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 Mesa Labs.
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 Mesa Labs.

Storage and Disposal:

1. Store **DriAmp** biological indicators at room temperature. Do not desiccate.
2. **DriAmp** biological indicators have 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 incineration or by exposure to a dry heat cycle that is two times the labeled kill time.

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