

# Biotest Laboratories, Inc.

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FDA Registered  
GMP  
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ISO 13485

ISO/IEC 17025

EN/ISO 17665

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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 maybe 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.