



# Mycobacti-Loop®

## INTENDED USE

Remel Mycobacti-Loop® products are ready-to-use, disposable inoculating loops containing stabilized, viable mycobacteria recommended for use in laboratory quality control procedures. They are a quality source for performance testing of culture media, reagents, stains, diagnostic test kits, susceptibility tests, and other products used in mycobacteriological procedures.

## SUMMARY AND EXPLANATION

Various methods of drying have been incorporated in the past to produce bacteria as stock cultures. Some methods dried bacteria in fluids such as saline, serum, or blood in a vacuum with dehydrating agents such as H<sub>2</sub>SO<sub>4</sub> or P<sub>2</sub>O<sub>5</sub>. Lord Stamp determined that gelatin and ascorbic acid have a beneficial effect on maintaining bacteria during the drying process.<sup>1</sup> Annear found that glucose had a marked preservative effect regardless of the drying process employed.<sup>2</sup> The procedure developed by Obara et al. made use of gelatin, skim milk, charcoal, ascorbic acid, and dextrose as a suspending medium.<sup>3</sup> Mycobacti-Loop® products employ a modification of this method, providing a convenient and quality source for the maintenance of stock cultures.

## PRINCIPLE

The gelatin serves to form a solid medium which contains the organism in the loop end. During the preservation process skim milk, carbohydrates, and ascorbic acid act as protective agents and charcoal neutralizes toxic substances. These microorganisms are derived from cultures of the American Type Culture Collection (ATCC®), under license.

## REAGENTS

Mycobacti-Loop® - Active ingredients:  
Gelatin                      Ascorbic Acid  
Skim Milk                    Charcoal  
Carbohydrates              Microorganism

\*Adjusted as required to meet performance standards.

## PRECAUTIONS

This product is For the Quality Control of *In Vitro* Diagnostic Products and should be used by properly trained individuals. Precautions should be taken against the dangers of microbiological hazards by properly sterilizing specimens, containers, and media after use. Directions should be read and followed carefully.

**Caution!** Each Mycobacti-Loop® contains viable microorganisms that are potentially infectious. Organisms should be handled at the appropriate Biosafety Level according to CDC/NIH guidelines.<sup>4</sup> Follow established laboratory safety procedures when working with acid-fast cultures and consult appropriate references for procedural information.<sup>5,6</sup> Refer to the Material Safety Data Sheet for additional information.

## STORAGE

This product is ready for use and no further preparation is necessary. Store each Mycobacti-Loop® in its original container at 2-8°C until used. Allow product to equilibrate to room temperature before use. Do not incubate prior to use.

## PRODUCT DETERIORATION

Each Mycobacti-Loop® should contain an intact, dried, black film. The product should not be used if (1) the color has changed, (2) there is evidence of hydration, (3) the expiration date has passed, or (4) there are other signs of deterioration.

## MATERIALS REQUIRED BUT NOT SUPPLIED

(1) Loop sterilization device, (2) Inoculating loop, (3) Incubators, alternative environmental systems, (4) Supplemental media, (5) Pipettes, (6) Mycobacteriological safety equipment.

## PROCEDURE

For rehydration to occur the film in the loop must come in contact with both **warmth and moisture**; follow the procedure outlined below. Media may be labeled with the peel-off label from the foil pouch.

1. Remove the red sheath and break the loop shaft off from the handle directly into the vial of rehydration fluid.
2. Place vial in foam rack and incubate at 35-37°C for 10-20 minutes.
3. Examine vial to confirm that black film has completely dissolved from the loop. Shake vial to resuspend the organism.
4. Inoculate appropriate media with a transfer pipette and, if plated media is used, streak for isolation. Multiple plates may be inoculated at this time.
5. Incubate media in an appropriate atmosphere and temperature for optimal growth of the organism for up to 8 weeks. Examine cultures twice weekly for visible growth.

**NOTE:** These instructions are for initial inoculation of Mycobacti-Loop®. Quality control of diagnostic products should be performed as specified in the manufacturer's instructions for use or other recommended guidelines.<sup>5,6</sup>

## QUALITY CONTROL

All lot numbers of Mycobacti-Loop® have been tested using standard laboratory procedures and have been found to be acceptable. If aberrant results are observed, the product should not be used for quality control testing procedures.

## LIMITATIONS

1. Media containing selective agents may inhibit initial growth of some organisms.
2. Each Mycobacti-Loop® contains an unspecified quantity of microorganisms and is not intended for use in quantitative analyses.

## BIBLIOGRAPHY

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4. Richmond, J.Y. and R.W. McKinney. 1999. *Biosafety in Microbiological and Biomedical Laboratories.* 4<sup>th</sup> ed. U.S. Dept. of H.H.S., CDC and National Institutes of Health, Washington, D.C.
5. Isenberg, H.D. 2004. *Clinical Microbiology Procedures Handbook.* 2<sup>nd</sup> ed. ASM, Washington, D.C.
6. Murray, P.R., E.J. Baron, J.H. Jorgensen, M.A. Pfaller, and R.H. Tenover. 2003. *Manual of Clinical Microbiology.* 8<sup>th</sup> ed. ASM, Washington, D.C.

## PACKAGING

Each Mycobacti-Loop® product contains the following items in a plastic bag: 1 Mycobacti-Loop® individually sealed in a foil pouch, 1 vial of specially formulated rehydration fluid, and a foam rack.

REF R4610012 .. *Mycobacterium fortuitum* subsp. *fortuitum* ATCC® 6841™\*  
REF R4610014 ..... *Mycobacterium kansasii* ATCC® 12478™\*  
REF R4610020 ..... *Mycobacterium tuberculosis* ATCC® 25177™\*

## Symbol Legend

<b>REF</b>	Catalog Number
<b>IVD</b>	In Vitro Diagnostic Medical Device
<b>LAB</b>	For Laboratory Use
	Consult Instructions for Use (IFU)
	Temperature Limitation (Storage Temp.)
<b>LOT</b>	Batch Code (Lot Number)
	Use By (Expiration Date)
	Biological Risk (Infectious Substance)

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