

BD BBL™ Oxidase Reagent Droppers



R_x Only



L001133(05)
2022-05
English

REF 261181

INTENDED USE

BD BBL™ Oxidase Reagent Droppers are used in the Kovacs oxidase test as a qualitative reaction in the identification of nonfermenters and miscellaneous gram-negative bacteria.^{1,2}

SUMMARY AND EXPLANATION

The oxidase test is based on the production of an enzyme called indophenol oxidase. This enzyme oxidizes a redox dye (present in the reagent) which results in a color change of yellow to dark purple.^{1,2}

PRINCIPLES OF THE PROCEDURE

Indophenol oxidase, in the presence of atmospheric oxygen, oxidizes the phenylenediamine oxidase reagent to form a dark-purple compound, indophenol.^{1,2}

REAGENTS

BD BBL™ Oxidase Reagent Droppers contain 0.5 mL of a 1% aqueous solution of N,N,N',N'-tetramethyl- *p*-phenylenediamine dihydrochloride which has been formulated with agents to ensure maximum stability.

WARNINGS AND PRECAUTIONS

For in vitro diagnostic use. For Use by Trained Laboratory Personnel.

Avoid contact with the skin. Rinse thoroughly with water if spilled.

Dispose of all used reagents and any other contaminated disposable materials following procedures for infectious or potentially infectious waste. It is the responsibility of each laboratory to handle solid and liquid waste according to their nature and degree of hazardness and to treat and dispose of them (or have them treated and disposed of) in accordance with any applicable regulations.

Storage Instructions

Store at controlled room temperature 15–30 °C (59–86 °F). Protect from light. The reagent droppers need no refrigeration.

Product Deterioration

This reagent is hermetically sealed in an ampule, which affords protection of the solution from chemical instability until expiration date. Do not use if reagent is other than light yellow.

PROCEDURE

Material Provided

BD BBL™ Oxidase Reagent Droppers.

Materials Required But Not Provided

Ancillary culture media, filter paper, quality control organisms and laboratory equipment as required for this procedure.

Test Procedure

1. Hold reagent dropper upright and **POINT TIP AWAY FROM YOURSELF**. Grasp the middle with thumb and forefinger and squeeze gently to crush ampule inside the dropper. **Caution: Break ampule close to its center one time only. Do not manipulate dropper any further, as the plastic may puncture and injury may occur.**
2. Tap bottom on tabletop a few times. Then invert for convenient drop-by-drop dispensing of reagent.
3. Preparation for testing
 - a. Colonies to be tested must be isolated from other colonies.
 - b. The use of fresh isolates (18–24 hour cultures) is recommended for routine testing.
 - c. If refrigerated, cultures must be allowed to reach room temperature prior to testing.

Note: Various conditions can affect the results obtained. Review the conditions listed in “Limitations of the Procedure.”
4. Performing the test: Filter Paper Method
 - a. Add a few drops of Oxidase test reagent to a strip of filter paper (Whatman No. 1 or equivalent).
 - b. Streak a loopful of bacteria onto the reagent-saturated paper with a platinum loop or wooden applicator stick. Use of steel or nichrome loops may cause false-positive reactions.²

USER QUALITY CONTROL

It is recommended that positive (*Pseudomonas aeruginosa* ATCC® 27853) and negative (*Escherichia coli* ATCC 25922) controls be run simultaneously with the organism to be tested.

Quality control requirements must be performed in accordance with applicable local, state and/or federal regulations or accreditation requirements and your laboratory's standard Quality Control procedures. It is recommended that the user refer to pertinent CLSI guidelines and CLIA regulations for appropriate Quality Control practices.

RESULTS

Positive reactions turn the bacteria violet to purple immediately, or up to 30 seconds. Negative reactions remain colorless or turn light pink/light purple after 30 seconds. Delayed reactions should be ignored.

Limitations of the Procedure

Allow up to 30 seconds for a positive reaction. Any delayed reaction should be considered negative.

Do not add excess reagent, as it may cause the reaction to fade on oxidase-positive organisms.

Steel loop, nichrome loop and wire loop containing iron may give a false-positive reaction.³ A platinum loop or wooden applicator stick is recommended.

Perform the oxidase test on gram-negative bacilli, but **only** on colonies from **nonselective** and/or **non-differential** media to ensure valid results. Selective or differential media can carry over the indicator to the filter paper and cause inaccurate results (false-negative reactions).²

Colonies grown on media with high concentrations of glucose may inhibit oxidase activity.³

False-negative results may occur with mixed cultures containing the two genera *Pseudomonas* and *Neisseria* (not all *Pseudomonas* spp. elaborate oxidase).²

Timing is critical for interpretation of results.²

Do not test strictly anaerobic organisms.²

Viscid colonies may be negative due to poor penetration of the reagent.

Reactions from weak oxidase-positive organisms, e.g., *Pasteurella* species, may be inaccurate. Results inconsistent with other biochemical reactions or with the organisms should be repeated.

PERFORMANCE CHARACTERISTICS

Prior to release, all lots of BD BBL™ Oxidase Reagent Droppers are tested to verify specific product characteristics. One drop of reagent is placed on filter paper. One colony of each organism is applied to the filter paper. *P. aeruginosa* ATCC® 15442 or 27853, *N. lactamica* ATCC® 23970, *A. hydrophilia* ATCC® or *C. jejuni* ATCC® 29428, ATCC® 33291 or ATCC® 33292 produce a purple color in less than 30 seconds. *K. pneumoniae* ATCC® 13883 or ATCC® 33495 and *E. coli* ATCC® 25922 produce no color in more than 60 seconds.

AVAILABILITY

Catalog Number Description

261181	BD BBL™ Oxidase Reagent Droppers, 50.
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REFERENCES

1. Kovacs, N. 1956. Identification of *Pseudomonas pyocyanea* by the oxidase reaction. *Nature (London)* 178: 703.
2. York, M.K., M.M. Traylor, J. Hardy, and M. Henry. 2004. Biochemical tests for the identification of aerobic bacteria, p. 3.17.39.1. In H.D. Isenberg (ed.), *Clinical microbiology procedures handbook* 2nd ed., vol. 1, 2 and 3. American Society for Microbiology, Washington, D.C.
3. Chapin, K.C. and T.L. Lauderdale. 2003. Reagents, stains, and media: bacteriology, p. 354–393. In P.R. Murray, E.J. Baron, J.H. Jorgensen, M.A. Pfaller and R.H. Tenover (ed.), *Manual of clinical microbiology*, 8th ed. American Society for Microbiology, Washington, D.C.

Technical Service and Support: In the United States contact BD at 1.800.638.8663 or bd.com.

For regions outside of the United States, contact your local BD representative or bd.com.

EU Only: Users shall report any serious incident related to the device to the Manufacturer and National Competent Authority.

Outside EU: Contact your local BD representative for any incident or inquiry related to this device.

Change History

Revision	Date	Change Summary
04	2022-03	Updated for IVDR 2017/746. Updated IVD symbol. Added "eIFU with URL" symbol, "Do not use if package is damaged" symbol and "Rx Only" symbol. Added Intended User statement. Added Serious Incident statement. Added Safe Disposal statement. Updated Technical Information statement. Updated Symbols Glossary. Updated Australian Sponsor address and EC REP symbol with address. Added New Zealand Sponsor address and CH REP address. Updated BD Trademark and Copyright statement.
05	2022-05	Updated Performance Characteristics section.


SYMBOLS GLOSSARY [L006715(06) 2021-08]

Some symbols listed below may not apply to this product.

US Customers only: For symbol glossary, refer to bd.com/symbols-glossary

Symbol	Meaning	Symbol	Meaning
	Manufacturer		Patient number
	Authorized representative in the European Community		This way up
	Authorised representative in Switzerland		Do not stack
	Date of manufacture		Single sterile barrier system
	Use-by date		Contains or presence of phthalate: combination of bis(2-ethylhexyl) phthalate (DEHP) and benzyl butyl phthalate (BBP)
	Batch code		Collect separately Indicates separate collection for waste of electrical and electronic equipment required.
	Catalogue number		CE marking; Signifies European technical conformity
	Serial number		Device for near-patient testing
	Sterile		Device for self-testing
	Sterilized using aseptic processing techniques		This only applies to US: "Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner."
	Sterilized using ethylene oxide		Country of manufacture "CC" shall be replaced by either the two letter or the three letter country code.
	Sterilized using irradiation		Collection time
	Sterilized using steam or dry heat		Cut
	Do not re-sterilize		Peel here
	Non-sterile		Collection date
	Do not use if package is damaged and consult <i>instructions for use</i>		Keep away from light
	Sterile fluid path		Hydrogen gas is generated
	Sterile fluid path (ethylene oxide)		Perforation
	Sterile fluid path (irradiation)		Start panel sequence number
	Fragile, handle with care		End panel sequence number
	Keep away from sunlight		Internal sequence number
	Keep dry		Medical device
	Lower limit of temperature		Contains hazardous substances
	Upper limit of temperature		Ukrainian conformity mark
	Temperature limit		Meets FCC requirements per 21 CFR Part 15
	Humidity limitation		UL product certification for US and Canada
	Biological risks		Unique device identifier
	Do not re-use		
	Consult <i>instructions for use</i> or consult electronic <i>instructions for use</i>		
	Caution		
	Contains or presence of natural rubber latex		
	In vitro diagnostic medical device		
	Negative control		
	Positive control		
	Contains sufficient for <n> tests		
	For IVD performance evaluation only		
	Non-pyrogenic		



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