

BIOLOGICAL INDICATOR SPORE STRIPS For Monitoring Chlorine Dioxide (ClO₂)

Crosstex Code: TCDS-06



Product Description

Biological Indicator Spore Strips for monitoring Chlorine Dioxide (ClO₂) processes consist of:

- An inoculated carrier, 7 mm x 38 mm (1.5" x 0.281"), of *Geobacillus stearothermophilus* (Cell Line 7953)
- Primary packaging in a Tyvek®/Tyvek® pouch

Intended Use

The Spore Strips may be utilized to monitor ClO₂ sterilization and disinfection process efficacy. The Spore Strips are labeled for industrial use only.

Instructions for Use

Place Spore Strips (a minimum of 10 per exposure is recommended) inside representative materials to be sterilized, directly in the sterilization chamber or disinfection area. Materials should be packaged or wrapped as usual.

Locate the Spore Strips in areas most difficult to sterilize or disinfect to maximize the challenge, as outlined in your specific protocol or according to standard operating procedure.

After processing, remove materials and/or Spore Strips from area or chamber.

Aseptically remove the Spore Strip from the primary packaging and transfer to Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, Crosstex Code GMBCP-100, may be utilized in place of the SCDB.

Transfer one Spore Strip which has not been processed as a Positive Control.

Incubation: At least one unused tube of culture medium from the same lot should be incubated with the test series as a Negative Control. Place the cultured Spore Strips, the Positive Control and the Negative Control in an incubator set at 55°C to 60°C.

Incubate the tubes for a minimum of seven days or per a validated reduced incubation period.

Monitoring: Examine the Spore Strips periodically during incubation. Record observations.

Interpretation:

Where SCDB (standard or unmodified) was utilized:

Tubes which demonstrate turbidity with cream colored sediment are considered positive for growth of *Geobacillus stearothermophilus*. Tubes which remain clear and without sediment are considered negative for growth.

Where modified medium, Crosstex Code GMBCP-100, was utilized:

Tubes which transition in color from purple to yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain purple in color and do not demonstrate turbidity are considered negative for growth.

For unexpected positives, it is recommended that a Gram stain be performed. Gram positive rods are characteristic of the indicator organism.

Positive Control: Tube should demonstrate turbidity and cream colored sediment or demonstrate a color transition from purple to yellow where modified medium has been utilized. If the Positive Control does not result in growth, the exposure is considered invalid. Check the conditions during incubation and verify the capability of the medium to support growth.

Negative Control: Tube of medium should remain clear and purple where modified medium was utilized. If the Negative Control results in growth, there is a potential for false positives.

Physical Properties

Process	Chlorine Dioxide
Strip Dimensions	7 mm x 38 mm (1.5" x 0.281")
Pouch Dimensions	29 mm x 75 mm
Packaging	100/Box

Monitoring Frequency

For greatest control of materials, it is recommended that a minimum of ten (10) Spore Strips be included with every sterilization/disinfection process.

Performance Characteristics

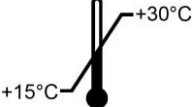




Population	1.0 to 5.0 x 10 ⁶ per strip
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Post-Market Criteria	Population: 50% to 300% of certified population

Compliance

ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements

Crosstex has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin entitled *Population Verification of Paper Carrier Biological Indicators* to ensure consistent methodologies are being utilized when performing verification testing.

Storage and Shelf Life

	15°C to 30°C		Protect from heat and radioactive sources
	20% to 70% Relative Humidity		Keep dry
<p>Shelf Life</p>	30 Months from the date of manufacture		
	<p>Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Strips. Do not use damaged Spore Strips. Do not use after the expiration date. The Spore Strips contain live cultures and should be handled with care.</p>		

Disposal

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

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