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Instructions for Use

ProAMP 5230 **Indicators for Monitoring Low Temperature Steam Sterilization**

1. Place ProAMP 5230 inside representative liquid containers to be sterilized. Package or seal as usual.
2. Locate test samples in areas of the load considered most difficult to sterilize or in convenient areas that have been validated. Identify test samples as to location in sterilizer.
3. After sterilizing, send ProAMP 5230 and products to test laboratory along with at least one non-sterilized ProAMP 5230 marked POSITIVE CONTROL.

Test Laboratory:

1. All ProAMP 5230 are fully self-contained BIs which do not require subculture.
2. Procedure:
 - a. ProAMP 5230 may be left in the sterilized container or transferred to a rack or container which allows visual observation during incubation.
 - b. Incubate ProAMP 5230 for three days at 35-39°C.
 - c. Observe daily for growth: Yellow = growth = non-sterile Red = no growth = sterile

ProAMP 5230 should show "no growth" if sterilization has been achieved. If color change to yellow occurs in ProAMP 5230 cultures, it indicates that the spores have survived the sterilization process and are non-sterile.

Controls:

Positive: At least one positive control should be included in each test series. Incubate a non-sterilized ProAMP 5230 with test series. Color change from red to yellow indicates that the medium possesses suitable growth promoting qualities and that the ProAMP 5230 contains viable spores. If positive control does not grow, do not use the units from that package.

Negative: The Negative Control (NC) is a media ampoule made from the same lot of media used to make the corresponding spore ampoules and can be utilized in one of two different ways:

1. The NC can follow the spore ampoule through the process to verify that any color change seen immediately upon removal from the process was a result of the process and not due to spore germination or growth.
2. The (unprocessed) NC can be incubated along with the positive control (also unexposed to the sterilant) and test spore ampoules. This illustrates that the media is sterile and can be used to compare against the positive control for color.

Storage and Disposal:

1. Refrigerate at 2-8°C. Protect from light.
 2. Incinerate or autoclave at 121°C for not less than 30 minutes.
- ProAMP 5230 biological indicators have a shelf life which is clearly designated on each package. Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.

Rev. 10 REF#7052