ProTest BI Test Pack

ProTest BI Test Pack is a pre-assembled Process Challenge Device (PCD) with an Instant Readout Integrator which can be used to immediately release non-implant loads and for the emergency release of implants.

ProTest BI Test Pack allows the user to immediately release non-implant loads based on the color change of the instant readout out integrator card as per AAMI Standards (see opposite side).

The instant readout integrator card can be used to aid in the emergency release of implant loads.

Unexposed

Pass

The pack is made of stacks of recyclable paper with the integrator card and ProTest biological indicator placed inside the pack. The integrator card is made with lead-free ink and the pack itself uses much less paper than the leading equivalent product.

The user can follow up the integrator card result by incubating the ProTest biological indicator. Final incubation results are available after only 24 hours, a full day faster than the leading equivalent product.

Control BI: The control unit should exhibit turbidity and/or a color change to or toward yellow. If the control unit does not show signs of growth, consider the test invalid.

Test BI: A failed sterilization cycle is indicated by turbidity and/or a color change to or toward yellow. A test unit that retains its original purple color indicates that sterilization parameters have been met.

Packaging

30 Test Packs/Case

with 5 Controls
Catalog # PT-3-BITP-5

with 30 Controls
Catalog # PT-3-BITP-30

http://www.ravenlabs.com/page/probitp

Related Quotes from AAMI/ANSI ST79:2006 Standards

10.5.2.1 General Considerations
When used within a PCD Class 5 integrating indicators or enzyme-only indicators may be used for release of non-implant loads…A Class 5 integrating CI or an enzyme-only indicator within a PCD (that also contains a BI) should be used to monitor each load containing implants and may be used as a basis for early load release in documented emergency situations only; however, loads containing implants should always be biologically monitored and, whenever possible, implants should be quarantined until the BI results (early readout or spore growth) are available.

10.5.3.2 Using biological indicators
Biological indicators should be used within PCDs for routine sterilizer efficacy monitoring at least weekly, but preferably every day that the sterilizer is in use. Biological indicators within PCDs should also be used for sterilizer qualification testing after sterilizer installation, relocation, malfunctions, and major repairs and after sterilization process failures…Addtionally, BIs within PCDs should be used to monitor every load containing implants.

Rationale: The use of BIs provides evidence of efficacy by challenging the sterilizer with a large number of highly resistant bacterial spores. Biological monitoring provides the only direct measure of the lethality of a sterilization cycle. Sterilizer manufacturers validate their sterilization cycles using BIs; therefore, routine sterilizer efficacy monitoring in health care facilities should also be conducted using BIs. In addition, Garner and Favero (1985) and CDC (2003a) recommend routine biological monitoring of sterilizer efficacy. While the performance of Class 5 integrating CIs and enzyme-only indicators has been correlated to the performance of BIs, these sterilization monitoring devices do not contain spores and thus do not directly measure the lethality of a sterilization cycle; however, they provide additional information about the attainment of the critical parameters of the sterilization process.

10.5.4 Process challenge devices (PCDs)
For routine release of loads containing implantable devices, a PCD containing a BI and either a Class 5 integrating CI or an enzyme-only indictor (a BI challenge test pack) and sterilizer qualification testing, the PCD should contain a BI and may contain one or more CIs as well.