



DriAmp™

**Dry Heat Biological Indicator Culturing Set
with Releasat® Culture Medium**

B. atrophaeus #9372⁽¹⁾

- The DriAmp™ biological indicator culturing set consists of a 1 mL snap top glass ampoule containing silica material inoculated with *Bacillus atrophaeus* spores and tubes of Releasat® proprietary sterile culture media.
- The Releasat media is specially formulated for rapid outgrowth (72 hours) of *Bacillus atrophaeus* spores that may have survived a dry heat exposure or submersion in oils and other non-water based solutions.

Instructions for Use:

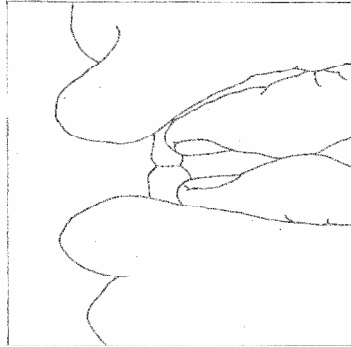
1. Place ampoule(s) with representative materials to be sterilized. Package as usual.
2. Locate test packages in areas of sterilizer most difficult to sterilize.
3. Identify test packages as to location in the dry heat sterilizer.
4. After sterilizing, forward ampoule(s) and media to test laboratory along with at least one non sterilized ampoule marked POSITIVE CONTROL.
5. All testing should be performed within confines of a laminar flow hood.
6. All transfers and manipulations must be done with rigid aseptic techniques to avoid “false positive” samples.

Procedure:

1. Let the ampoules cool for at least ten minutes before culturing.
2. Before the ampoule is placed in the workstation, the ampoule should be sprayed with 70% IPA.
3. Remove the caps of the ampoules as follows:
 - a. Hold the top of the ampoule with one hand and the body of the ampoule with the other hand (See Figure 1).
 - b. Place thumbs tip-to-tip over the scored glass line at the neck of the ampoule.
 - c. Snap the top off of the ampoule by using the thumb tips as a hinge and applying pressure at the scored glass line.

⁽¹⁾ Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

Figure 1



- d. Slowly pour the contents from the ampoule into a test tube of Releasat medium, one tube for each ampoule.
- e. Incubate at 36-38°C.
- f. Results are read at not less than 72 hours.⁽¹⁾
- g. Observe tubes daily for growth. Yellow = growth = non-sterile
Red = no growth = sterile

⁽¹⁾ Reduced incubation time confirmed using FDA Protocol.

DriAmp Advantages:

- Results are final in three days.
- Dramatic color change for positive cultures.
- The only product of its kind on the market.
- Complies with the global industry standard ISO 11138-1 and -4.

Certification:

The DriAmp Biological Indicator Culturing Set with Releasat Media is certified for reference number and population. D-value and performance are certified using Releasat media. Each set includes DriAmp ampoules and Releasat media.

DriAmp ampoules are manufactured in compliance to USP and ISO 11138.

DriAmp Biological Indicator Culturing Sets with Releasat Media are available as follows:

	Sets per Box	Cat. No.
DriAmp and Releasat Culture Media50 <i>B. atrophaeus</i> 10 ⁶		DRH/50