INSTRUCTIONS FOR USE

UV-BioTAG™ Microorganisms

INTENDED USE

UV-BioTAG™ microorganisms are lyophilized, reference stock culture preparations. These microorganism preparations are intended to be used for research and development and as quality control agents in contained environments.

FORMULA COMPONENTS

The lyophilized preparation consists of:

- Microorganism population
- Skim milk (Bovine – USA origin)
- Carbohydrate
- Gelatin (Porcine – USA or 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™ microorganisms contain a Green Fluorescent Protein (GFP) marker that produces fluorescence of the culture that is visible under UV or blue wave light. This allows for easy differentiation of these control strains from contaminants. The GFP reporter has been integrated into the chromosome. These modifications do not result in increased toxigenicity.

UV-BioTAG™ swab kits: 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 hydration 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 kits: Each UV-BioTAG™ vial kit consists of 6 vials each containing 1 lyophilized pellet of an individual microorganism strain.

UV-BioTAG™ Panel kit: Each UV-BioTAG™ Panel kit consists of 5 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. The panel consists of five different microorganism strains in a swab format.

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.
- Blue wave (475 – 495 nm) light (for use with Listeria sp. strains)
- Blue light barrier glasses (for use with Listeria sp. strains)
- Long wave (UVA 315 – 400 nm) UV light (for use with all strains except Listeria sp. Strains)

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 hydration fluid.
3. Squeeze the bulb at the top of the UV-BioTAG™ swab to rehydrate the pellet.
4. Using a pinching action on the bottom portion of the unit, crush the pellet in the fluid until the pellet 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 UV-BioTAG™ swab.
8. 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, Tryptic Soy Broth, or Brain Heart Infusion Broth).
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 a true positive sample.
2. A long wave UV or blue wave lamp and a dark room are needed for the detection of fluorescence. UV-BioTAG™ microorganisms' fluorescence is best detected using a UV or blue wave lamp that emits the following wavelengths:
    a. 475 – 495 nm (for use with Listeria sp. strains; use simultaneously with blue light barrier glasses)
    b. 315 – 400 nm (for use with all other strains)
3. Hold the lamp over the microorganism culture being tested for fluorescence. Visually examine the culture and determine whether 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.
4. Green fluorescent proteins will continue to be expressed upon sub-culturing, 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

- Specific strain characteristics are listed on the item page found at www.microbiologics.com.
- Not intended for clinical use.
- Not intended for human, animal or pet consumption.
- This product is for contained use only.
- This product is for research and development and use as a quality control agent only under 40 CFR Part 725.234.
- Refer to the Safety Data Sheet (SDS) for more detailed information. The SDS can be located at www.microbiologics.com or by contacting Technical Support at **techsupport@microbiologics.com**.
- These products contain viable microorganisms that are pathogenic and considered a biohazard. The strains have not been attenuated. 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 measures, records or notifications required by local and federal governments.

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.

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

KEY OF SYMBOLS

Symbol	Meaning	Symbol	Meaning
LOT	Batch code (lot)		Manufacturer
	Biological risks		Temperature limitation
REF	Catalog number		Use-by date
	Caution, consult accompanying documents		Warning

Please refer to product labels for applicable symbols.

PRODUCT WARRANTY

These products are covered under warranty 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.
- The rehydrated material is frozen, Microbiologics cannot guarantee the stated characteristics of the product.

WEBSITE

Visit our website, **www.microbiologics.com**, for current technical information and product availability.

ASSISTANCE

Microbiologics, Inc.
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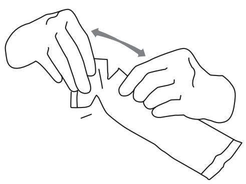
Tel: +1.320.253.7400
U.S. Toll Free: +1.800.599.2847
Email: info@microbiologics.com

Additional copies of this product insert may be obtained at **www.microbiologics.com** or by emailing info@microbiologics.com

UV-BioTAG™

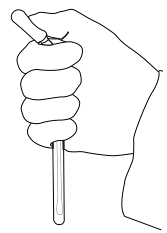
ILLUSTRATED INSTRUCTIONS – SWABS

1



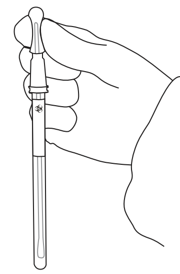
Allow unopened UV-BioTAG™ Swab to equilibrate to room temperature. Tear open pouch at notch and remove the UV-BioTAG™ Swab unit.

2



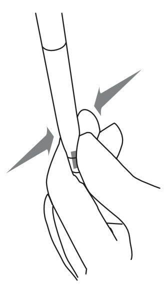
Break red snap valve at the top of the UV-BioTAG™ Swab to release the hydration fluid.

3



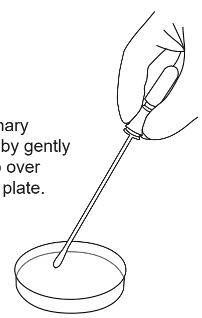
Squeeze the bulb at the top of the UV-BioTAG™ Swab to rehydrate the pellet.

4



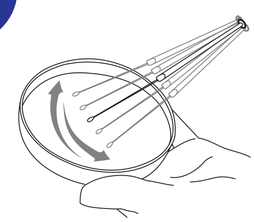
Using a pinching action on the bottom portion of the unit, crush the pellet in the fluid until the pellet suspension is homogenous.

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 **UV-BioTAG™ Swab.**

8

Immediately incubate the inoculated primary culture plate(s) at temperature and conditions appropriate to the microorganism.

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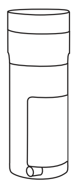
UV·BioTAG™

ILLUSTRATED INSTRUCTIONS – VIAL KITS

1

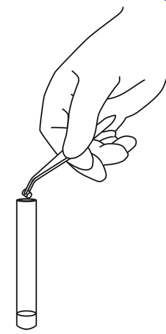


Remove the plastic container containing the vials of pellets from refrigerated storage. Remove the vials to be used; immediately place the plastic container containing the remaining vials back into refrigerated storage to maintain product stability.

2

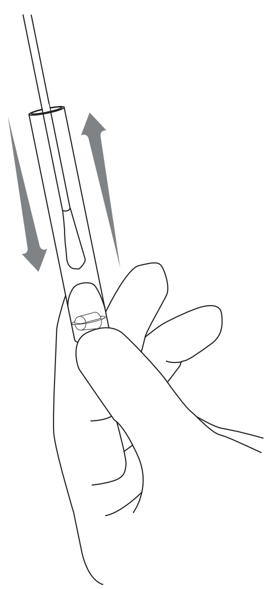
Aseptically remove 1 pellet with sterile forceps from the vial. Do not remove desiccant.

3



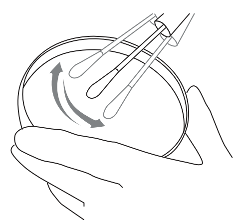
Place the pellet in 0.5 ml of sterile fluid (water, saline, TSB, or BHIB).

4



Crush the pellet with a sterile swab until the suspension is homogenous.

5



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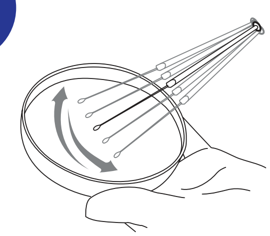
6

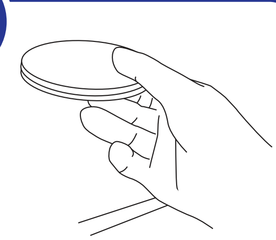


Continue according to laboratory protocol.

7

Using proper biohazard disposal, discard the remaining hydrated material.

8



Immediately incubate the inoculated media at temperature and conditions appropriate to the microorganism.

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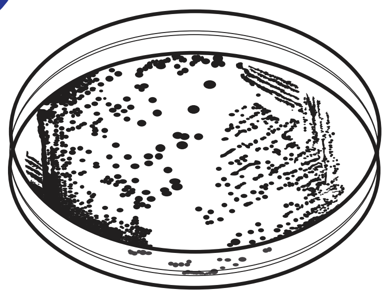
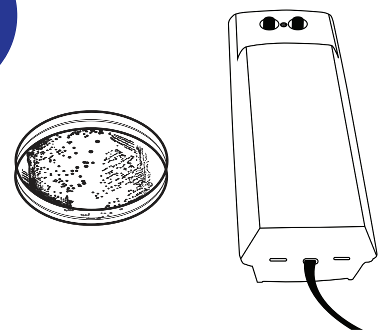
ILLUSTRATED INSTRUCTIONS – FLUORESCENCE DETECTION

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

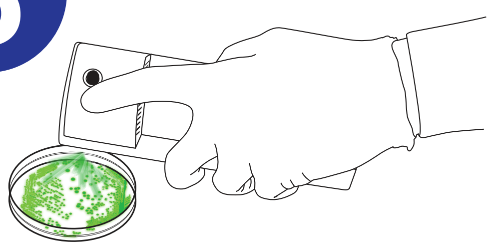


A long wave UV lamp and a dark room are needed for the detection of fluorescence. **UV-BioTAG™** microorganisms' fluorescence is best detected using a UV lamp that emits the following wavelengths:

a. 315 – 400 nm (for use with *Escherichia, Salmonella* and *Shigella* strains)

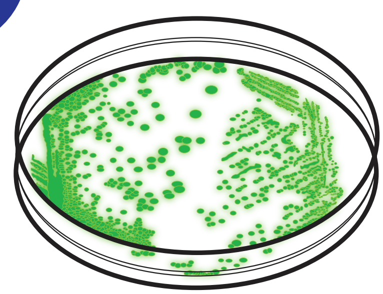
b. 475 – 495 nm (for use with *Listeria monocytogenes* strains)

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 laboraory's processes may produce fluorescence with varying colors, or may mask the expression of the GFP due to biochemical byproducts produced during the test.

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.

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