

INSTRUCTIONS FOR USE



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

INTENDED USE

KWIK-STIK™, KWIK-STIK™ Plus and LYFO DISK™ 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

KWIK-STIK, KWIK-STIK Plus and LYFO DISK 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

KWIK-STIK, KWIK-STIK Plus and LYFO DISK pellets contain a pure population of microorganisms and excipients for the purpose of structure and/or stability including gelatin, skim milk, ascorbic acid, carbohydrate, and charcoal.

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 3 passages or fewer from the reference culture and are guaranteed to recover when processed using the recommended media and incubation requirements. Available in packs of 2 or 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 guaranteed to recover when processed using the recommended media and incubation requirements. 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 3 passages or fewer from the reference culture and are guaranteed to recover when processed using the recommended media and incubation requirements.

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 Safety Data Sheet (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.
- KWIK-STIK, KWIK-STIK Plus and LYFO DISK microorganisms are not made with natural rubber latex.

MATERIALS REQUIRED BUT NOT PROVIDED

- LYFO DISK microorganisms require sterile tubes and 0.5 ml of a 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.
- KWIK-STIK, KWIK-STIK Plus and LYFO DISK microorganisms require non-selective, nutritive or enriched agar media and specific incubation times and conditions to optimize growth and recovery.

The Technical Information Bulletin (TIB.081) *Recommended Culture Methods* lists the recommended media and incubation requirements. This bulletin is available 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. Over the edge of the work bench or counter, crack the ampoule at the top of the KWIK-STIK (just below the fluid meniscus) to release the hydrating fluid.
4. Hold vertically and tap on a hard surface to facilitate flow of the fluid through the shaft into the bottom of the unit where the pellet is contained.

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 the appropriate 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 inverted inoculated primary culture plate(s) at temperature and conditions appropriate to the microorganism. Culture method can be found on the product's page at www.microbiologics.com

B. LYFO DISK Microorganism Procedure

1. Remove the unopened LYFO DISK vial from 2°C to 8°C storage and allow 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 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 inverted inoculated primary culture plate(s) at temperature and conditions appropriate to the microorganism. Culture method can be found on the product's page at www.microbiologics.com

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



Consult Instructions for Use



Batch Code (Lot)



In Vitro Diagnostic Medical Device



Biological Risks



Manufacturer



Catalog Number



Temperature Limitation



Caution, Consult Accompanying Documents



Use By



CE Mark

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.
- 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 and product availability.

ACKNOWLEDGEMENTS



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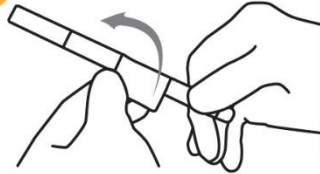
ILLUSTRATED INSTRUCTIONS

1



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

2

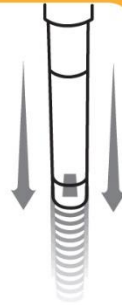


Tear off pull-tab portion on the label and attach it to the primary culture plate or QC record. Do not disassemble the device during

3

Over the edge of the work bench or counter, crack the ampoule at the top of the KWIK-STK (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 the fluid through the shaft into the bottom of unit where the pellet is contained.

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

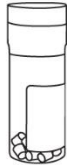
Culture method can be found on the product's page at microbiologics.com

LYFO·DISK™

ILLUSTRATED INSTRUCTIONS

1

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



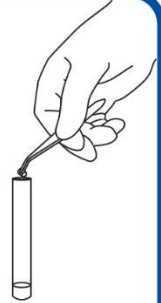
2

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



3

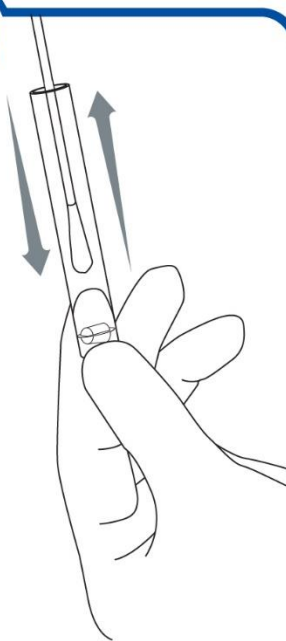
Place the pellet in 0.5 ml of sterile fluid (water, saline, TSB, or BHIB). Immediately stopper and recap vial and return to 2°C to 8°C storage.



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.



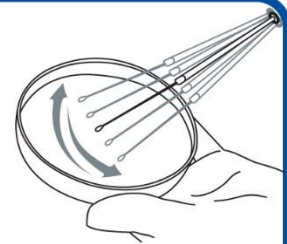
5

Inoculate the primary culture plates(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 inverted inoculated primary culture plate(s) at temperature and conditions appropriate to the microorganism.

Culture method can be found on the product's page at microbiologics.com

