

# DriAmp™

Dry Heat Biological Indicator Culturing Set  
with Releasat® Culture Medium  
For Industrial Use Only

## CERTIFICATE OF ANALYSIS

Reorder No.: DH/50

*Bacillus atrophaeus*: 9372<sup>(1)</sup>

Biological Indicator for: Dry Heat Sterilization.

Culture: 36 to 38°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

Purity: No evidence of contaminants using standard plate count techniques.

Ampoule Lot No.: DA-000

Media Lot No.: RM-000

Manufacture Date: YEAR MONTH DAY

Expiration Date: 12 months from Manufacture Date.

Heat Shocked Population: 0.0x10<sup>6</sup> Spores / Unit

Assayed Resistance:	D-Value <sup>(2)</sup>	Survival	Kill	
Dry Heat 150°C	0.0	00.0 <sup>(4)</sup>	00.0 <sup>(4)</sup>	
Dry Heat 160°C	0.0	00.0 <sup>(3)</sup>	00.0 <sup>(3)</sup>	
Dry Heat 170°C	0.0	00.0 <sup>(4)</sup>	00.0 <sup>(4)</sup>	minutes

Z-value °C

D-value reproducible only when exposed in a BIER vessel and cultured under the exact conditions used to obtain results reported here. MPN method used.

Units are manufactured in compliance with SGM Biotech's quality standards, USP, and ISO 11138 guidelines and all appropriate subsections.

(1) Culture is traceable to a recognized culture collection identified in USP and ISO11138.

(2) D-value calculated using the Limited-Holcomb-Spearman-Karber method.

(3) Survival/Kill values are calculated according to a formula in USP and ISO 11138. SGM uses a D-value rounded four decimal places in this calculation.

(4) Empirically derived data.

Certified By: \_\_\_\_\_

Complete Quality Control testing results available upon request.

# DriAmp™

Biological Indicator Culturing Set with Releasat® Culture Medium  
Biological Indicators for demonstrating adequacy of dry heat sterilization.

## INSTRUCTIONS

### Sterilization

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. Identify test packages as to location in the dry heat sterilizer.
3. After sterilizing, forward ampoule(s) and media to test laboratory along with at least one non-sterilized ampoule marked POSITIVE CONTROL.

### Test Laboratory

1. All testing should be performed within confines of a laminar flow hood. All transfers and manipulations must be done with rigid aseptic techniques to avoid "false positive" samples.
2. Procedure:
  - a. Let the ampoules cool for at least ten minutes before culturing.
  - b. Before the ampoule is placed in the workstation, the ampoule should be sprayed with 70% IPA.
  - c. Remove the caps of the ampoules as follows:
    - Hold the top of the ampoule with one hand and the body of the ampoule with the other hand.
    - Place thumbs tip-to-tip over the scored glass line at the neck of the ampoule.
    - Snap the top off of the ampoule by using the thumb tips as a hinge and applying pressure at the scored glass line.
  - 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 NLT 72 hours. (Reduced incubation time confirmed using FDA Protocol.)
  - g. Observe tubes daily for growth. Yellow = growth = non-sterile  
Red = no growth = sterile

Test cultures should show no growth if sterilization has been achieved. A yellow color and/or turbidity indicates bacterial growth occurred in culture tubes. Tubes can be sub-cultured if identification of positive growth is desired. Recommended sub-culturing procedure techniques are available from SGM Biotech.

### 3. Controls

**Positive:** One or more positive controls should be included in each test series. Transfer a non-sterilized ampoule to Releasat culture medium and incubate with test series. Yellow color and turbidity indicates that the medium possesses suitable growth promoting qualities and that the carrier contains viable spores. If positive control does not grow, do not use the units from that package. Contact SGM Biotech.

### Storage and Disposal:

1. Store **DriAmp** biological indicators at room temperature. Do not desiccate.
2. **DriAmp** biological indicators have a 12 month shelf life which is clearly designated on each box. Rotate your stock accordingly.

**NOTE:** Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.

10 Evergreen Drive Suite E  
Bozeman, MT 59715  
406-585-9535  
www.sgmbiotech.com