "C" position validates the proper reagent function and assures that the correct test procedure was followed.

PERFORMANCE CHARACTERISTICS

Detection limit

The detection limit determined with purified recombinant proteins of OXA-23 has been evaluated at 0.1 ng/mL.

Cross-reactivity

Cross-reactivity confirmed that *EZER*TM OXA-23 Carbapenemase Rapid Test does not react with the organisms that exhibit antibiotic resistance mechanisms other than the OXA-23 Carbapenemase, as described below for specific resistant mechanisms evaluated.

OXA-1, OXA-2, OXA-10, OXA-24, OXA-51, OXA-58, OXA-48, OXA-181, OXA-232, KPC-2, KPC-3, NDM-1, NDM-3, NDM-5, IMP-1, IMP-4, VIM-1, AmpC, blaADC-26, blaADC-154, CTX-M-55, CTX-M-65, CTX-M-15, MCR-1, SHV-1, SHV-11, SHV-53, SHV-51, SHV-105, SHV-12, SHV-123, TEM-1, aac(3)-IIId, aac(3')-Ia, aac(3)-IVa, aac(6')-Ib-D181Y, rmtB, aadA3, aadA5, aadA16, arr-3, marA, marR, acrA, acrB, acrD, msbA, mdtB, mdtC, baeR, mdfA, CBP-1, tet(A), tet(B), oqxA, oqxB, sul1, sul2, dfrA14, dfrA17, dfrA27, qnrS1, qnrB6, qnrA1, qnrB91, floR, PmrF, FosA6, FosA5, fosA3, fosA, catII, catB3, mecA, VanA, OmpK37, KpnG, KpnH, KpnE, KpnF.

Clinical Evaluation

The performance comparison of OXA-23 detection of the EZER™ OXA-23 Carbapenemase Rapid Test

		molecular method		
		+	–	Total
OXA-23	+	235	0	235
Carbapenemase	–	0	38	38
Rapid Test	Total	235	38	273

Relative Sensitivity: 100.00%

Relative Specificity: 100.00%

Accuracy: 100.00%

LIMITATIONS OF THE PROCEDURE

1. A positive or a negative test does not rule out the presence of other mechanisms of antibiotic resistance.
2. False negative results may occur with multiple subcultures of a bacterial isolate without any selective pressure.
3. This test is a qualitative assay and will not yield any quantitative result.

AVAILABILITY

Product	Cat. No.	Contents
EZER™ OXA-23 Carbapenemase Rapid Test	P261103	20 Tests

REFERENCES

1. Dijkshoorn L, Nemec A, Seifert H. An increasing threat in hospitals: multidrug-resistant *Acinetobacter baumannii*. *Nat Rev Microbiol* 2007;5:939–951.
2. Lee CR, Lee JH, Park M, Park KS, Bae IK et al. Biology of *Acinetobacter baumannii*: pathogenesis, antibiotic resistance mechanisms, and prospective treatment options. *Front Cell Infect Microbiol* 2017;7:55.
3. Higgins PG, Dammhayn C, Hackel M, Seifert H. Global spread of carbapenem-resistant *Acinetobacter baumannii*. *J Antimicrob Chemother* 2010;65:233–238.
4. Mugnier PD, Poirel L, Naas T, et al. Worldwide dissemination of the bla OXA-23 carbapenemase gene of *Acinetobacter baumannii*. *Emerg Infect Dis.* 2010;16 (1):35–40.

Index of Symbols

 Attention, see instructions for use	 Tests per kit	 Authorized Representative
 For in vitro diagnostic use only	 Use by	 Do not reuse
 Store between 2–30°C	 Lot Number	 Catalog #



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