

Bioquell | HPV-BI

Biological Indicator Type: 6-log *Geobacillus stearothermophilus* ATCC 12980

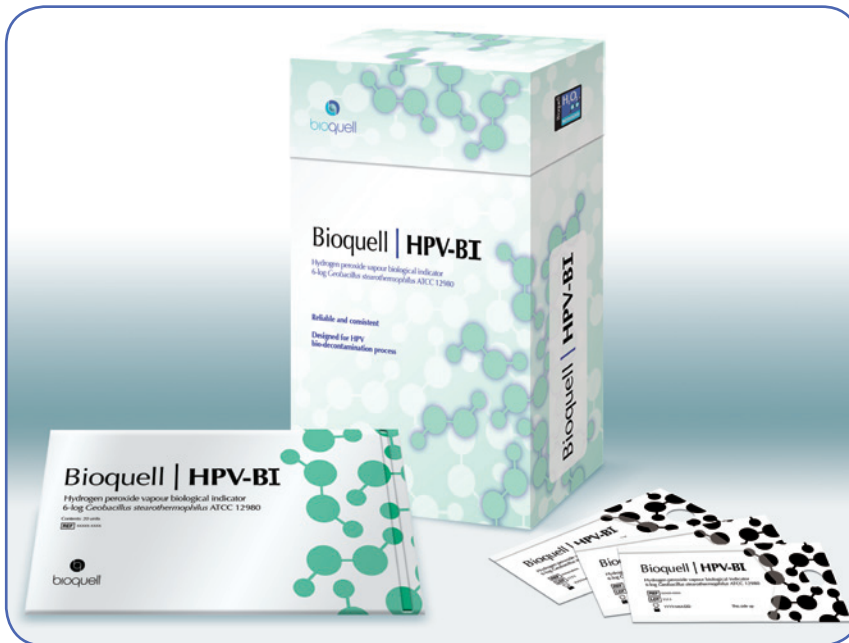


Image 1. Bioquell HPV-BIs provide assurance of a 6-log reduction in bioburden

Bioquell HPV-BI is a biological indicator that has been specifically designed for HPV bio-decontamination processes. It is inoculated with 6-log *Geobacillus stearothermophilus* ATCC 12980 endospores to provide assurance that a 6-log reduction of the bioburden is achieved on every HPV bio-decontamination cycle. HPV-specific biological indicators are commonly inoculated with bacterial endospores due to their resistance to many different decontamination processes, including HPV.

Bioquell HPV-BI has been designed to be a high-quality, consistent and reliable biological indicator. The Bioquell HPV-BI inoculum is produced from a traceable type culture stain (ATCC 12980) and prior to inoculation on the carrier disc, the endospores undergo a set of intricate cleaning steps to remove surplus media and cellular debris. In addition, the shape and surface finish of the carrier disc facilitates the even distribution of the spores across the disc.

Each batch of Bioquell HPV-BI is thoroughly tested to ensure a consistent biological challenge for HPV bio-decontamination processes. Bioquell HPV-BIs are shipped with a certificate of analysis that specifies the number of microorganisms on each carrier disc and the D-value (or decimal reduction time in minutes required for a 1-log - 90% - reduction of the microorganisms under specified lethal conditions). Batch lot numbers are also marked on each biological indicator for product traceability.

- **Biological indicator specifically designed for hydrogen peroxide vapour (HPV) bio-decontamination process**
- **6-log efficacy challenge**
- **High quality formulation ensuring reliable and consistent results**

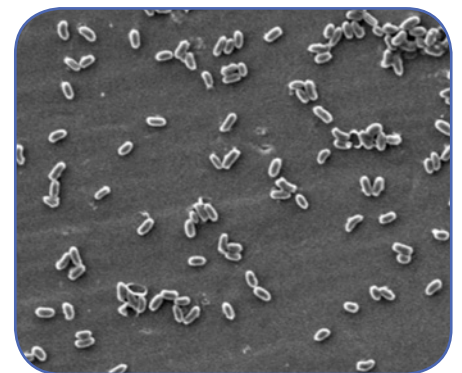


Image 2. Scanning electron microscope image showing even *Geobacillus stearothermophilus* endospore dispersal across Bioquell HPV-BI carrier disc

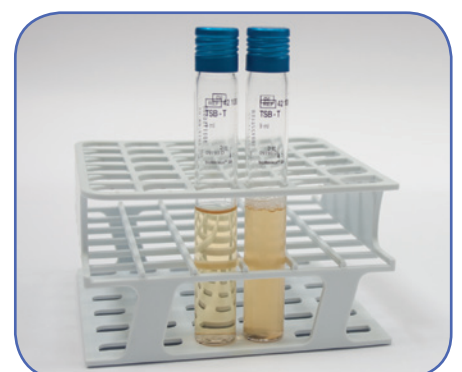


Image 3. After seven days incubation, Bioquell HPV-BIs will provide assurance of a 6-log reduction in bioburden

Technical specification

| | |
|---------------|--|
| Specification | Biological indicators to provide assurance of a 6-log reduction in bioburden following a HPV bio-decontamination cycle. Type: 6-log <i>Geobacillus stearothermophilus</i> ATCC 12980 Suitable for all Bioquell HPV generators. |
| Wallet sizes | 20 BI indicator pouches per individual foil wallet |
| Box sizes | Boxes carry 1 or 5 foil wallets* |

*Indicated on batch/expiry label

Key features

Bioquell HPV-BI endospore inoculum is derived from type culture strain ATCC 12980. This strain is specifically recommended for HPV bio-decontamination assessment and is a non-pathogenic microorganism. A minimum of 1.0×10^6 spores are on each carrier disc.

The carrier disc is formed out of 316L grade stainless steel. These discs are 9mm in diameter. Each carrier has a specially designed dish shape and an even surface finish to minimise 'clumping'.

The inoculated carriers are enclosed in a 1073B Tyvek pouch. The high porosity of these pouches enables rapid HPV penetration through to the disc. Each pouch also comes with a chevron peel to allow easy handling even when wearing gloves. A pre-punched hole facilitates the easy hanging of the biological indicators inside isolators or other enclosures.

Bioquell HPV-BIs are designed to provide consistent D-value results in HPV processes and assurance that a 6-log reduction in bioburden has been achieved during a HPV cycle.

Operation

The Bioquell HPV-BIs should be kept in the sealed foil wallet until required. Prior to the bio-decontamination cycle, Bioquell HPV-BIs should be placed in suitable locations within the target zone. After the Bioquell HPV process, each Bioquell HPV-BI should be incubated in a suitable medium following the manufacturer's advice.

Applications

Bioquell HPV-BIs can be used by many different sectors including food processing, pharmaceutical production, life sciences, defence, and healthcare. Applications include validation, re-validation, cycle development and efficacy testing of new equipment.

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