

INSTRUCTIONS FOR USE



-  LYFO DISK™
-  KWIK-STIK™
-  KWIK-STIK™ Plus

INTENDED USE

LYFO DISK™, KWIK-STIK™ and KWIK-STIK™ Plus microorganisms are intended to be used as controls to verify the performance of assays, reagents or media that are intended to be used in microbial testing for the detection and identification of a cultured microorganism isolate.

SUMMARY AND EXPLANATION

Microorganisms with known and predictable characteristics are used in quality control, education and proficiency programs.

PRINCIPLE

LYFO DISK™, KWIK-STIK™ and KWIK-STIK™ Plus microorganisms provide equivalent results to traditional methods used in preparing, storing and maintaining reference stock culture collections. The microorganism preparations are traceable to the American Type Culture Collection (ATCC®) or other authentic reference culture collections.

COMPOSITION

LYFO DISK™, KWIK-STIK™ and KWIK-STIK™ Plus microorganism pellets consist of a microorganism population (>1000 CFUs per pellet), gelatin, skim milk, ascorbic acid, carbohydrate, and charcoal. 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. The charcoal is included to neutralize any toxic substances formed during the lyophilization process.



PRODUCT DESCRIPTION

- A. KWIK-STIK™**: each KWIK-STIK™ unit contains a lyophilized microorganism pellet, an ampoule of hydrating fluid, and an inoculating swab. Each device is sealed within a laminated pouch that contains a desiccant to prevent adverse moisture accumulation. KWIK-STIK™ microorganisms are 4 passages or fewer from the reference culture, and are available in packs of 2 and 6.
- B. KWIK-STIK™ Plus**: each KWIK-STIK™ Plus unit contains a lyophilized microorganism pellet, an ampoule of hydrating fluid, and an inoculating swab. Each device is sealed within a laminated pouch that contains a desiccant to prevent adverse moisture accumulation. KWIK-STIK™ Plus microorganisms are 2 passages from the reference culture and are available in packs of 5.
- C. LYFO DISK™**: LYFO DISK™ microorganisms are packaged in a resealable vial that contains 6 lyophilized microorganism pellets and a desiccant to prevent adverse moisture accumulation. The LYFO DISK™ microorganisms are 4 passages or fewer from the reference culture.

These products have been registered as a medical device under Pakistan's medical device rules.

WARNING AND PRECAUTIONS

- These products are for in-vitro diagnostic use.
- Not intended for human, animal or pet consumption.
- 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 **320.229.7045** or U.S. Toll Free **1.866.286.6691**.
- The hydrating fluid in the KWIK-STIK™ and KWIK-STIK™ Plus may cause 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.
- Wear protective gloves/protective clothing/eye protection/face protection. Wash hands thoroughly after handling.
- These devices contain viable microorganisms that may produce disease. Proper techniques must be employed to avoid exposure and contact with any microorganism growth.
- The microbiology laboratory must be equipped and have the facilities to receive, process, maintain, store and dispose of biohazard material.
- Only trained laboratory personnel should use these devices.
- Agencies and statutes regulate the disposal of all biohazard materials. Each laboratory must be aware of and comply with the proper disposal of biohazard materials.
- LYFO DISK™, KWIK-STIK™ and KWIK-STIK™ Plus microorganisms are not made with natural rubber latex.

MATERIALS REQUIRED BUT NOT PROVIDED

- LYFO DISK™ microorganisms 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.
- LYFO DISK™, KWIK-STIK™ and KWIK-STIK™ Plus microorganisms require non-selective, nutrient or enriched agar media and specific incubation times and conditions to optimize growth and recovery.

The Technical Information Bulletin (TIB.081) **Recommended Growth Requirements** lists the recommended media and incubation requirements. This bulletin is available in our website's document library at www.microbiologics.com.

INSTRUCTIONS FOR USE

A. KWIK-STIK™ and KWIK-STIK Plus™ Microorganism Procedure

1. Allow the unopened KWIK-STIK™ pouch to equilibrate to room temperature. Tear open pouch at notch and remove the KWIK-STIK™ unit.
2. Tear off Pull-Tab portion on the label and attach it to the primary culture plate or QC record. Do not disassemble the device during hydration.
3. Pinch (once only) the ampoule at the top of the KWIK-STIK™ (just below the fluid meniscus of the ampoule) found in the cap to release the hydrating fluid.
4. Hold vertically and tap on a hard surface to facilitate flow of fluid through shaft into bottom of unit containing pellet. Allow the hydrating fluid to flow through the swab shaft and into the bottom portion of the unit containing the pellet.
5. Using a pinching action on the bottom portion of the unit, crush the pellet in the fluid until the pellet suspension is homogenous.
6. Immediately heavily saturate the swab with the hydrated material and transfer to agar medium, or use according to the laboratory's SOP.
7. Inoculate the primary culture plate(s) by gently rolling the swab over one-third of the plate.
8. Using a sterile loop, streak to facilitate colony isolation.
9. Using proper biohazard disposal, discard the KWIK-STIK™.
10. Immediately incubate the inoculated primary culture plate(s) at temperature and conditions appropriate to the microorganism.

B. LYFO DISK™ Microorganism Procedure

1. Remove the unopened LYFO DISK™ vial from 2°C to 8°C storage and allow the unopened vial to equilibrate to room temperature.
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). Immediately stopper and recap vial and return the resealed vial to 2°C to 8°C storage.
4. Crush the pellet with a sterile swab until the suspension is homogenous. Immediately heavily saturate the same swab with the hydrated material and transfer to agar medium.
5. Inoculate the primary culture plate(s) by gently rolling the swab over one-third of the plate.
6. Using a sterile loop, streak to facilitate colony isolation.
7. Using proper biohazard disposal, discard the remaining hydrated material.
8. Immediately incubate the inoculated media at temperature and conditions appropriate to the microorganism.

STORAGE AND EXPIRATION


Store LYFO DISK™, KWIK-STIK™ and KWIK-STIK™ Plus microorganisms at 2°C to 8°C in the original, sealed vial or pouch containing the desiccant. LYFO DISK™, KWIK-STIK™ and KWIK-STIK™ Plus microorganisms should not be used if:

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

LIMITATIONS


This product may not be suitable for use with all kits and procedures.

KEY OF SYMBOLS


 Authorized Representative in the European Community

 Batch Code (Lot)

 Biological Risks


 CE Mark

 Catalog Number


 Caution, Consult Accompanying Documents

 *In Vitro* Diagnostic Medical Device

 Manufacturer

 Temperature Limitation

 Use By

 Consult Instructions for Use

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

WEBSITE

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

ACKNOWLEDGEMENTS



Microbiologics, Inc.
200 Cooper Avenue North
St. Cloud, MN 56303 USA

Customer Service

Tel. 320-253-1640
U.S. Toll Free. 800-599-BUGS (2847)
Email. info@microbiologics.com

Technical Support

Tel. 320-229-7045
U.S. Toll Free 866-286-6691
Email. techsupport@microbiologics.com
www.microbiologics.com



MediMark® Europe
11, rue Emile Zola B.P. 2332
38033 Grenoble Cedex 2, France
Tel. 33 (0)4 76 86 43 22
Fax. 33 (0)4 76 17 19 82
Email. info@medimark-europe.com

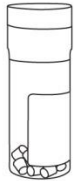


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LYFO·DISK™

ILLUSTRATED INSTRUCTIONS

1



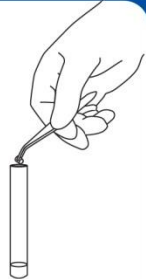
Remove the unopened LYFO DISK™ vial from 2°C to 8°C storage and allow the unopened vial to equilibrate to room temperature.

2



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

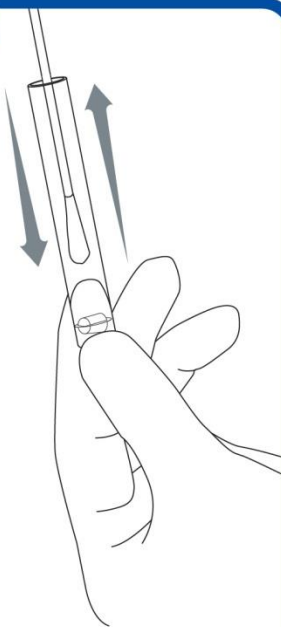
3



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

Immediately stopper and recap vial and return the resealed vial to 2°C to 8°C storage.

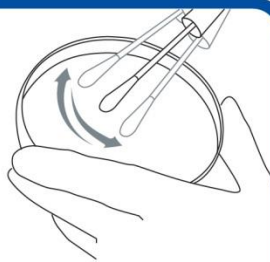
4



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

Immediately heavily saturate the same swab with the hydrated material and transfer to agar medium.

5



Inoculate the primary culture plate(s) by gently rolling the swab over one-third of the plate.

6



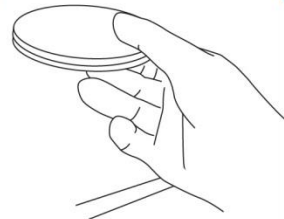
Using a sterile loop, streak to facilitate colony isolation.

7



Using proper biohazard disposal discard the remaining hydrated material.

8



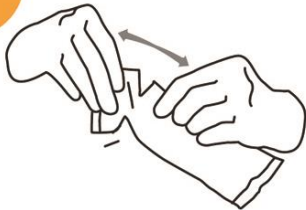
Immediately incubate the inoculated media at temperature and conditions appropriate to the microorganism.

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A safer, healthier world.

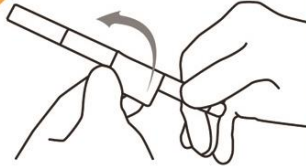
ILLUSTRATED INSTRUCTIONS

1



Allow the unopened KWIK-STIK™ pouch to equilibrate to room temperature. Tear open pouch at notch and remove the KWIK-STIK™ unit.

2



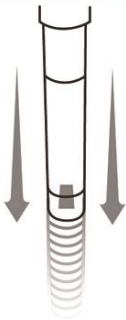
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3



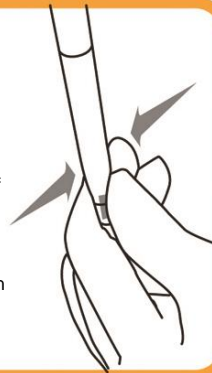
Pinch (once only) the ampoule at the top of the KWIK-STIK™ (just below the fluid meniscus of the ampoule) found in the cap to release the hydrating fluid.

4



Hold vertically and tap on a hard surface to facilitate flow of fluid through shaft into bottom of unit containing pellet. Allow the hydrating fluid to flow through the swab shaft and into the bottom portion of the unit containing the pellet.

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

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Immediately heavily saturate the swab with the hydrated material and transfer to agar medium, or use according to the laboratory's SOP.

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Inoculate the primary culture plate(s) by gently rolling the swab over one-third of the plate.

8



Using a sterile loop, streak to facilitate colony isolation.

9

Using proper biohazard disposal, discard the KWIK-STIK™



10

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