BAG HEALTH CARE

BETTER with 72 hour-read-out

BAG-DriAMP for Dry Heat

Biological Indicator for Monitoring Dry Heat Sterilization Processes at High Temperatures, incl. Media Ampoules with 72-Hour-Read-Out

Order-No.	**Packaging unit**
75370	50 spore ampoules + 50 media tubes

Specifications

BAG-DriAMP for dry heat is a hermetically sealed ampoule (4.9 x 1.1 cm) containing silica sand inoculated with Bacillus atrophaeus spores >10^6. This application enables monitoring longer dry heat sterilization processes and cycles with higher temperatures (180-240°C) respectively, while regular paper spore strips might lose integrity. BAG-DriAMP provides a greater challenge to dry heat cycles as resistance data (D-value) exceed specifications in ISO 11138.

Every packaging unit includes 50 ampoules with inoculated silica sand and 50 tubes containing a special growth medium providing a reduced incubation time with a final read-out after 72 hours. Just crack the ampoule at the designated point and transfer the silica sand into a media tube.

Incubation and evaluation

Incubation temperature is 36-38°C. The silica sand has to be aseptically transferred into the included media ampoules. A not sterilized sample has to be incubated as positive growth control. The recommended read-out-time is 72 hours. If needed check and record results daily for growth/no growth. A color change to yellow indicates growth = not sterile.

Accompanying certificates include data for D-value, z-value, nominal population, survival and killing time in dry heat sterilization processes.

Storage: dry, 15-27°C
Expiry: 12 months from date of manufacture
Disposal: sterilize all ampoules showing growth (yellow color)

06/12

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PERFORMANCE DATA for DriAMP™

ORGANISM: ***Bacillus atrophaeus derived from*** **(ATCC #9372*)**

POPULATION:* **3.4 x 10^6** CFU'S** / ampoule

RESISTANCE CHARACTERISTICS:

D_{160} VALUE:*** **4.0** minutes

* Culture is traceable to a recognized culture collection identified in USP and ISO 11138
** Colony forming units
*** D-values are calculated using the Limited-Holcomb-Spearmen-Karber method.

AGENT	CONDITIONS	SURVIVES	KILLED
Dry Heat	160 ± 2°C	18.1 min	42.1 min

INCUBATION: 72 hours at 36°C - 38°C in supplied Releasat® Culture Medium
STORAGE: 15-27°C (60-80°F), 30-70% RH, away from sterilizing agents, direct sunlight and all other forms of UV light. (DO NOT REFRIGERATE)
DISPOSAL: Do not use after expiration date. Sterilize all cultures before discarding.

 **05/13** LOT **DH-105**

DriAMP - Instructions for Use

1. Include several biological indicators with each sterilizer cycle to be monitored. Place in the most difficult to sterilize location in chamber.
2. After sterilization:
   a. Let the ampoule cool for at least ten (10) 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 72 hours.
   g. Observe tubes daily for growth.
      Yellow = growth = non-sterile / Red = no growth = sterile.
3. **Positive Control:** 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.

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