



# Sample Submission Form

**Section 1 - Sponsor (Report will be mailed to)**

**Billing (Invoice will be mailed to)**  Same as Sponsor

Contact:	Contact:
Company:	Company:
Address:	Address:
City: State:	City: State:
Country: Zip:	Country: Zip:
Bus Phone:	Bus Phone:
Cell Phone: Fax:	Other Phone: Fax:
E-mail:	E-mail:

**Section 2 - Quote No.:** \_\_\_\_\_ (If known) **PO No.:** \_\_\_\_\_ **Samples Clinically Used**  Y  N

	Test Code. See pages 2-3	Description of Test	No. of Samples	Lot Number
1				
2				
3				
4				
5				
6				
7				

Check all that apply.

**NOTE: PLEASE SIGN WHERE INDICATED BELOW ON THIS FORM.**

**Sample ID:**

Product Name \_\_\_\_\_

Catalog/Part # \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Sample Storage:**

Refrigerate upon arrival

Store at room temperature

Store Frozen

Light Sensitive

**Sample Disposition:**

Discard

Return (Extra charge)

Fed Express # \_\_\_\_\_

UPS# \_\_\_\_\_

Other \_\_\_\_\_

**Section 3 - Special Instructions:**

**Note: Please list if the return sample address is different than the address where final reports are returned.**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Sponsor's Authorization Signature:** \_\_\_\_\_ **Date:** \_\_\_\_\_

Fax Preliminary Results       E-Mail Preliminary Results       Phone Preliminary Results

**LABORATORY USE ONLY**

Sales Order Number: \_\_\_\_\_ Received by: \_\_\_\_\_

Study Number: \_\_\_\_\_ Date: \_\_\_\_\_



# HIGHPOWER

Validation Testing & Lab Services  
(888) 722-1529 • www.highpowervtls.com

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Page: 2 of 4  
Authorized By: Ex. Management

**INSTRUCTIONS:** Complete page 1 of this form as follows;

1. Please fill in appropriate company and contact information in Section 1.
2. Fill in PO No. and Quote No. (if known) in Section 2. Please mark the box Yes or No if samples were "Clinically Used".
3. Fill in the Table in Section 2 with the Test Code of the test being performed, a description of the test, the number of samples sent and any lot/traceability number of the samples. **Please review our "Test Code Definition Guide" for additional help in filling out Section 2 of this form.**
4. If more than seven tests are requested, fill out a 2<sup>nd</sup> page 1 of the "Sample Submission Form" with the additional test as required.
5. Fill in the Sample ID, Sample Storage and Sample Disposition information in Section 2. Check each box that applies and provide any shipper numbers that are required to ship samples back after testing is completed.
6. Please list any "Special Instructions" and Sign and Date the form in Section 3.
7. **Send first page of the Sample Submission Form along with test samples to the address listed at the bottom of page 1.**

(Please contact us for any test not shown below. We add new lab tests frequently.)

TEST CODE	STERRAD H2O2
MC-100S	STERRAD® 100S Cycles
SE-100S	STERRAD 100S Efficacy
SE-200	STERRAD 200 Efficacy
MC-NX	STERRAD® NX Cycles
SE-NX-STD	STERRAD NX STD Cycle Efficacy
SE-NX-ADV	STERRAD NX ADV Cycle Efficacy
MC-100NX	STERRAD® 100NX Cycles
SE-100NX-STD	STERRAD 100NX STD Cycle Efficacy
SE-100NX-EXP	STERRAD 100NX EXP Cycle Efficacy
SE-100NX-FLX	STERRAD 100NX FLEX Cycle Efficacy
SE-100NX-DUO	STERRAD 100NX DUO Cycle Efficacy
RESID-H2O2	H2O2 Residual Testing
STEAM PRE-VAC/GRAVITY/SFPP	
MC-STEAM	Steam Cycles
SE-STEAM	Steam Efficacy
TP-STEAM	Thermal Profile Study
DT-STEAM	Drying Time Study
MISC-STEAM	BD, Air Leak or Miscellaneous Test
VAL-ST55	AAMI ST-55 Sterilizer Validation
VAL-ST8	AAMI ST-08 Sterilizer Validation
ETHYLENE OXIDE	
MC-ETO	ETO Cycles @ 446, 567, 725 or 759 mg/l
SE-ETO	ETO Efficacy Validation
RESID-ETO	ETO Residual Testing
DRY HEAT	
MC-DRY	Dry Heat Cycles
SE-DRY	Dry Heat Efficacy
TP-DRY	Dry Heat Thermal Profile Study
STERIS VPROPlus H2O2	
MC-VPRO	VPRO Lumen/Non Lumen Cycles, etc.
CHEMICAL IMMERSION	
SE-COLD	OPA, Glutaraldehyde etc.
MC-COLD	Chemical Immersion Cycle
HIGH LEVEL DISINFECTION	
HLD	High Level Disinfection
TP-WASH	Thermal Disinfection – Ao Study
CHEMICAL VAPOR	
MC-CHEMI	Chemiclave Cycles
SE-CHEMI	Chemiclave Efficacy
TSO3 STERIZONE	
MC-SZ	STERIZONE Cycle

TEST CODE	ACCELERATED AGING TEST
SL-ACCEL	Accelerated Aging ASTM F 1980
AEROSOL CHALLENGE – Whole Package Integrity Test	
AC-STEAM	STEAM Whole Package Integrity Test
AC-ETO	ETO Whole Package Integrity Test
AC-STERRAD	STERRAD Whole Package Integrity Test
AC-VPRO	VPro Whole Package Integrity Test
AC-SZ	TSO3 Whole Package Integrity Test
AC-Custom	Custom Whole Package Integrity Test
ISO 11607 and RELATED PACKAGE TEST	
DM-ISO	Dye Migration ASTM F 1929
BT-ISO	Burst Test ASTM F 1140
BE-ISO	Bubble Emission ASTM F 2096
SP-ISO	Seal Peel ASTM F 88
VIS-ISO	Visual Inspection ASTM F1886/F1886M
BFE	Bacterial Filtration Efficiency ASTM F 2101
Simulated and In Use Testing	
SIM-USE	Simulated Use Test Per FDA Guidance
IN-USE	In Use Test Per FDA Guidance Document
DEVICE CLEANING VALIDATION	
MAN-3LOG	Manual TIR 12 - 3 Log Reduction
MEC-3LOG	Mechanical TIR 12 - 3 Log Reduction
MAN-PRO	Manual TIR 30 - Protein Marker
MEC-PRO	Mechanical TIR 30 - Protein Marker
MAN-TOC	Manual TIR 30 - TOC Marker
MEC-TOC	Mechanical TIR 30 - TOC Marker
MAN-HEMO	Manual TIR 30 - Hemoglobin Marker
MEC-HEMO	Mechanical TIR 30 - Hemoglobin Marker
MAN-PRO3	Man. TIR 30/Abrev. FDA - Protein Marker
MEC-PRO3	Mech. TIR 30/Abrev. FDA - Protein Marker
MAN-TOC3	Manual TIR 30/Abrev. FDA - TOC Marker
MEC-TOC3	Mech. TIR 30/Abrev. FDA - TOC Marker
MAN-HEMO3	Man. TIR 30/Abrev. FDA - Hemoglobin Marker
MEC-HEMO3	Mech. TIR 30/Abrev. FDA-Hemoglobin Marker
MAN-PRO6	Manual TIR 30/Full FDA - Protein Marker
MEC-PRO6	Mech. TIR 30/Full FDA - Protein Marker
MAN-TOC6	Manual TIR 30/Full FDA - TOC Marker
MEC-TOC6	Mechanical TIR 30/Full FDA - TOC Marker
MAN-HEMO6	Man. TIR 30/Full FDA - Hemoglobin Marker
MEC-HEMO6	Mech. TIR 30/Full FDA-Hemoglobin Marker
MC-WASH	Mechanical Washer Repetitive Cleaning
MC-MANUAL	Manual Wash Repetitive Cleaning

RESISTOMETER TESTING/ISO 11140	
RES-STEAM	Steam Resistometer Cycle
RES-ETO	ETO Resistometer Cycle
RES-DRY	Dry Heat Resistometer Cycle
RES-VHP	VHP Resistometer Cycle
RES-FORM	FORM Resistometer Cycle
CI-ISO1	Table 2 of ISO 11140-1 -STEAM
CI-ISO2	Table 3 of ISO 11140-1 -DRY HEAT
CI-ISO3	Table 4 of ISO 11140-1 -ETO
CI-ISO5	Table 6 of ISO 11140-1 -FORM
CI-ISO6	Table 7 of ISO 11140-1 -VHP
BD-ISO	Bowie Dick Testing to ISO 11140-5
STERILITY	
STERILITY	Article Sterility Test
BIO-BURDEN	Article Bio-Burden Count
MISCELLANEOUS	
CONSULT	Consulting
HFACTOR	Human Factor Testing
TRAINING	Training on site or at HIGHPOWER
FEASIBILITY	Feasibility Testing

REAL TIME SHELF LIFE – PACKAGING SYSTEMS	
SL-ETO	ETO Real Time Shelf Life
SL-STERRAD	STERRAD Real Time Shelf Life
SL-STEAM	Steam Real Time Shelf Life
SL-VPRO	VPRO Real Time Shelf Life
SL-SZ	STERIZONE Real Time Shelf Life
SL-MSCL	Misc. Process or Shelf Life Study
BIOCOMPATIBILITY	
BIO-CYTO	MEM Elution
BIO-SENS	Sensitization
BIO-IRRI	Irritation
BIO-SYST	Systemic Toxicity
BIO-GENO	Genotoxicity
BIO-HEMOL	Blood Hemolysis
BIO-TESTING	Custom Biocompatibility Test
BIOLOGICAL INDICATOR TESTING	
BI-DV-STEAM	Steam D-value Analysis
BI-DV-DRY	Dry Heat D-value Analysis
BI-DV-ETO	ETO D-value Analysis
BI-SK	Survival/Kill
BI-ASSAY	BI Population Verification
BI-PURITY	Product Purity Testing

For Test Not Listed - Contact us at "info@highpowervtls.com"

## Standard Terms and Conditions

- GENERAL.** These Terms and Conditions shall govern all orders for laboratory tests, laboratory services, sterilization services, or other services (collectively, "Services") as provided by HIGHPOWER Validation Testing & Lab Services Inc. ("HIGHPOWER") to you ("Customer"). These Terms and Conditions shall be automatically incorporated by reference into each quote given by and each Purchase Offer (as defined below) accepted by HIGHPOWER. A PO shall only be effective if HIGHPOWER accepts such PO in writing or actually begins performance of the Services requested thereon.
- PRICE TERMS.** All prices or fees for Services quoted by HIGHPOWER are stated in U.S. dollars, and are valid for ninety (90) days unless otherwise specified therein. Prices and related quotes are based on test descriptions provided to HIGHPOWER by Customer and detailed in such quote. Any change in test descriptions or process parameters provided by Customer may require any previously quoted prices or fees for Services to be adjusted and HIGHPOWER reserves the right to make such adjustments. In the event HIGHPOWER issues conflicting oral and written quotes, the written quote shall control.
- PURCHASE ORDERS.** Upon Customer's satisfaction with a quote, the Customer must submit a written purchase order ("PO") to cover each Service which HIGHPOWER is requested to perform. Submission of such PO will be accompanied by a signed sample submission form (as set forth above) executed on behalf of the Customer, and such submission shall be conclusive proof that Customer has accepted all of these Terms and Conditions. Each PO must contain the applicable quote number, if any, from HIGHPOWER. Acceptance of a PO by HIGHPOWER is expressly conditioned upon these Terms and Conditions being incorporated therein and superseding any conflicting term or provision contained in such PO. Customer hereby acknowledges and agrees that any such conflicting term or provision shall be deemed immediately null and void upon HIGHPOWER's acceptance of such PO. If Customer wishes to establish a standing PO to facilitate order processing, please contact HIGHPOWER's customer service dept. at (585) 743-1930 (ext. 1953). Any re-performance of Services required by the Customer in connection with a previously completed PO will require a separate PO, the performance of and payment for which shall also be governed by these Terms and Conditions.
- PAYMENT TERMS.** For Services quoted, with domestic customers in good standing for whom HIGHPOWER has performed Services for more than one (1) year, payment is due within thirty (30) days from the date of HIGHPOWER's invoice to Customer in connection with such Services. On all such orders in excess of Fifty Thousand Dollars (\$50,000), HIGHPOWER will not begin performance of any Services until HIGHPOWER has received pre-payment from Customer equal to fifty percent (50%) of the total quoted price or fees, and any balance remaining shall be due within thirty (30) days from the date of HIGHPOWER's invoice to Customer in connection with such Services. All customers for whom HIGHPOWER has not performed Services for more than one (1) year (unless other arrangements have been made) and all non-domestic customers must pay 100% of any quoted price or fees prior to HIGHPOWER commencing the Services. Commencement of any Services is conditioned upon credit approval of Customer to the satisfaction of HIGHPOWER, and Customer hereby grants to HIGHPOWER the authority to obtain any required credit information of Customer. HIGHPOWER reserves the right to revise these payment terms at any time. All balances which are due and owing by the Customer to HIGHPOWER and not paid when due hereunder shall accrue interest at a rate of one and twenty-five hundredths percent (1.25%) per month until payment is received in full. HIGHPOWER shall have the right to suspend all Services under any PO upon Customer's failure to pay any amount due hereunder. A charge of Fifty Dollars (\$50) will be incurred for each returned check. All amounts due hereunder are payable in U.S. dollars. Customer shall notify HIGHPOWER within twenty-four (24) hours of Customer's becoming insolvent, filing for bankruptcy, being placed in receivership, making an assignment for the benefit of creditors or commencing proceedings seeking protection from its creditors. Upon the occurrence of any such event, all amounts hereunder shall become immediately due and payable and HIGHPOWER shall have the right to suspend or cancel any Services not yet provided.
- PAYMENT METHODS.** Customer may make payment by check, automated clearing house transfer or wire transfer. If payment is made by check, such check must be drawn on a U.S. bank. Handling charges may be applied due to additional documentation required for shipping and customs. If Customer has any questions regarding HIGHPOWER's wire transfer routing information, contact HIGHPOWER customer service at (585) 743-1932. If payment is to be made via wire transfer, Customer shall add \$50 to each applicable invoice to cover the administrative costs associated with such wire transfer.
- FREIGHT & INSURANCE.** All of Customer's products, test articles, reports, data, waste and excess material shipped to or from HIGHPOWER shall be shipped F.O.B. to HIGHPOWER's facility in Rochester, NY. HIGHPOWER will invoice Customer for freight charges or will bill Customer's UPS or FedEx account, if requested by Customer. For all items shipped to Customer by HIGHPOWER, if Customer determines that standard carrier coverage is deemed inadequate, Customer shall conspicuously note such on the applicable PO, and shall include thereon the value of the items to be shipped. Any additional costs associated with any requested increase in insurance coverage shall be the responsibility of Customer and shall be added to the applicable invoice.

All claims for freight damage shall be made directly against the freight carrier responsible for such damage. HIGHPOWER shall have no liability for any damage which occurs while any shipment is in the possession of any carrier and Customer hereby releases HIGHPOWER from the same. It is the Customer's responsibility to properly insure shipments to and from HIGHPOWER.

7. **TURNAROUND TIME (TAT).** HIGHPOWER shall make all reasonable efforts to meet any final report release date provided in writing to the Customer in the applicable written quote, if any. HIGHPOWER makes no guarantee, representation or warranty that any such report release date will be met. Customer shall not hold HIGHPOWER responsible for any damages, cost or expenses resulting or arising from delay in the release of a final report or study delay, whatever the cause. If such a delay arises, HIGHPOWER will so inform the Customer.
8. **HAZARDOUS MATERIALS.** All hazardous materials submitted to HIGHPOWER for Services must be accompanied by a Material Safety Data Sheet or similar safety information. HIGHPOWER will add a handling fee for Services performed on hazardous materials. In the event HIGHPOWER incurs costs in connection with the disposal of any hazardous materials, such costs shall be invoiced to the customer. In the event any item shipped to HIGHPOWER was, prior to shipping, used in any clinical or other similar setting wherein it was placed in contact with any organism or foreign contaminant, the packing for such item must clearly state so, and such item must be accompanied by a certification from Customer that such item has been cleaned, sterilized and decontaminated and that no foreign contaminants remain on such item. Customer agrees that it will indemnify and hold HIGHPOWER harmless from any damages, claims, suits, causes of action, administrative action (including action by any governmental agency or sub-agency) resulting from Customer's failure to comply with the above requirements.
9. **CANCELLATION.** If for any reason Customer cancels any Services subsequent to acceptance by HIGHPOWER, Customer will be billed for (1) the portion of the Services that HIGHPOWER has performed at the time of cancellation and (2) all materials purchased by HIGHPOWER specifically relating to the cancelled Services.
10. **CONFIDENTIALITY.** In the event HIGHPOWER and Customer execute a confidentiality agreement in connection with the Services, and a conflict should arise between these Terms and Conditions and the terms and conditions thereof, these Terms and Conditions shall govern.
11. **WARRANTIES.** HIGHPOWER warrants that all Services will be performed with reasonable care, skill and diligence and in accordance with standards generally applicable in the industry and shall at all times comply with applicable law. Unless specified in written correspondence to Customer, the results of the Services are not indicative or representative of the qualities of any samples from the same or other lots on which Services were not performed. The Services may result in damage to the applicable samples and the Customer assumes all such risk and agrees to indemnify and hold HIGHPOWER harmless from any consequences of such damage. EXCEPT AS OTHERWISE PROVIDED HEREIN, HIGHPOWER DISCLAIMS ALL WARRANTIES, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.
12. **LIMITATION OF LIABILITY.** HIGHPOWER shall not be liable for any damages, whether direct, indirect, consequential, incidental, punitive or special damages (including without limitation, lost profits), resulting from or arising out of the Services, whether based in tort, contract or otherwise, and regardless of whether HIGHPOWER had advance notice of the possibility of such damages. Customer's sole remedy against HIGHPOWER arising out of the Services shall be limited to requiring HIGHPOWER's re-performance of such Services or a refund of any amounts paid to HIGHPOWER for such Services. In any case, HIGHPOWER's liability to Customer shall be limited to and shall not exceed the price or fees paid by Customer to HIGHPOWER towards the quote provided for the Services. Services shall be re-performed without cost only in the event of HIGHPOWER's gross negligence or willful misconduct.
13. **INDEMNIFICATION.** The Customer shall defend, indemnify and hold harmless HIGHPOWER, its affiliates, officers, directors, shareholders, members, employees, agents and representatives, from and against any and all claims, demands, suits, actions, controversies, verdicts, liabilities or costs relating to and arising out of the Services (collectively, "Costs"), including but not limited to any Costs arising in connection with the items and materials referred to in Section 8 hereof, except to the extent that any such claims, demands, suits, actions, controversies, verdicts, liabilities or costs are the direct result of gross negligence or willful misconduct by HIGHPOWER.
14. **FORCE MAJEURE.** In the event HIGHPOWER is delayed in or prevented from the performance of any Services by reason of acts of God, weather, strikes, lockouts, labor troubles, inability to procure materials, power failure, government laws or regulations, riots, insurrections, war, fire or other casualty, shortage of transportation facilities or any other reason of a similar nature not reasonably in the control of HIGHPOWER, the period for the performance of the Services shall be extended for the period of the delay, and for a reasonable time thereafter.
15. **CHOICE OF LAW/CHOICE OF FORUM.** These Terms and Conditions shall be governed by the laws of the State of New York, without giving effect to the conflict of law provisions thereof. Any and all suits, actions or proceedings arising out of or related to the Services shall be brought in the Supreme Court of New York located in Monroe County or the United States District Court for the Western District of New York located in Monroe County. Each party hereto consents to the non-exclusive jurisdiction of such courts and, to the fullest extent permitted by law, waives any objection that it may have to the laying of venue in such court or that such venue is inconvenient. Process in any such suit, action or proceeding may be served on any party anywhere in the world, whether within or without the jurisdiction of any such court.
16. **SEVERABILITY.** The lack of enforceability or invalidity of any provision or provisions contained in these Terms and Conditions shall not render any other provision or provisions herein contained unenforceable or invalid and the provisions found to be unenforceable or invalid shall be enforced to the maximum extent permitted by law.
17. **NON-WAIVER.** No waiver by HIGHPOWER of any condition, or of any breach of any term contained herein, in any one or more instances, shall be deemed to be a further or continuing waiver of any condition or of any breach of any term, nor may any waiver be deemed effective unless it is in writing and signed by an agent authorized to bind HIGHPOWER.
18. **ENTIRE AGREEMENT.** These Terms and Conditions, the applicable PO and, if applicable, the confidentiality agreement referred to Section 10 hereof contain the entire agreement and understanding of the parties and supersede all prior agreements, negotiations, arrangements, and understandings relating to the subject matter of these Terms and Conditions and may not be changed except in writing duly acknowledged by HIGHPOWER and Customer.
19. **REQUIRED CLAUSE.** Any clause required to be included in a document of this type by any applicable law or administrative regulation having the effect of law shall be deemed to be incorporated herein.
20. **ASSIGNMENT.** Customer shall not assign any of its or his rights or obligations under these Terms and Conditions without the advance written consent of HIGHPOWER.
21. **INTELLECTUAL PROPERTY.** Customer shall have no rights in HIGHPOWER's patents, trademarks, copyrights or other intellectual property.