

# Biotest Laboratories, Inc.

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FDA Registered  
GMP

ISO 13488

ISO/IEC 17025  
EN 554

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## BIOBURDEN TEST REQUEST FORM

COMPANY: \_\_\_\_\_ CONTACT NAME: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

PRODUCT NAME/#: \_\_\_\_\_

LOT #: \_\_\_\_\_

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 product(s)**

RETURN SHIPPING INFORMATION: METHOD \_\_\_\_\_ ACCOUNT # \_\_\_\_\_ PRIORITY \_\_\_\_\_

ADDRESS: \_\_\_\_\_ ATTN: \_\_\_\_\_

### Bioburden Tests (Liquid)

Check (√) Code	Quantity	Test Code	Test Description
		BB/05a	TSA & EMB Media
		BB/05b	R <sub>2</sub> A & SAB Media

### Bioburden Tests (Product)

Check (√) Code	Quantity	Test Code	Test Description
		BB/01a	Total Aerobes
		BB/01b	Total Fungi
		BB/02a	Total Aerobes & Anaerobes
		BB/02b	Total Aerobes & Sporeformers
		BB/02c	Total Aerobes & Fungi
		BB/03a	Total Aerobes, Anaerobes, & Sporeformers
		BB/03b	Total Aerobes, Sporeformers, & Fungi
		BB/03c	Total Aerobes, Anaerobes, & Fungi
		BB/04	Total Aerobes, Anaerobes, Sporeformers, & Fungi

### Bioburden Validation Tests

Check (√) Code	Quantity	Test Code	Test Description
		BB/06	Includes up to 5 devices, 4 extractions per device (if necessary inoculation and population verification), and final report
		MS/01	Qualification Studies (per hour basis)

APPLICABLE RECOVERY FACTOR (#) \_\_\_\_\_ OR BIOBURDEN VALIDATION FINAL REPORT #: \_\_\_\_\_

Special

Instructions: \_\_\_\_\_

**RESULTS: Will be faxed followed by hardcopies in mail.**

FOR:  FDA SUBMISSION  CE MARK  VALIDATION  ROUTINE  RESEARCH & 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](http://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.

FORM G-051 REV. 2

EFFECTIVITY DATE: 04/29/05