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Instructions for Use

OXISTRIPS™ OXIDASE STRIPS AND OXISTICKS™ OXIDASE SWABS

Cat. no. Z93	OxiStrips™ Oxidase Strips	25 strips/vial
Cat. no. Z193	OxiSticks™ Oxidase Swabs	25 swabs/vial

INTENDED USE

Hardy Diagnostics OxiStrips™ Oxidase Strips and OxiSticks™ Oxidase Swabs are used for the detection of cytochrome oxidase activity in bacteria.

SUMMARY

Cytochrome containing organisms produce an intracellular oxidase enzyme. This oxidase enzyme catalyzes the oxidation of cytochrome c. Organisms which contain cytochrome c as part of their respiratory chain are oxidase-positive and turn the reagent blue/purple. Organisms lacking cytochrome c as part of their respiratory chain do not oxidize the reagent, leaving it colorless within the limits of the test, and are oxidase-negative.

OxiStrips™ Oxidase Strips are ready to use test strips with a convenient plastic handle so the user can avoid skin contact with the reaction area.

OxiSticks™ Oxidase Swabs are swabs containing reagents impregnated in the tip of the swab for ease of use.

REAGENT FORMULA

OxiStrips™ Oxidase Strips and OxiSticks™ Oxidase Swabs are impregnated with N,N,N',N'-tetramethyl-p-phenylenediamine dihydrochloride, in a preservative solution.

STORAGE AND SHELF LIFE

Storage: Upon receipt store at 15-30ºC. Products should not be used if there are any signs of deterioration or if the expiration date has passed. Store OxiStrips™ and OxiSticks™ with a desiccant in the vial at all times.

The expiration date on the product label applies to the product in its intact packaging when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below.

Refer to the document "Storage" for more information.

PRECAUTIONS

This product may contain components of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not guarantee the absence of transmissible pathogenic agents. Therefore, it is recommended that these

products be treated as potentially infectious, and handle observing the usual Universal Precautions for blood. Do not ingest, inhale, or allow to come into contact with skin.

This product is for *in vitro* diagnostic use only. It is to be used only by adequately trained and qualified laboratory personnel. Observe approved biohazard precautions and aseptic techniques. All laboratory specimens should be considered infectious and handled according to "standard precautions." Refer to the document "Guidelines for Isolation Precautions" from the Centers for Disease Control and Prevention.

For additional information regarding specific precautions for the prevention of the transmission of all infectious agents from laboratory instruments and materials, and for recommendations for the management of exposure to infectious disease, refer to CLSI document M29: *Protection of Laboratory Workers from Occupationally Acquired Infections.*

Sterilize all biohazard waste before disposal.

Refer to the document "Precautions When Using Media" for more information.

PROCEDURE

Specimen Collection: This product is not intended for primary isolation of patient specimens. This product is used in conjunction with other biochemical tests to identify cultures of isolated organisms.

Method of Use:

OxiStrips™ Oxidase Strips: Place oxidase test strip in a petri dish and moisten an area of the strip to be tested with water. Do not saturate strip. With either a platinum loop or wooden applicator stick, smear a bacterial paste from 3-4 well isolated colonies onto the moistened area. Use colonies that are 18-24 hours old.

OxiSticks™ Oxidase Swabs: Remove swab from container without touching the tip. Use the swab to carefully collect 3-4 well isolated colonies. There is no need to pre-moisten the swab. Use colonies that are 18-24 hours old.

INTERPRETATION OF RESULTS

Appearance of a blue/purple color within 30 seconds indicates a positive test.

Important: Any color appearing after this time should be disregarded.

LIMITATIONS

The oxidase test may be used in the presumptive identification of *Neisseria* spp. and in the differentiation and identification of gram-negative bacilli. All oxidase-positive organisms should be examined by gram stain to determine cellular morphology and gram reaction. It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed on colonies from pure culture for complete identification.

Using nichrome or other iron containing inoculating devices may cause false-positive reactions.

Oxidase reactions of gram-negative bacilli should be determined on colonies obtained from non-selective and non-differential media to ensure valid results.

Most *Haemophilus* spp. are oxidase-positive. Less sensitive oxidase test strips or reagents may yield false-negative results. Consult listed reference for more information.[7]

Weakly oxidase-positive organisms, such as *Pasteurella multocida*, may take longer to show a positive reaction on the test strips.

It is recommended to use colonies that are 18-24 hours old. Older colonies may produce weaker reactions.

The oxidase test should be performed on isolates at or above 15-30ºC.

Any color development appearing after 30 seconds of inoculation should be disregarded.

Refer to the document "Limitations of Procedures and Warranty" for more information.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as loops, pipets, incubators, and incinerators, etc., as well as biochemical and serological reagents, are not provided.

QUALITY CONTROL

Hardy Diagnostics tests each lot of commercially manufactured media using appropriate quality control microorganisms and quality specifications as outlined on the Certificate of Analysis (CofA) and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media*. The following microorganisms are routinely used for testing at Hardy Diagnostics:

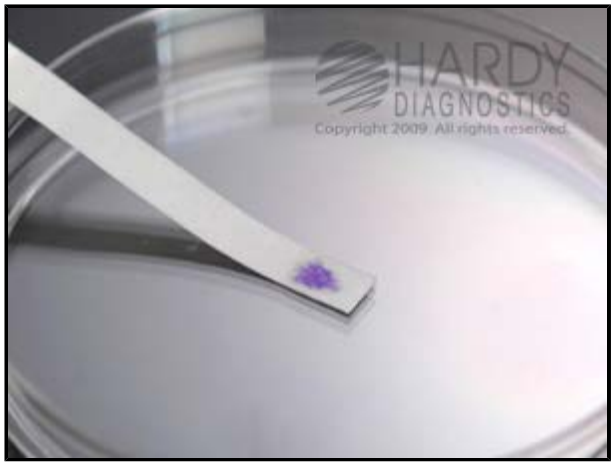
Test Organisms	Reaction
Pseudomonas aeruginosa ATCC® 27853	Oxidase-positive; blue/purple color develops within 10-20 seconds
Escherichia coli ATCC®25922	Oxidase-negative; no color develops

USER QUALITY CONTROL

End users of commercially prepared culture media should perform QC testing in accordance with applicable government regulatory agencies, and in compliance with accreditation requirements. Hardy Diagnostics recommends end users check for signs of contamination and deterioration and, if dictated by laboratory quality control procedures or regulation, perform quality control testing to demonstrate growth or a positive reaction and to demonstrate inhibition or a negative reaction, if applicable. Hardy Diagnostics quality control testing is documented on the certificate of analysis (CofA) available from Hardy Diagnostics Certificate of Analysis website. Also refer to the document "Finished Product Quality Control Procedures," and the CLSI document M22-A3 *Quality Assurance for Commercially Prepared Microbiological Culture Media* for more information on the appropriate QC procedures. See the references below.

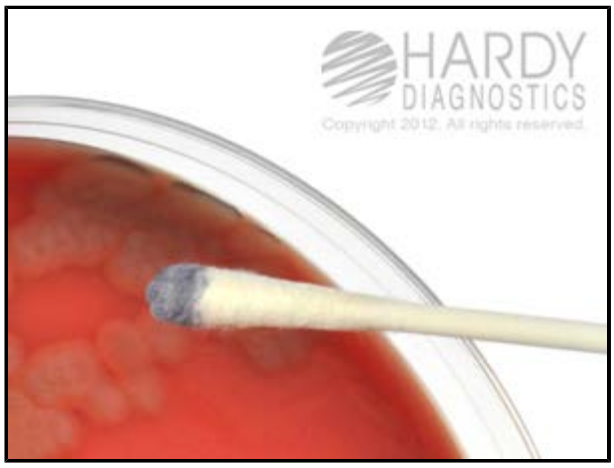
PHYSICAL APPEARANCE

OxiStrips™ Oxidase Strips are reagent test strips with a plastic handle, and white in color. OxiSticks™ Oxidase Swabs are polypropylene shafted swabs with dacron tips that are white in color.



Pseudomonas aeruginosa (ATCC® 27853) applied to an OxiStrip™ (Cat. no. Z93). The development of a blue/purple color within 10-20 seconds was indicative of a positive oxidase reaction.

Escherichia coli (ATCC® 25922) applied to an OxiStrip™ (Cat. no. Z93). No development of a blue/purple color within 10-20 seconds was indicative of a negative oxidase reaction.



Pseudomonas aeruginosa (ATCC® 27853) applied to an OxiStick™ (Cat. no. Z193). The development of a blue/purple color within 10-20 seconds was indicative of a positive oxidase reaction.

REFERENCES

1. Versalovic, J., et al. *Manual of Clinical Microbiology.* American Society for Microbiology, Washington, D.C.

2. Tille, P., et al. *Bailey and Scott's Diagnostic Microbiology,* C.V. Mosby Company, St. Louis, MO.

3. *Commission on Laboratory Accreditation, Laboratory Accreditation Program Microbiology Checklist.* College of American Pathologists. Rev. 9/30/2004.

4. Koneman, E.W., et al. *Color Atlas and Textbook of Diagnostic Microbiology,* J.B. Lippincott Company, Philadelphia, PA.

5. MacFaddin, J.F. *Biochemical Tests for Identification of Medical Bacteria,*, Lipincott Williams & Wilkins, Philadelphia, PA.

6. Isenberg, H.D. *Clinical Microbiology Procedures Handbook,* Vol. I, II & III. American Society for Microbiology, Washington, D.C.

7. Holt, J.G. and N.R. Krieg. 1984. *Bergy's Manual of Systematic Bacteriology*, Vol. I. Williams & Wilkins, Baltimore, MD.

8. Centers for Medicare and Medicaid, *Appendix C, Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services* . Subpart K - Quality System for Non-Waived Testing. 493;1200-1265. www.cms.hhs.gov/clia.

IFU-10636[A]

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The Hardy Diagnostics manufacturing facility and quality management system is certified to ISO 13485.

HDQA 2207F [D]