

<b>Laboratory Use Only</b>
Accession Number _____
Logged By/Date/Time _____

**MEDICAL DEVICE Test Request Form**

Purchase Order #:	Quote #:
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Customer Information		
Contact:		
Company:		
Phone:		
Email:		
Address:		
City:	State:	Zip:

Billing Information			Same as Customer <input type="checkbox"/>
Contact:			
Company:			
Phone:			
Email:			
Address:			
City:	State:	Zip:	

Sample Information	
<i>Please use exact wording to be included on the Certificate of Analysis</i>	
Sample Description:	
Part Number:	Sample Storage: <input type="checkbox"/> Ambient <input type="checkbox"/> Refrigerate
Lot Number:	Sample Disposition: <input type="checkbox"/> Discard <input type="checkbox"/> Return
Quantity Submitted for Testing:	Testing priority: <input type="checkbox"/> Standard <input type="checkbox"/> RUSH (extra charge)
Samples to be Tested: <input type="checkbox"/> Individually <input type="checkbox"/> Pooled (for one result)	Type of Testing Desired: <input type="checkbox"/> GMP <input type="checkbox"/> Non-GMP
Additional Information:	

Tests Requested
<b>If Limits or Ranges are not specified on the Request Form, testing will be considered to be For Information Only (FIO).</b>

**Bioburden Testing** – Limit: NMT \_\_\_\_\_ CFU

<input type="checkbox"/> Immersion <input type="checkbox"/> Fluid Pathway <input type="checkbox"/> Solution	<input type="checkbox"/> <i>plus</i> Yeast/Mold <input type="checkbox"/> <i>plus</i> Sporeformers <input type="checkbox"/> <i>plus</i> Anaerobes <input type="checkbox"/> <i>plus</i> Dilutions: _____
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**Bioburden Extraction Efficiency**

Natural Exhaustive (Multiple Wash)  
 Inoculated (Single Wash)

**LAL|Endotoxin Testing** – Limit: NMT \_\_\_\_\_ EU/Device

Device:  Immersion  Fluid Pathway

Solution Limit: NMT \_\_\_\_\_ EU/ \_\_\_\_\_ ml

**Water Testing**

**Heterotrophic Plate Count**  
 Limit: NMT \_\_\_\_\_ CFU/ \_\_\_\_\_ ml  
 Volume to be Tested: \_\_\_\_\_

**Coliform Detection**  
 Limit: NMT \_\_\_\_\_ CFU/ \_\_\_\_\_ ml  
 Volume to be Tested: \_\_\_\_\_

**pH** – Range: \_\_\_\_\_

**Conductivity** – Per USP <645> |  FIO

**Total Organic Carbon**  
 Limit: NMT \_\_\_\_\_  PPM |  PPB

**Sterility Testing - ANSI/AAMI/ISO 11137-2**

Method 1:  Immersion  Fluid Pathway  
 VD<sub>max</sub>:  Immersion  Fluid Pathway

**Sterility Testing - ANSI/AAMI/ISO 11737-2**

**Bacteriostasis/Fungistasis**

C. albicans  S. aureus  
 A. brasiliensis  K. rhizophila  
 B. subtilis  C. sporogenes

**Sterility Testing of Bioindicators**  
 Incubation Duration: \_\_\_\_\_  
 Incubation Temperature: \_\_\_\_\_ °C

**Bioindicator Population Verification**  
 (Please provide CoA with Request Form)

**Environmental Monitoring**  
 1<sup>st</sup> Incubation Temperature: \_\_\_\_\_ °C  
 1<sup>st</sup> Incubation Duration: \_\_\_\_\_  
 2<sup>nd</sup> Incubation Temperature: \_\_\_\_\_ °C  
 2<sup>nd</sup> Incubation Duration: \_\_\_\_\_

**Bacterial Gram Stain Identification**

**Microorganism Identification—DNA Sequencing**  
 All Unique Colonies |  Top \_\_\_\_ Forming Colonies

**Subculture**

**Medical Device Feasibility**

Customer Signature:	Date:
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Client agrees to Infinity Laboratories' terms and conditions.