

Oxidase Test Stick

Rapid test for detection of cytochrome oxidase enzymatic activity.

INTENDED PURPOSE

Rapid test for detection of cytochrome oxidase enzyme on bacterial isolates. This test is intended as an aid in the diagnosis, requiring further tests to complete the diagnostic results.

DESCRIPTION

Oxidase Test Stick are filter paper sticks (strips) impregnated with a reagent for differentiation and microbial identification, particularly of Gram-negative bacteria, based on the presence of enzyme cytochrome oxidase. This enzyme is characteristically produced by a number of microorganisms, including *Neisseria* and *Pseudomonas* species while *Enterobacteriaceae* are oxidase negative (with the exception of *Plesiomonas*, which is the only oxidase-positive genus in this family).

KIT CONTENT

50 sticks (strips)

METHOD PRINCIPLE

Oxidase-positive bacteria produces the enzyme cytochrome oxidase (indophenol oxidase) that catalyzes the transport of electrons from donor compounds (NADH) to electron acceptors (usually oxygen). Tetramethyl-p-phenylenediamine dihydrochloride (TMPD) contained in Oxidase Test Stick acts as an artificial electron donor and is oxidized by oxidase-positive bacteria forming the coloured compound indophenol blue.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as: inoculating loop, pipettes, culture media, quality control organisms.

REAGENTS

• Each stick has a reaction zone impregnated with a solution of N,N,N',N'-tetramethyl-p-phenylenediamine dihydrochloride.

SPECIMEN

Collect specimens in sterile containers or with sterile swabs and transport to the laboratory. Process each specimen using procedures appropriate for that sample. This product is recommended for use only with pure cultures.

Refer to specific guidelines for more detailed information.

TEST PROCEDURE

- 1. Allow product to reach room temperature before use, for minimizing condensation on the stick.
- 2a. Pick up one or more than one well isolated colony from a fresh culture plate (18-24 hours old) and wipe off by the reaction zone (indicated by arrows) at the tip of the stick.

or

- 2b. Use a suspension of the test organism to perform the test: Transfer a few drops of the suspension to the reaction zone or dip stick directly into the microbial suspension.
- 3. Observe for color development within 60 seconds at the position of inoculated area.

Note: Positive and negative controls should be run simultaneously with the organism to be tested (see QUALITY CONTROL).

INTERPRETING RESULTS

A positive oxidase reaction is indicated by development of a blue-purple color.

No color change corresponds to a negative test, i.e. the organism under investigation does not produce the enzyme cytochrome oxidase.

STORAGE

Store at 2-8°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

2 years.

QUALITY CONTROL

Control strain		Characteristic reactions
Escherichia coli	WDCM 00013 ATCC* 25922 NCTC 12241	
Cronobacter sakazakii	WDCM 00214 ATCC [®] 29544 NCTC 11467	Negative reaction: No color change
Cronobacter muytjensii	WDCM 00213 ATCC® 51329	
Pseudomonas aeruginosa	WDCM 00025 ATCC* 27853 NCTC 12903	Positive reaction:
Pseudomonas fluorescens	WDCM 00115 ATCC* 13525 NCTC 10038	Colour change to blue-purple

PERFORMANCE CHARACTERISTICS

Performance testing of Oxidase Test Stick was carried out using the QC strains listed above. The results obtained met the established criteria.

LIMITATIONS

The most suitable cultures for the oxidase test are those from culture media without dyes, indicators or inhibitors. Bacterial colonies taken from media with pH values below 5.5 (e.g. after the metabolism of carbohydrates with subsequent acidification of the culture medium) can give a false negative oxidase reaction.

Colonies taken from media containing nitrate may give unreliable results.

Use of nickel-chrome loops may produce false positive results from oxidation because of the iron contained in the loops. A platinum or plastic loop, or wooden applicator stick is recommended.

The colonies taken from media containing nitrates may give unreliable results.

Oxidase-cytochrome production might be inhibited by the generation of acids and falsely negative reactions can be obtained by bacteria cultured on media containing fermentable carbohydrates such as Mac Conkey, TCBS Agar etc.

WARNING AND PRECAUTIONS

- 1) For in vitro diagnostic use (IVD).
- 2) For laboratory professional use only.
- 3) Operators must be trained and have certain experience. Please read the instructions carefully before using the product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.
- 4) Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.
- 5) Do not use if the product or packaging appears to be damaged.
- 6) Follow standard precautions. All patient specimens should be considered potentially infectious and handled accordingly.
- 7) Handle all specimens as if infectious using safe laboratory procedures. Dispose of hazardous or biologically contaminated materials according to the practices of your institution.
- 8) Avoid cross-contamination of samples by using disposable tips and changing them after each sample.
- 9) Do not mix reagents of different batches. Please use the product within the validity period.
- 10) Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- 11) Results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors.

- 12) Ensure laboratory equipment is calibrated and maintained in accordance with the laboratory's procedure.
- 13) When test results are transmitted from the laboratory to an informatics centre, attention has to be done to avoid erroneous data transfer.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

See the references at the end of this document.

TABLE OF SYMBOLS

See the table of symbols at the end of this document.

ORDER INFORMATION

Product	Packaging	Ref.
Oxidase Test Stick	50 tests	88029

Revision History

Revision	Release Date	Change Summary
6	2024-09-16	Added notice to report any malfunction, defect or incident.
5	2023-05-15	Updated layout and content in compliance with IVDR 2017/746.

In case of malfunctions or defects, contact immediately Liofilchem (*) or the local representative.

In case of incident associated with the device, notify immediately Liofilchem (*) or its local representative and the National Competent Authority.

This IFU document and the SDS are available from the online Support Center:

liofilchem.com/ifu-sds

^{*}Please login to https://www.liofilchemstore.it/login.php (user ID and password required) and click on Complaint.