

Biotest Laboratories, Inc.

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Brooklyn Park, MN 55445

FDA Registered
GMP
www.biotestlabs.com

ISO 13485

ISO/IEC 17025

EN/ISO 17665

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STERILITY TEST REQUEST FORM

COMPANY: _____ CONTACT NAME: _____

ADDRESS: _____

PRODUCT NAME/#: _____

LOT #: _____

STERILE LOT#: _____ STERILIZATION: [] ETO [] STEAM [] RADIATION [] Other _____

BI LOT#: _____ EXPIRATION DATE: _____ POSITIVE CONTROL SENT [] YES [] NO

PURCHASE ORDER # (REQUIRED): _____

CUSTOMER SIGNATURE: _____ DATE: _____

SAMPLE STORAGE: [] ROOM TEMP [] REFRIGERATE [] FREEZE

SAMPLE DISPOSITION POST TEST: [] DISCARD [] RETURN

**The following must be provided for return of products(s)

RETURN SHIPPING INFORMATION: METHOD _____ ACCOUNT # _____ PRIORITY _____

ADDRESS: _____ ATTN: _____

Sterility Tests

Check (√) Code	Quantity	Test Code	Test Description
		ST/01	Spore Strips
		ST/02	Inoculated Threads
		ST/03	Self-Contained Biological Indicators
		ST/04	Challenge Packs
		ST/05	Inoculated Product – Direct transfer
		ST/06	Inoculated Product – Filtration
		ST/07	Native Product – Direct Transfer
		ST/08	Native Product – Filtration
		ST/09	Gamma Dose Audit
		PC/01	Positive Control – spore strip <i>Bacillus atrophaeus</i>
		PC/02	Positive Control – mini spore strip <i>Bacillus atrophaeus</i>
		PC/03	Positive Control – spore strip <i>Geobacillus stearothermophilus</i>
		PC/04	Positive Control – self-contained biological indicator (<i>Bacillus atrophaeus</i>)
		PC/05	Positive Control – self-contained biological indicator (<i>Geobacillus stearothermophilus</i>)
		BF/01	Bacteriostasis/Fungistasis

Special Instructions: _____

RESULTS: Will be faxed followed by hardcopies in mail.

FOR: [] FDA SUBMISSION [] CE MARK [] VALIDATION [] ROUTINE [] RESEARCH AND DEVELOPMENT

CONTACT NAME: _____

PHONE: _____ FAX: _____

Specific test results may not be indicative of the characteristics of any other samples from the same lot or similar lots. Liability is limited to the costs of the tests.

Form may be downloaded from WWW.BIOTESTLABS.COM. This is a revision controlled form within the Biotest Laboratories, Inc. Quality System. Modifications of the controlled information within this form are prohibited.