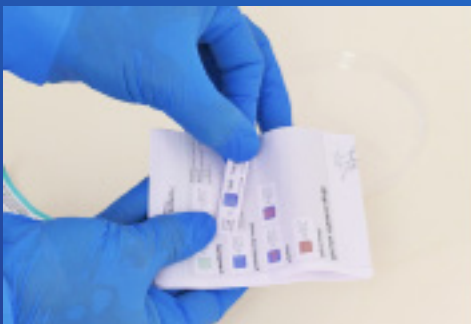




Guarantee your Regulated Medical Waste Treatment System Integrity

Evacle 80 Biological and Chemical Indicator Kits



Compliance Made Easy

The Evacle 80 can treat 80 liters of infectious and sharps medical waste in just 20 minutes – sterilizing to STAATT Level IV – our test kits will help you confirm it.

At Evacle, we understand the importance of complying with sterilization regulations – it's what we do every day. We have developed two tools designed to allow you to guarantee the effectiveness of your Evacle 80's sterilization process and to comply with the STAATT recommendations. Using these testing kits routinely will give you peace of mind, by providing empirical evidence of your RMW (Regulated Medical Waste) system integrity and that your sterilization efficacy target is met

Sterilization, Disinfection and STAATT Guidelines

| Process | Definition | Inactivation Level | STAATT Level |
|---------------|--|--|--------------|
| Disinfection | Demonstrates a reduction of most pathogenic organisms from a system | Disinfection demonstrates a 4 log ₁₀ reduction of bacterial endospores and 6 log ₁₀ reduction of vegetative bacterial cells | Level III |
| Sterilization | Demonstrates the complete elimination of all pathogenic microorganisms' forms, including bacterial endospores. | Sterilization demonstrates a 6 log ₁₀ reduction of bacterial endospores and 6 log ₁₀ reduction of vegetative bacterial cells | Level IV |

What is a Biological Indicator?

A biological indicator is a non-pathogenic microorganism used to test the sterilization processes. Evacle's testing kits use *Geobacillus Stearothermophilus* ATCC 7953 as a biological indicator to represent the presence or absence of other microorganisms after sterilization. This microorganism is an endospore forming bacteria, and therefore is the most challenging in the sterilization process.

What is a Bacterial Endospore?

A bacterial endospore is a dormant, firm, non-reproductive and non-metabolically active structure produced by some of the Phylum Firmicutes bacterial families. A bacterial endospore can survive extreme environmental conditions that would in any other circumstance eliminate the vegetative bacterium. It is therefore the perfect candidate to test the efficacy of sterilization processes.

The Biological Performance Verification Kit Process

Routine monitoring of your sterilization process is of critical importance. Evacle's specially designed Performance Verification Biological Kits make the testing process easier, and provide an actual demonstration of spore elimination based on PAA sporicidal activity. We recommend users of the Evacle 80 perform the verification testing process at least once a month, in line with STAATT guidelines.

Disinfection Performance Verification by Biological Kit

Evacle's biological performance verification kit provides empirical, biological evidence of the efficacy of your sterilization process, including the combined parameters of PAA concentration, temperature and duration. As a form of biological qualitative challenge testing, our procedure means you will be able to accurately verify the growth / no growth of spores following treatment results. The kit includes two main steps:

1 The treatment of the spores envelope in the Evacle 80 unit.



2 A laboratory step requiring the spores strip to be incubated for 24 hours. The above indicates a 'passed' test.



Quick and Clear Results Verification

Evacle has designed an easy-to-use color coded verification method so you can quickly interpret the results of your testing. In order for the results to be valid, the Growth Medium used for incubating spores' strips which have not been disinfected (positive control) should turn yellow (See image above). If after 24 hours no color change is visible on the growth medium tube containing the treated strip (Test), the disinfection process was successful, meaning the result is negative. Any failure in the disinfection process will be clearly indicated by the growth medium indicator turning yellow.

Evacetic Integrity Verification

It's also critically important to routinely test the concentration of your Evacetic solution, along with the Evacle 80 dosage pump accuracy and embedded water heater. Evacle recommends that you test this on a weekly basis, or any time a new Evacetic batch is used.

This form of testing allows you to establish the efficacy of your disinfection process when integration conditions reach established parameters - temperature (°C), duration (min) and PAA concentration (ppm).

The test is designed to verify that the Evacetic solution contains an adequate concentration of the active substance Peracetic Acid, in combination with the process temperature and exposure duration. Giving you complete peace of mind, the test will return an "Optimal" result if the entire complex of parameters complied with your process definition.



Order your Performance Verification Test Kits today!

To carry out both performance verification tests, the following utensils are required. All of which may be purchased directly from your distributor. For more information, contact us at www.envomed.com

| Process | Code | Kit | Contents |
|--|------------|--|--|
| Biological performance verification | EVAKBT 400 | Spore Culture Medium+Spore strips 100 pcs per pack | The kit contains: <ul style="list-style-type: none"> • 100 non-absorbent material envelope. Within the envelope, there is polyethylene fiber strip containing 106 Geobacillus Stearotherophilus ATCC 7953 spores per strip. • 100 units, 2ml tubes of a color changing indicative culture medium specially designed for Geobacillus Stearotherophilus culture. |
| Biological performance verification | IC10/20 | Dual Biological indicator Incubator | Incubator includes a heating block with 10 positions for culture medium. The incubator is pre-set to 60±2°C. |
| Evacetic integrity, performance verification | EVA-401PAA | Peracetic Acid Chemical Indicator 100 pcs per pack | This chemical indicator kit contains 100 nonabsorbent material envelope. Within the envelope, there is an indicator strip, printed with a color changing reactive ink specific for PAA reaction. |