

DTB

Desarrollo en Tecnología Biomédica

Biological & Chemical INDICATORS



Guide to Biological and Chemical Indicators
for Assuring the Sterility Guarantee for all sterilizing
processes in accordance with AAMI and ISO

Smart Quality by **DTB**

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Desarrollo en Tecnología Biomédica



Desarrollo en Tecnología Biomédica offers the most complete and highest quality line in the world in biological and chemical indicators to ensure the sterility guarantee for all sterilizing processes

Smart Quality by **DTB**



BI

Biological indicators self-contained in TUBE



EZTest®
EZTest® self-contained Biological Indicator designed for monitoring sterilization cycles by steam saturation, ethylene oxide, hydrogen peroxide or by propylene oxide.



ProTest
ProTest self-contained Biological Indicator, designed for monitoring sterilization cycles by steam saturation or by ethylene oxide.



ProSpore2
ProSpore2 self-contained Biological Indicator, designed for monitoring sterilization cycles by steam saturation or by ethylene oxide (EO).



ProTest H₂O₂
ProTest H₂O₂ self-contained Biological Indicator designed for monitoring the effectiveness of hydrogen peroxide sterilization processes.

Filter paper strip with spores



Spore Strips
Spore Strips, Biological Indicators in Strip. DTB offers the most complete line of strips with spores for sterility testing in different sterilization processes.



MesaStrip
MesaStrip Biological Indicators in Strip, ideal for monitoring industrial sterilization processes by steam, ethylene oxide, dry heat, chlorine dioxide, formaldehyde steam at low temperature and gamma radiation.

Smart Quality by DTB



Releasat
Kit with Biological Indicators in Strip and calibrated culture medium and especially formulated with a color indicator to evaluate the effectiveness of sterilization by chlorine dioxide, ethylene oxide and steam.

The RELEASAT is a Kit with Biological Indicators in Strip and calibrated culture medium in test tubes specially formulated with a red indicator that turns into a dramatic yellow when the spores grow. This kit is available to evaluate the effectiveness of sterilization by chlorine dioxide, ethylene oxide, dry heat and steam sterilization.

The color indicator provides an unmistakable visual result in 24 hours for steam sterilization processes, 48 hours for chlorine dioxide process and 72 hours for ethylene oxide and dry heat processes. This represents a great advantage against traditional seven-day results.

RELEASAT culture medium is used to culture the MesaStrip strips instead of the generic culture medium. Each batch of Releasat culture tubes is quality controlled for use in conjunction with their corresponding MesaStrips.

Biological indicators self-contained in VIAL



MagnaAmp

MagnaAmp are self-contained Biological Indicators in ampoules with spores of *Geobacillus stearothermophilus* for monitoring liquid steam sterilization in sterilizing containers or washing machines.

MagnaAmp contains a specially formulated culture medium that turns dramatic yellow when spores grow. Easy visual confirmation of sterilization in 48 hours without the need for hard laboratory work.



DriAmp

DriAmp are 1ml ampoules containing silica material inoculated with 10⁶ *Bacillus atrophaeus* spores (# 9372) with a removable lid, all materials are compatible with extremely high temperatures such as those found in dry heat ovens for sterilization or depyrogenation, in ampoules for the

monitoring of liquid steam sterilization in sterilizing containers or washing machines.

It comes in a kit with its individual Releasat tube specially formulated for the rapid growth of *B. atrophaeus* spores designed for easy aseptic transfer and cultivation. This indicator is suitable for direct exposure to air at high temperatures or immersion in oils or other non-water based solutions.



ProSpore Ampoule

ProSpore Ampoules are self-contained Biological Indicators in ampoules for monitoring liquid vapor sterilization at 121 °C cycles.



SterilAmp II

SterilAmp II are self-contained Biological Indicators in ampoules with *Geobacillus stearothermophilus* spores for monitoring liquid vapor sterilization in small containers.

SterilAmp II contains a specially formulated culture medium that turns dramatic yellow when spores grow. Easy visual confirmation of sterilization in 48 hours without the need for hard laboratory work.



SterilAmp II "5230"

SterilAmp II "5230" are self-contained Biological Indicators in ampoules with *Bacillus subtilis* "5230" spores for monitoring sterilization at low temperature (110 - 118 °C) of liquids in small containers.

SterilAmp II "5230" contains a specially formulated culture medium that turns dramatic yellow when spores grow. Easy visual confirmation of sterilization in 48 hours without the need for hard laboratory work.

Spore suspension for inoculation and stainless steel discs



Spore Suspensions

Spore Suspensions are calibrated bacterial spore suspensions suitable for direct inoculation of products for monitoring sterilization processes by steam, ethylene oxide, dry heat, hydrogen peroxide and gamma radiation.



Stainless Steel Discs

Stainless Steel Discs are stainless steel discs inoculable with any organism we manufacture. The advantage of using discs is their size and the material of the disc. The discs are compatible with the different sterilization requirements that manufacturers and validation specialists have. An example is that the discs are representative of the materials found in an insulator and are compatible with sterilization by hydrogen peroxide.

Specialty chemical and biological indicators



Stainless Steel Coupons

Stainless Steel Coupons are small inoculated stainless steel sheets, the same size as MesaStrip strips. Coupons are compatible with dry heat ovens and other processes with extremely high temperatures. Inoculated with 10^6 B. atrophaeus spores can be used to correlate spore death with endotoxin reduction in the process.



Indicadores Biológicos APEX

APEX Biological Indicators are specifically designed for the Pharmaceutical, Medical Device and Food industries that use steam sterilization of hydrogen peroxide. The stainless steel carrying indicators is designed for use in insulators and filling lines, it can be in the form of a disc, tapes or a spore solution.



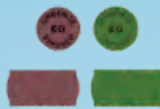
Bowie-Dick

The Bowie and Dick test is designed to evaluate the performance of vacuum systems sterilizers with pre-vacuum system.

GAMMA



ETHYLENE OXIDE



Chemical Indicators

Chemical Indicators

Process Indicators are chemical indicators that distinguish items subjected to sterilization processes from those not subjected to these processes. They adhere properly to solid materials, fabrics, non-woven fabrics, and other materials subjected to sterilization processes. The Chemical Indicator changes color when exposed to the specific process. We have adhesive tapes, square labels, round labels, rectangular labels and are compatible with steam sterilization, chemiclave, ethylene oxide (EO) and gamma radiation processes.

Smart-Read[®] Monitoring System



This biological monitoring system allows the manufacturer to release sterile product with true biological confirmation quickly and easily. This system consists of a real Biological Indicator without enzymes or chemical integrators that is incubated, evaluated and documented in a simple and automated operation. Depending only on the growth of the spore, the Smart-Read system can detect the sterilization failure in an interval of only 3 to 5 hours and the negative results can be confirmed with an additional 5 hours of incubation, in total 10 hours.

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The system includes the Smart-Read EZTest[®] Self-Contained Biological Indicator which requires no special processing and can be used in place of any existing Self-Contained Biological Indicator. The Smart-Read biological indicator contains Bacillus stearothermophilus spores and is suitable for steam sterilization processes. It is specially designed for rapid evaluation in the advanced Smart-Well[®] Incubator incubator. The incubator can evaluate up to ten EZTest-Smart-Read[®] biological indicators independently, and contains an additional cell for a positive control unit.

Based on approved and proven technologies, the Smart-Read system can be implemented in any organization with a minimum of training and validation.



Smart-Read EZTest[®]

Smart-Read EZTest[®] is a self-contained Biological Indicator that changes color, with which you are familiar. Specifically designed for rapid evaluation in the Smart-Well[®] incubator. It does not require any special processing and can be used in place of any existing self-contained Biological Indicator. The Smart-Read biological indicator contains Bacillus stearothermophilus spores and is suitable for steam sterilization processes.

Standard biological indicators are easy to use and are available for industrial use or for healthcare providers.

Manufacturers or validation specialists sometimes have specific manufacturing situations that require a specialty or modified Biological Indicator to assist in sterilization process validation processes where traditional biological indicators are not compatible due to size, packaging, or material where they are inoculated.

At DTB we offer a complete line of Biological Indicators for industrial use that cover the unique needs of the medical device industry and the pharmaceutical industry.



ProTest BI Test Pack

Process Challenge Device for steam sterilization pre-assembled with Integrator for instant reading.



EZTest® BI Test Pack

It is a product designed to emulate the performance of the AAMI Test pack, it includes EZTest® self-contained biological indicators and a registration card with a Chemical integrator.

DTB offers the most complete and highest quality line in the world in biological and chemical indicators

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Av. Tamaulipas 127 - 5

Col. Condesa 06140 Mexico City

Tel. +(52) (55) 5553 6625

Fax. +(52) (55) 5211 1943

contacto@dtb.com.mx

www.dtb.com.mx