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OxyBlue™ Anaerobic Indicator Product Insert

Intended Use

OxyBlue™ Anaerobic Indicator is a methylene blue based color indicator intended for in vitro use as an aid in confirming that anaerobic conditions have been reached within a sealed OxyPlate™ or other sealed container. It is an accessory to Oxyrase, Inc. anaerobic culture media and is not used to isolate, cultivate, or identify microorganisms.

Intended Users

For use by trained laboratory personnel in clinical, reference, research, industrial, pharmaceutical, and veterinary microbiology settings.

Principle of the Procedure

OxyBlue™ contains a methylene blue solution. Methylene blue is blue in its oxidized state and colorless when reduced. When applied to the inside of an OxyPlate™ lid or container, the indicator changes from a dark to medium blue coloration to a white coloration once the sealed environment has reached anaerobiosis. The rate of color change is dependent on the size of the drop. OxyBlue™ is reusable several times within the same plate or container after being applied, by simply resealing the original OxyPlate™ or container, unless the adhesive dries.

Warnings and Precautions

- For In Vitro Diagnostic Use.
- Plates bearing the indicator may contain viable cultures. Handle and dispose of them in accordance with the instructions for the culture medium in use and with applicable regulations.
- A Safety Data Sheet (SDS) is available on our website.

Storage and Handling

- OxyBlue™ is supplied in a 1/4 oz white dropper bottle and will arrive at room temperature.
- Store the product at 2°C to 25°C.
- When stored as directed, the bottle will maintain its effectiveness to the printed expiration date. Refer to the label for the actual expiration date.

Materials Required But Not Provided

Sealed OxyPlate™ plates or another sealed anaerobic container, and an incubator capable of 35–37°C.

Directions for Use

1. Uncap the OxyBlue™ bottle and visually confirm the blue coloration of the indicator.
2. Gently squeeze the bottle until a small bead of OxyBlue™ (approximately 1 mm) forms at the tip of the dispenser.
3. Lightly touch the bead to the inside of the OxyPlate™ lid or container to transfer the indicator. The bead will release from the dispenser onto the surface. Do not let the bead fall.
4. Recap the bottle to prevent drying or leakage.
5. Close and seal the plate or container.
6. Incubate at 35–37°C and observe for the color change, which occurs within 8 to 24 hours depending on the size of the container used.

On average, one bottle will dot at least 150 plates.

Results and Interpretation

Indicator appearance	Interpretation
Dark to medium blue	Oxygen is present; anaerobic conditions have not been reached.
White	Anaerobic conditions have been reached.

User Quality Control

Oxyrase, Inc. certifies that samples of each lot were quality control tested and performed acceptably to Oxyrase, Inc. specifications, which incorporate CLSI M22-A3. Stock growth was observed on Schaedler OxyPlate™ (OSCW, anaerobic) at 37°C. The following results were confirmed:

Organism	ATCC No.	Result
B. fragilis	25285	White
C. perfringens	13124	White
F. nucleatum	25586	White
P. levii	29147	White
P. anaerobius	27337	White
B. adolescentis	15703	White
P. melaninogenica	25845	White
F. naviforme	25832	White
S. aureus	25923	White
P. mirabilis	12453	White
E. coli	25922	White

Aerobic controls incubated at 25°C and at 37°C produced a blue indicator in all cases.

Each laboratory should establish its own quality control program in accordance with applicable accreditation and regulatory requirements. To ensure consistency between uses, an internal timeline verification may be developed for reaching anaerobic conditions based on the organism and container size used.

Limitations

- Do not leave the OxyBlue™ bottle uncapped for prolonged periods, as this will result in drying of the adhesive within the dispenser.
- When OxyBlue™ is used inside a container other than an OxyPlate™, the incubation time needed to ensure the appropriate color change may need to be extended.
- OxyBlue™ indicates the oxygen state of the sealed environment only. It does not confirm the growth, viability, or identity of any microorganism.

Product Guarantee

Oxyrase, Inc. guarantees a 3-month shelf life from the shipment date under recommended storage and use conditions. If a longer shelf life is needed, arrange this at the time the order is placed. If OxyBlue™ arrives with less than a 3-month shelf life, is contaminated, or fails when used as specified, Oxyrase, Inc. will refund the purchase price. To request a refund, contact Oxyrase, Inc. with the product lot number printed on the bottle label; return of the product may be required for investigation. Oxyrase, Inc. welcomes questions regarding this product and its applications.

Bibliography

1. Clinical and Laboratory Standards Institute (CLSI). Quality Assurance for Commercially Prepared Microbiological Culture Media; Approved Standard—Third Edition. CLSI document M22-A3.

Key to Symbols

Symbol	Meaning
IVD	For in vitro diagnostic use
REF	Catalog number
LOT	Batch code / lot number
⧗ (hourglass)	Use-by / expiration date
2–25°C	Temperature limit (store at 2°C to 25°C)
⌂ (factory)	Manufacturer
ⓘ (book)	Consult instructions for use

Products

Catalog No. (REF): A-OX-0003

Manufactured by Oxyrase, Inc., 3000 Park Ave. West, Mansfield, OH 44906, USA. **For In Vitro Diagnostic Use.**