Key Code TSMX9252A

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MICROBACT™ OXIDASE STRIPS

MB0266B..... Σ 100 **EN**

1. INTENDED USE

Microbact Oxidase Strips are strips impregnated with N,N,N',N'-tetramethyl-*p*-phenylenediamine dihydrochloride for the qualitative detection of bacterial cytochrome oxidase enzyme from isolates grown on agar.
The device is used in a diagnostic workflow to aid clinicians in the treatment options for patients suspected of having bacterial infections.

The test can be used to aid the identification of isolates from food or food related samples.

The device is not automated, is for professional use only and is not a companion diagnostic

2. SUMMARY

The Microbact Oxidase Test can be used to differentiate *Neisseria* sp, and to separate *Pseudomonadaceae* from the Oxidase-negative *Enterobacteriaceae*.[1,2] Most gram-positive bacteria are Oxidase-negative, and many of the gram-negative bacteria other than the *Enterobacteriacerae*, are variable.[3]

3. PRINCIPLE OF THE TEST

The Microbact Oxidase strips are used to detect the production of intracellular oxidase enzyme. In the presence of the cytochrome oxidase system, activation of the oxidation of reduced cytochrome by molecular oxygen occurs, in turn acting as an electron acceptor in the final stage of the electron transport system. In the test, microorganisms which contain the oxidase enzyme, in the presence of atmospheric oxygen, cytochrome c and the phenylenediamine reagent, react to produce indophenol, a purple coloured compound.

4. KIT CONTENTS, PREPARATION FOR USE AND STORAGE

The kit contains 100 paper strips impregnated with N,N,N',N'-tetramethyl-*p*-phenylenediamine dihydrochloride.

The expiration of the kit is stated on the package label.

If unopened, store at 2-8°C. Allow the container to reach room temperature before opening to prevent condensation of moisture on the strips.

Remove the required number of strips for testing and reseal the container.

Instructions for use (IFU)

5. PRECAUTIONS

This product is for *in vitro* diagnostic use only.

5.1. Specimen material may contain pathogenic organisms. Handle with the appropriate precautions.
5.2. Discard used material into a suitable waste container or disinfectant.
5.3. Do not use the product beyond its stated expiry date.
5.4. Do not use if there is evidence of contamination, or other signs of deterioration.
5.5. Do not touch the reaction area on the strips.
5.6. Do not leave the strips in direct sunlight.
5.7. Do not use if packaging is damaged.
5.8. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
5.9. In the event of malfunction do not use device.

6. SPECIMEN COLLECTION AND TRANSPORT

For details of specimen collection and treatment a standard reference should be consulted.[4]

7. TEST PROCEDURE

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer
- Disposable plastic or a platinum wire loop.
- A suitable laboratory disinfectant.
- Positive control: from a recognized culture collection
- Negative control: from a recognized culture collection

PROCEDURE
Allow the container to reach room temperature before opening to prevent condensation of moisture on the strips.
Remove the required number of strips for testing and reseal the container.
Either

a) Touch the colony to be tested with the Oxidase Strip and observe for up to 5 seconds. A deep blue/violet colour indicates a positive reaction

Or

b) Transfer the colony to be tested to an Oxidase Strip, using a disposable plastic or platinum wire loop. Spread the culture on the strip and observe for up to 5 seconds. A deep blue/violet colour indicates a positive reaction.

8. QUALITY CONTROL

Quality control should be run with each shipment and new lot number received. Each laboratory should follow their State and local requirements.

8.1. Positive Control: use a suitable positive control e.g. *Pseudomonas aeruginosa* ATCC 27853 (Culti-Loops™ R4607060), and/or *Neisseria gonorrhoeae* ATCC 43069 (Culti- Loops R4607043), following the method described in the test procedure.

8.2. Negative Control: use a suitable negative control e.g. *Escherichia coli* ATCC 25922 (Culti- Loops R4607050) following the method described in the test procedure.

Do not use the test if the reactions of the control organisms are incorrect.

9. RESULTS

INTERPRETATION

Positive Result

A result is positive if a deep blue/violet colour develops within 5 seconds. This identifies the strain as oxidase-positive.

Negative Result

A negative result is obtained if no colour change occurs within 5 seconds. This identifies the strain as oxidase-negative.

10. PERFORMANCE LIMITATIONS

10.1. False negative results can occur if insufficient colony is transferred to the strip.

10.2. False negative results can occur if taking colonies from carbohydrate containing media. The low pH of the test colony and the surrounding media may result in false negative results.

10.3. False positive results can occur if nichrome wire loops are used. Nichrome contains iron which may catalyse the oxidation of the oxidase reagent.

10.4. False positive results can occur when testing colonies from blood containing media. Red blood cells contain cytochrome oxidase which may give rise to false positive results.

11. BIBLIOGRAPHY

1 Kovacs, N. 1956. Nature. 178:703

2 Cowan, S.T. and K.J. Steel. 1966. Manual for the Identification of Medical Bacteria. Cambridge University Press, Cambridge, UK

3 Steel, K.J. 1962. J.Appl.Bacteriol. 25:445-455

4 http://www.microbelibrary.org/library/laboratory-test/3229-oxidase-test-protocol

12. SYMBOL LEGEND

Symbol	Definition
	Catalogue number
	In Vitro Diagnostic Medical Device
	Batch code
	Temperature limit
	Use-by date
	Do not re-use
	Consult instructions for use
	Contains sufficient for <n> tests
	Keep away from sunlight
	Do not use if packaging damaged and consult instructions for use
	Manufacturer
EC REP	Authorized representative in the European Community/ European Union
	European Conformity Assessment
	UK Conformity Assessment

Oxoid Ltd, Wade Road.
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For technical assistance please contact your local distributor.

Revision Information

Version	Date of issue and modifications introduced
1.0	2022-07-12. New document. (LIVE)