

INSTRUCTIONS FOR USE



UV·BioTAG™

■ UV-BioTAG™ Microorganisms

INTENDED USE

UV-BioTAG™ microorganisms are lyophilized, reference stock culture preparations containing a single strain of a microorganism. These microorganism preparations are intended to be used for research and development and as quality control agents in controlled environments. The microorganisms contain a Green Fluorescent Protein (GFP) marker that produces fluorescence of the culture that is visible under UV light, and also Chloramphenicol resistance as a selective marker. This allows for easy differentiation of these control strains from contaminants.

FORMULA COMPONENTS

The lyophilized preparation consists of:

- Microorganism population
- Skim milk (Bovine – USA origin)
- Carbohydrate
- Gelatin (Porcine – USA of Canada origin)
- Ascorbic acid

The gelatin serves as a carrier for the microorganism. Skim milk, ascorbic acid, and carbohydrate protect the microorganism by preserving the integrity of the cell wall during freeze-drying and storage.

UV-BioTAG™ microorganisms conform with Article 5 of EC 1069/2009 as they have reached the end point in the manufacturing chain and are no longer subject to the requirements of EC 1069/2009. The products are considered derived products per Article 36 of EC 1069/2009 and do not pose any significant risk to public or animal health.

PRODUCT DESCRIPTION

UV-BioTAG™ Swab Microorganisms: Each **UV-BioTAG™ Swab** kit consists of 6 individually packaged swabs. Each **UV-BioTAG™ Swab** unit contains a lyophilized pellet of a single microorganism strain, a reservoir of hydrating fluid and an inoculating swab. Each swab is sealed within a laminated pouch that contains a desiccant to prevent adverse moisture accumulation.

UV-BioTAG™ Vial Microorganisms: Each **UV-BioTAG™ Vial** kit consists of 6 vials each containing 1 lyophilized pellet of an individual microorganism strain.



INSTRUCTIONS FOR USE

A. UV-BioTAG™ Swab Microorganism Procedure

1. Allow the unopened **UV-BioTAG™ Swab** pouch to equilibrate to room temperature. Tear open pouch at notch and remove the **UV-BioTAG™ Swab** unit.
2. Break red snap valve at the top of the **UV-BioTAG™ Swab** to release the hydrating fluid.
3. Squeeze the bulb at the top of the **UV-BioTAG™ Swab** to rehydrate the pellet.
4. Inoculate a primary culture plate(s) by gently rolling the swab over one-third of the plate.
5. Continue according to laboratory protocol.
6. Using proper biohazard disposal, discard the **UV-BioTAG™ Swab**.
7. Immediately incubate the inoculated primary culture plate(s) at temperature and conditions appropriate to the microorganism.

B. UV-BioTAG™ Vial Microorganism Procedure

1. Remove the plastic container containing the vials of pellets from refrigerated storage. Remove the vials to be used; immediately place the plastic container containing the remaining vials back into refrigerated storage to maintain product stability.
2. Aseptically remove 1 pellet with sterile forceps from the vial. Do not remove desiccant.
3. Place the pellet in 0.5 ml of sterile fluid (water, saline, TSB, or BHIB).
4. Crush the pellet with a sterile swab until the suspension is homogenous.
5. Inoculate a primary culture plate(s) by gently rolling the swab over one-third of the plate.
6. Continue according to laboratory protocol.
7. Using proper biohazard disposal, discard the remaining hydrated material.
8. Immediately incubate the inoculated media at temperature and conditions appropriate to the microorganism.

C. Fluorescence

1. Following completion of the incubation period or test method, colonies growing on agar may be examined for fluorescence to determine whether the growth originated from the control strain or from contaminants.
2. A long wave UV lamp and a dark room are needed for the detection of fluorescence. **UV-BioTAG™ microorganisms** fluorescence will be detectable using a UV lamp that emits light at wavelengths ranging from 315 nm to 400 nm.
3. Hold the lamp over the microorganism culture being tested for fluorescence. Visually examine the culture and determine whether or not it fluoresces. The expected result when the culture is being grown on Tryptic Soy Agar is a green fluorescence. Other agars and variables within each lab's processes may produce fluorescence with varying colors, or may mask the expression of the GFP due to biochemical byproducts produced during the test. It is advisable to always subculture results on such media back to either LB agar with Chloramphenicol or TSA to confirm fluorescence.
4. Green fluorescent proteins will continue to be expressed upon subculturing, but it is recommended that a new pellet suspension be used for each test. If the resuscitated culture is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

PRECAUTIONS AND LIMITATIONS

- This product is resistant to Chloramphenicol.
- Not intended for clinical use.
- Not intended for human, animal or pet consumption.
- This product is for research and development and use as a quality control agent only under 40 CFR Part 725.234.
- Refer to the SDS for more detailed information. The SDS can be located on our website at www.microbiologics.com or by contacting Technical Support at **1.866.286.6691**.
- These products, and growth of these microorganisms, are considered biohazard material.
- These products contain viable microorganisms that may produce disease. Proper techniques must be employed to avoid exposure and contact with any microorganism growth.
- Product must be used by, or directly under the supervision of, a technically qualified individual.
- Wash hands thoroughly after handling.
- Wear protective gloves/protective clothing/eye protection/face protection.
- Causes serious eye irritation.
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue Rinsing. If irritation persists: get medical advice/attention.
- This product is not intended to be used outside of a structure and shall be contained to prevent release into the environment.
- Product must be rendered inactive prior to disposal.
- Users of this product are responsible for any containment and inactivation records required under 40 CFR 725.234 and 725.235.
- **UV-BioTAG™ microorganisms** are not made with natural rubber latex.

TECHNICAL NOTES

Shelf Life and Stability

Exposure to heat, moisture, and oxygen can adversely affect the stability of the product. Expiration dating, reproducibility and stability are predicated on proper storage of the lyophilized pellets in the original desiccant-containing pouch.

Fluorescence

Along with the expression of green fluorescent proteins, **UV-BioTAG™ microorganisms** also have a selective marker which is Chloramphenicol resistance. Selective agar such as Luria-Bertani (LB) agar with Chloramphenicol may be used for selective isolation of the **UV-BioTAG™ microorganisms**.

STORAGE AND EXPIRATION

Store the **UV-BioTAG™ Vials** and **UV-BioTAG™ Swabs** at 2°C–8°C in the original, sealed vial or pouch containing the desiccant. Stored as directed, the lyophilized microorganism preparation will retain, until the expiration date stated on the device label, its specifications and performance within the stated limits.

The GFP microorganisms should not be used if:

- Stored improperly
- There is evidence of excessive exposure to heat or moisture
- The expiration date has passed

MATERIALS REQUIRED BUT NOT PROVIDED

- **UV-BioTAG™ Vials** require sterile tubes and 0.5 ml of sterile liquid such as Tryptic Soy Broth, Brain Heart Infusion Broth, saline, or deionized water to hydrate the lyophilized preparation. Sterile swabs or inoculating loops are needed to transfer the hydrated preparation to an agar plate.
- **UV-BioTAG™ Vials** and **UV-BioTAG™ Swabs** require non-selective, nutrient or enriched agar media and specific incubation times and conditions to optimize growth and recovery. Selective agar such as Luria-Bertani (LB) agar with Chloramphenicol may also be used for isolation and recovery.
- Long wave (UVA 315 – 400 nm) UV light

KEY OF SYMBOLS



Batch Code (Lot)



Biological Risks



Catalog Number



Caution, Consult Accompanying Documents



Manufacturer



Temperature Limitation



Use By



Warning

PRODUCT WARRANTY

- These products are warranted to meet the specifications and performance printed and illustrated in product inserts, instructions, and supportive literature.
- The warranty, expressed or implied, is limited when:
 - The procedures employed in the laboratory are contrary to printed and illustrated directions and instructions
 - The products are employed for applications other than the intended use cited in product inserts, instructions, and supportive literature
- If the resuscitated culture is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

WEBSITE

Visit our website, www.microbiologics.com, for current technical information, product availability, biohazard cleanup and Certificate of Analysis.

ACKNOWLEDGEMENTS



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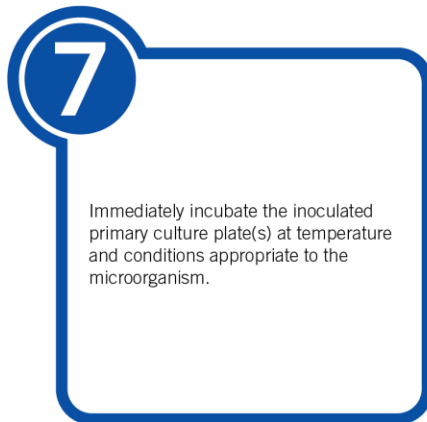
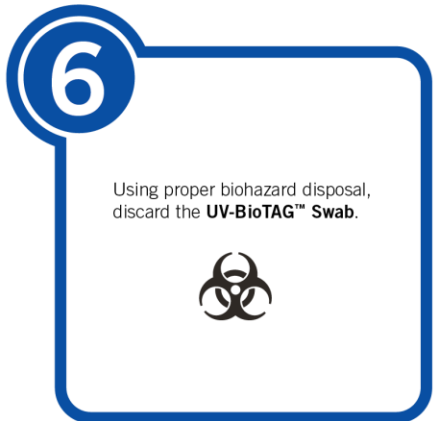
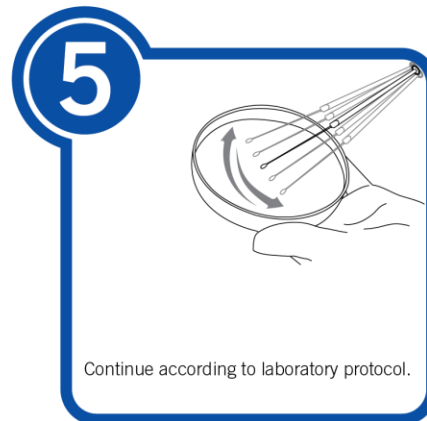
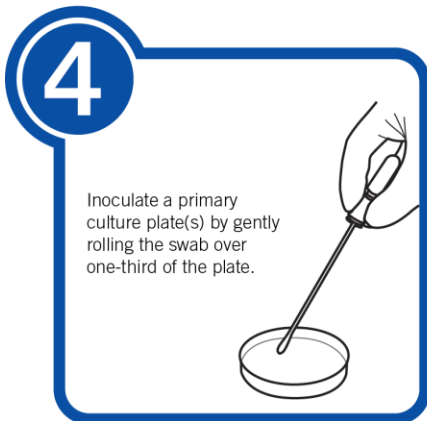
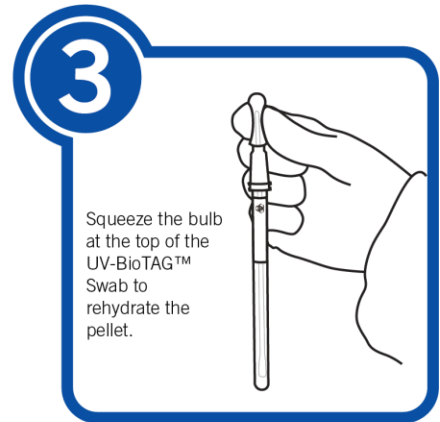
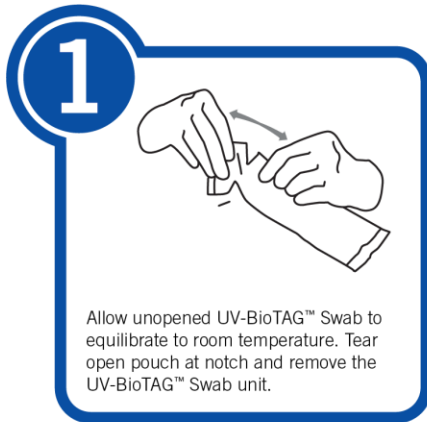
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UV·BioTAG™

ILLUSTRATED INSTRUCTIONS

Each **UV-BioTAG™ Swab** kit consists of 6 individually packaged swabs. Each **UV-BioTAG™ Swab** unit contains a lyophilized pellet of a single microorganism strain, a reservoir of hydrating fluid and an inoculating swab. Each swab is sealed within a laminated pouch that contains a desiccant to prevent adverse moisture accumulation.

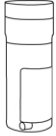



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A safer, healthier world.

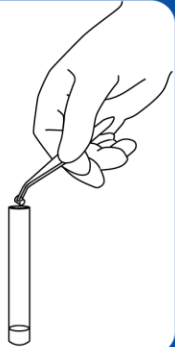
UV·BioTAG™

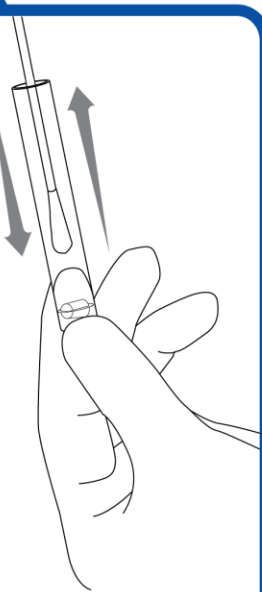
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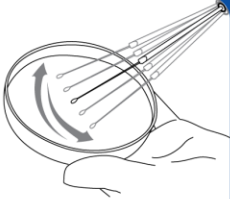
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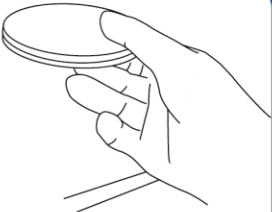
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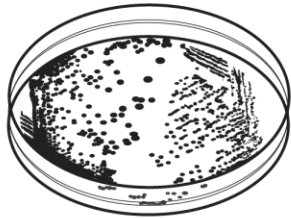
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ILLUSTRATED INSTRUCTIONS

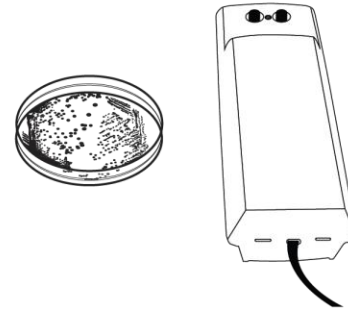
Illustrated instructions for **UV-BioTAG™ microorganisms** fluorescence detection.

1



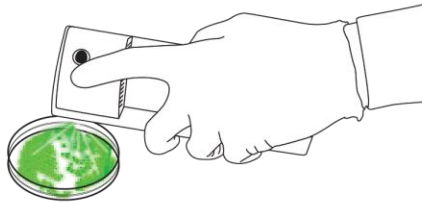
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2



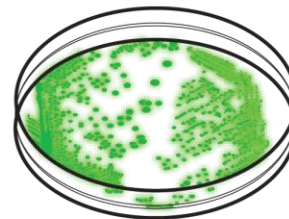
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