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2019 | Service Guide

Nelson Labs™
A Sotera Health company

Safeguarding Global Health™
with every test we complete.

Every year, thousands of medical device, pharmaceutical, and tissue companies make Nelson Labs their testing laboratory of choice. For them, the decision is easy. We look beyond the test results and partner with you to achieve your long-term business goals — mitigating risk and being first to market.

Nelson Labs is a business unit of Sotera Health. Together with sister companies, Nordion and Sterigenics, Sotera Health is the world's leading, fully integrated protector of global health. We touch the lives of more than 180 million people around the world each year. Sotera Health is a portfolio company of Warburg Pincus and GTCR.

On October 31, 2017, Nelson Labs acquired Toxikon Europe N.V., the European division of Toxikon Corporation—which is now Nelson Labs' Europe. With the addition of this Leuven, Belgium-based laboratory, we are now one of the premier global Extractables & Leachables testing laboratories for the pharmaceutical and medical device industries.

On August 7, 2018, Nelson Labs' parent company acquired New Jersey-based Gibraltar Laboratories. Gibraltar Laboratories is a leading outsourced provider of microbiology and analytical chemistry testing for pharmaceutical and medical device manufacturers and is known for USP compendial microbiology, sterility assurance, and analytical chemistry testing. The company, formerly owned and operated by the Prince family since 1970, runs two laboratories in the New Jersey tri-state area. The acquisition of Gibraltar Labs strengthens our testing capabilities for our customers in the pharmaceutical industry - giving our East Coast customers a local lab.

Sincerely,

Jeffrey R. Nelson - President, Nelson Laboratories, LLC

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WHY CHOOSE NELSON LABS

Safeguarding Global Health™
with every test we complete.

Nelson Labs is a clear leader in the microbiology and analytical chemistry testing industry, offering more than **700 laboratory tests and employing more than 700 scientists and staff in state-of-the-art facilities in 13 global locations.**
We are known for exceptional quality and rigorous testing standards, but it is our focus on the bigger picture that sets us apart.

Scope of Service

Research & Development

Process Validation
Material Assessment
Drug Development and Stability

Biocompatibility
ISO 10993

In Vitro and In Vivo
Toxicological Assessments
Extractable & Leachable Studies

Sterilization Validation
ISO 11135/11137

Radiation
EO
Steam
VHP®
STERRAD®
Filtration

Product Validation
ISO/AAMI/ASTM

Cleaning
Disinfection
Reuse
Barrier Tests
Physical Tests
Microbiologic

Packaging Validation
ISO 11607

Stability
Container Closure
Aging
Distribution
Physical
Microbial

Lot Release (QC Tests)
ISO/AAMI/USP

Bioburden
Sterility
Particulates
Bacterial Endotoxin
EO Residuals
BI Sterility

Expert Advisory Services

Regulatory Support, Quality Management System (QMS), & Test Consultations
Study Design Justification & Development of Acceptance Criteria
Facility Validations, Onsite Process Validations, & Technical Problem Solving

Your products are as important to us as the patients they represent.

That is why we deliver:

- Improved patient outcomes & minimized risk
- Resolution to complex problems
- Superior testing solutions and service
- Increased product safety and efficacy

Industries

Nelson Laboratories offers a broad range of regulatory compliance and product performance evaluations for:

MEDICAL DEVICE | PHARMACEUTICAL | TISSUE

Nelson Labs™
A Sotera Health company

EXPERT ADVISORY SERVICES

MEDICAL DEVICE PHARMACEUTICAL TISSUE

Our highly qualified team of expert advisors understand that every product impacts a patient's life. They are uniquely equipped to help clients at every phase of the product life cycle. Our expert advisorss services encompasses product development, facility and process validation, product performance testing as well as regulatory support.

Each advisor brings a unique perspective based on years of industry, regulatory, and scientific expertise. By participating in industry groups, actively working on the standards committees (AAMI/ISO/ASTM/PDA) and experience working with a broad range of MedTech companies and product types, our advisors bring a breadth of experience to each relationship.

Discovery Team

- Observation and onsite review of client processes, quality management systems, validation files, and product development phase gates.
- Assessment and needs discovery related to product development to support validation for regulatory compliance and product submissions.
- Collaborative development of process changes and tailored solutions for continuous product improvement.

Expert Advisory Services

- Product design file review and design phase input.
- Facility validations (environmental, process controls, and water systems).
- Test plans, protocols, and written justifications for method selection related to:
  - Biocompatibility and material characterization risk assessments (ISO 10993)
  - Sterilization validations (EP/Steam/Radiation/VHP/Liquid Chemical)
  - Packaging validations (ISO 11607)
  - Reusable device process validations (AAMI TIR12, AAMI TIR30, ISO 17664)
  - Product-specific validations and failure investigations
  - Development and review of product IFUs
  - Product or family groupings
  - Unique process validations
  - Product adoptions
- Regulatory support for submissions, product changes, detentions, or rejection notices.

Client Education

- Onsite and client-training related to industry best practices, current regulatory, and test guidance.
- Custom webinars and seminars for client training, regulatory updates, and product-specific case studies.

Contact our expert advisors via email **AdvisoryServices@NelsonLabs.com** or phone **+1 801.290.7522**.

EUROPEAN CENTER OF EXCELLENCE

MEDICAL DEVICE PHARMACEUTICAL TISSUE

The addition of the center of excellence in Leuven, Belgium makes **Nelson Labs the leading global extractables and leachables lab testing platform** to serve the pharmaceutical and medical device industries. Based on analytical standards, **Nelson Labs Unique Compound Screener Database** is an expansive library of nearly 5000 compounds across three different chromatographic platforms. With almost two decades of experience, Nelson Labs Europe is an established partner with pharmaceutical and medical device manufacturers.

Testing Services Available

- **Extractables & Leachables for Pharmaceutical Containers**
- **Extractables & Leachables for Medical Devices**
- **Material Characterization Screens for Raw Materials**
- **Combination Products Testing**
- **Impurities Identification in Drug Components and APIs**
- **Stability Studies – Pharmaceutical**
- **Method Development – Pharmaceutical**
- **Cleaning and Disinfection Validation**
- **Microbiological Testing**

Nelson Labs Leuven-based facility is ISO 17025 accredited and GLP-certified and has received a GMP accreditation from the European Authorities. The location is FDA registered.

Nelson Labs N.V.
Romeinsestraat 12
B-3001 Leuven, Belgium
+32.16.400484
InfoEurope@NelsonLabs.com

GIBRALTAR LABORATORIES

MEDICAL DEVICE PHARMACEUTICAL TISSUE

Gibraltar Laboratories, a business unit of Nelson Labs

Nelson Labs acquired Gibraltar Laboratories on August 8, 2018. The New Jersey-based company, operating since 1970, provides microbiology and analytical chemistry services in stability and quality control to the pharmaceutical, medical device, biotech, nutraceutical, cosmetic, specialty chemical, and tissue bank industries.

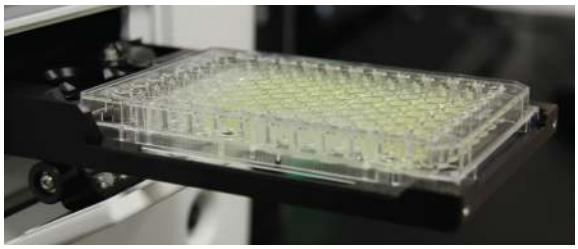
Testing Services Available

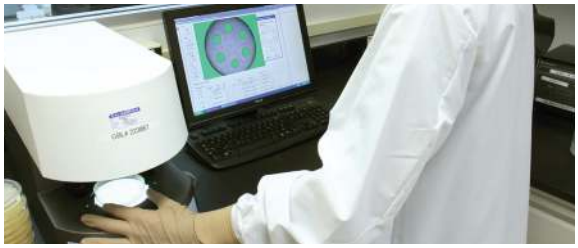
- **Analytical Chemistry**
- **Environmental Monitoring**
- **Microbiology**
- **Sterilization Services**
- **Validations / Calibrations**
- **Virology**

Gibraltar Laboratories is ISO 17025 accredited, GMP & GLP certified, and FDA registered.

Gibraltar Laboratories Audits
122 Fairfield Road
Fairfield, NJ 07004
+1 (973) 227-6882

"Gibraltar Laboratories is a well-respected laboratory known for its strong customer relationships with U.S.-based pharmaceutical manufacturers" - Michael B. Petras Jr., CEO of Sotera Health





GLOBAL LOCATIONS

MEDICAL DEVICE PHARMACEUTICAL TISSUE

Our global network enables us to serve customers where they need us – when they need us. With the addition of Nelson Labs Europe and Gibraltar Laboratories, our 13 global locations are comprised of eight fully integrated laboratories within Sterigenics' sterilization facilities and five stand-alone laboratories.

GLOBAL LAB HEADQUARTERS

Nelson Labs
6280 S. Redwood Road, Salt Lake City, UT 84123 USA
+1 (801) 290-7500

EUROPEAN CENTER OF EXCELLENCE

Nelson Labs NV
Romeinsestraat 12, B-3001 Leuven, Belgium
+32.16.400484

NEWLY ACQUIRED

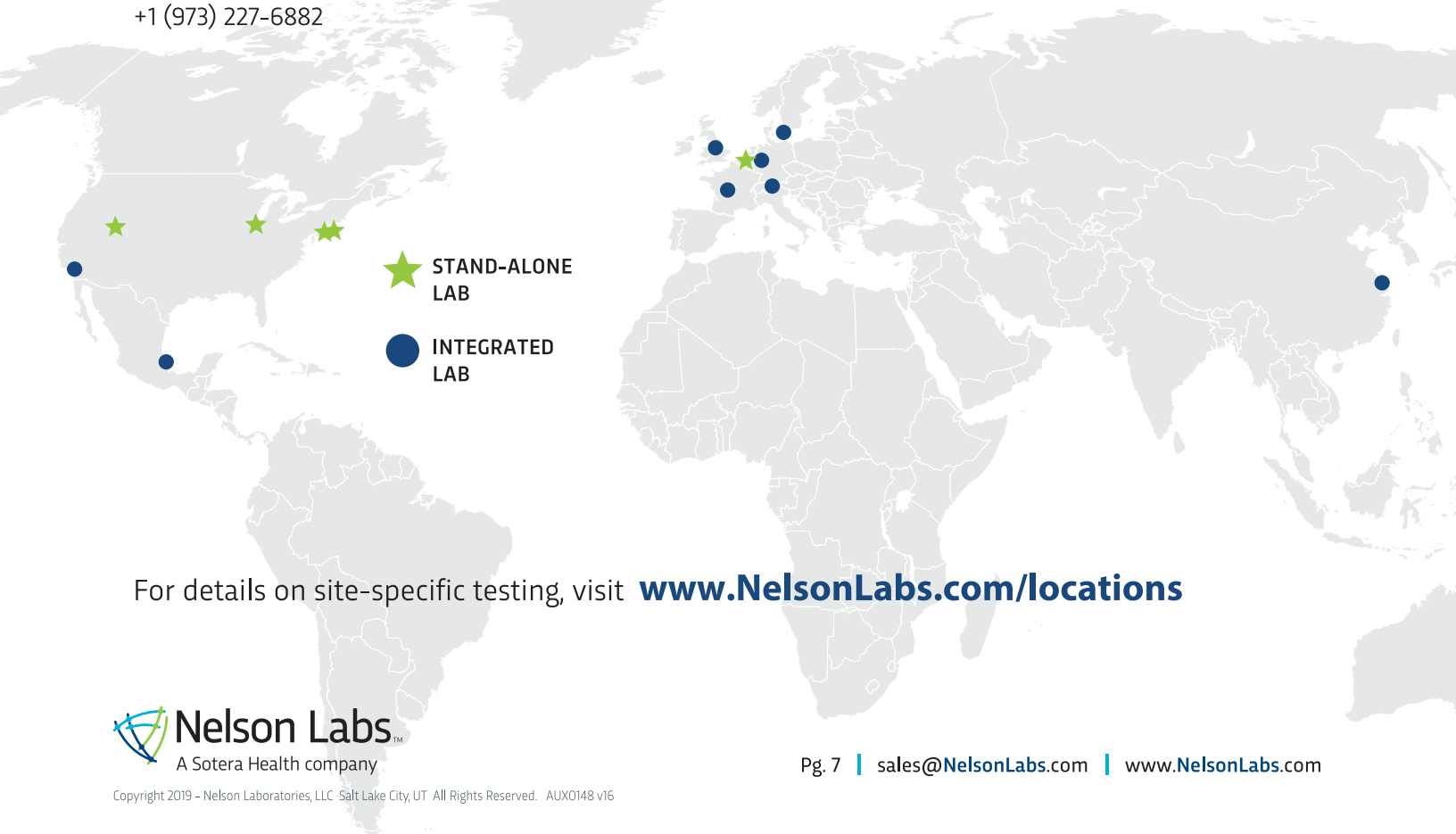
Gibraltar Laboratories, Inc.
122 Fairfield Road, Fairfield NJ, 07004
+1 (973) 227-6882

INTERNATIONAL LOCATIONS

North America
Itasca, IL: +1 (630) 285-9121
Ontario, CA: +1 (909) 969-2902
Mexico City, Mexico: +52 (55) 2620.9076

Asia
Shanghai, China: +86 (21) 6828 0215

Europe
Espergaerde, Denmark: +45 (0) 49 12 79 72
Petit-Rechain, Belgium: +32 (0) 87 30 70 63
Rantingy, France: +33 (0) 3 44 73 88 42
Somercotes, England: +44 (0) 1773 543 257
Wiesbaden, Germany: +49 611 880 46 134



For details on site-specific testing, visit **www.NelsonLabs.com/locations**

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How to Set Up Your Account

If you are new to Nelson Labs – welcome! We offer several services online that we hope you will find valuable as you build a relationship with us, including an online secure site for report downloads (for customers of U.S. labs.

To provide the best service and ensure your tests are properly set up, we recommend you set up an account prior to submitting samples to the lab. This includes standard accounting information, commercial credit application, preferences for report handling, and verification of your contact information. Once your account has been set up, you may begin submitting samples for analysis.

To set up your account, please contact our Accounting Department.
+1 801-290-7507 or **accounting@nelsonlabs**.com.

How to Submit Samples for Analysis

1. Contact Sales for a price quote number for your project(s). During the quote process, appropriate lab and scientific personnel will be consulted to ensure your test needs are met and that an appropriate test plan has been determined.
2. Complete a Sample Submission Form (www.**nelsonlabs**.com/SubmitSample)
3. Send your product/samples with the completed Sample Submission Form to the address provided on your quote.

Note: Please reference your quote number on the Sample Submission Form to ensure appropriate billing. International clients please see International Shipping Tips for more detailed shipping information.

Upon receipt, the product/samples will be inspected and counted to verify information as listed on the Sample Submission Form. A lab number will be assigned for each project and a confirmation will be sent by fax or e-mail to the contact listed on the Sample Submission Form.

At this time, new clients of our U.S. Labs will also be assigned a unique username and password granting them access to the Nelson Laboratories secure client website (**secure**.**NelsonLabs**.com). The secure site allows clients to view test progress by date and download a PDF version of the final report when available.

Visit us on-line for test and service updates: www.**NelsonLabs**.com
Hours of Operation: 7:00 AM - 6:00 PM MST (SLC Facility)

For international shipping tips, visit
https://www.nelsonlabs.com/international-shipments/

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Toxicology & Biocompatibility - ISO 10993

Nelson Laboratories offers a full range of material assessments using chemical characterization, *in vivo* and *in vitro* test services to meet US FDA, EU CE mark Japan MHLW and other international requirements. For general information about Toxicology and Biocompatibility tests specific to your product, please review the ISO 10993 biocompatibility matrix. Contact the Sales Department at sales@nelsonlabs.com for a product consultation and to assess test requirements for your regulatory submission.

Chemical Characterization

ISO 10993-12; ISO 10993-18

Test Description	Test Code
Differential Scanning Calorimetry (DSC)	
Sample preparation and analysis, each	DSC101
Repeat scan with thermal cycle, each	DSC105
Fourier Transform Infrared Analysis (FTIR) and Micro FTIR Analysis	
Micro FTIR offers microscopic assessment of materials; standard FTIR is qualitative only	
Complete FTIR sample analysis w/ library search & peak labels, each	IRX100
Complete FTIR sample analysis w/ library search & peak labels - RMM, each	IRX115
Complete FTIR sample analysis with Microscopy method, library search, & peak labels, each	IRX200
Complete FTIR sample analysis with Microscopy method, library search, & peak labels – RMM, each	IRX215
Sample preparation (extraction or KBr press), Peak Label or Library search, each	
Physicochemical test, USP plastics USP <661>	
If the nonvolatile residue is ≤5 mg then the residue on ignition is not required, per USP	
Standard USP 661 - Complete	PCT101
Includes water extraction, buffering capacity, heavy metals, nonvolatile residue (NVR), residue on ignition	
Standard USP 661 - Complete, without residue on ignition	PCT105
Includes water extraction, buffering capacity, heavy metals, nonvolatile residue(NVR)	
Polypropylene/Polyethylene USP 661 - Complete	PCT301
Includes USP 661 complete tests plus non-aqueous extraction with NVR, FTIR and DCS on extracts.	
Polypropylene/Polyethylene USP 661 - Complete, without residue on ignition	PCT305
Includes USP 661 complete tests plus non-aqueous extraction with NVR, FTIR and DCS on extracts.	
*** Contact lab for information related to new USP 661 requirements for ICP-MS and related test methods*	
Chemical Characterization and Extractables/Leachables	
Protocol Development, Report and Consultation	MCP100
FTIR scan (high LOD, qualitative)	MCP200
FTIR Micro scan (low LOD, qualitative)	MCP205
Differential scanning calorimetry (DSC, melting point)	MCP215
Gravimetric Analysis – Residue ASTM F2459	MCP220
GC-MS for Volatile organic compounds	MCP300
GC-MS for Semi-volatile organic compounds	MCP305
LC/MS for Non-Volatile organic compounds	MCP315
ICP-MS, 62 metals (full scan)	MCP330
ICP-MS, 31 metals (common scan)	MCP335
Phthalates Scan	MCP340
Scanning Electron Microscope (SEM)	MCP350
USP 661 – Nonvolatile residue	MCP400
Other methods	Consult

Cytotoxicity – ISO 10993-5, USP <87>

Test Description	Test Code
Agar Overlay cell culture assay	
24 hours incubation, triplicate, L929 cells	CTX101
MEM Elution cell culture assay	
MEM elution, 48 hours incubation, L929 cells, 24 hr. extraction	CTX110
MEM elution, 48 hours incubation, L929 cells, 72 hr. extraction (Prolonged and Permanent Contact)	CTX112
MEM elution, 72 hours incubation, L929 cells, 24 hr. extraction	CTX115
MEM elution, L929, titration method, 4 dose levels	CTX125
Other methods or Japan MHLW	
Per additional read or time point	CTX701

Genotoxicity – ISO 10993-3

Test Description	Test Code
Ames Mutagenicity Tests, OECD 471, ICH S2 (R1)	
Ames test: Solids	
2 extracts, 5 strains, plate incorporation	GTX110
Ames test: Soluble chemicals	
5 strains, 1 dose, plate incorporation	GTX140
5 strains, 5 doses, plate incorporation (OECD 471)	GTX145
Ames test: Base Oils, ASTM E1687-98	
Pre-incubation, 1 strain	GTX150
Chromosomal Aberration, OECD 473, ICH S2 (R1)	
Solid/Device – extraction test utilizing CHO cells, 2 extracts	GTX220
Liquid/ Power - utilizing CHO cells, 3 concentrations (OECD 473)	GTX330
Mouse Micronucleus	SCX510
Mouse Lymphoma	SCX530

Hemocompatibility – ISO 10993-4, ASTM F756-13

** Complement and PTT tests should be conducted with a predicate device for data comparability.*
Price listed includes one device and one predicate to provide baseline data requisite with interpretation of results.

Test Description	Test Code
Hemolysis with human blood	
ASTM Hemolysis, indirect - device/material (human blood)	HCX140
ASTM Hemolysis, direct contact - device/material (human blood)	HCX145
*** For devices with >3 hrs blood contact both extract & direct contact are recommended*	
Complement activation * *** Consult lab for testing without predicate and interpretation of results*	
SC5b-9, one test article and one predicate (recommended)	HCX245
Partial thromboplastin time (PTT test) * *** Consult lab for testing without predicate and interpretation of results*	
Human plasma, one test article and one predicate (recommended)	HCX225
Platelet and Leukocyte Count (PLC test)	SCX660
Platelet and Leukocyte Count (PLC test) with Predicate	SCX665
Dog Thrombogenicity	SCX670
Pig Thrombogenicity	SCX680
Sheep Thrombogenicity	SCX690

Toxicology & Biocompatibility (*In Vivo*) – ISO 10993

Nelson Laboratories offers a full range of *in vivo* test services on a subcontract basis through qualified partner labs. We can assist you with *in vivo* studies for Sensitization, Irritation, Systemic Toxicity, Sub-chronic Toxicity, Implantation Studies, Genotoxicity, Thrombogenicity, and other required tests per ISO 10993 for US FDA submissions. Consult required for testing intended for submission to European Union (EU), Japanese (MHLW), and other notified bodies. Contact the Sales Department at sales@nelsonlabs.com for more information or for consultation on *in vivo* test services.

**Custom biocompatibility *in vitro* and in *vivo studies* and consultations are available. ISO 10993 biocompatibility summary report, highlighting biocompatibility testing results and conclusions, is also available upon request. For more information contact Sales at sales@nelsonlabs.com.

Biological Evaluation Plans (BEP) and Toxicological Risk Assessments are available through our Expert Advisory Services team AdvisoryServices@nelsonlabs.com.

Test Description	Test Code
Sensitization	
Maximization (ISO)	SCX110
Buehler Method	SCX130
Irritation	
Intracutaneous Reactivity (USP)	SCX210
Intracutaneous Toxicity (ISO)	SCX220
Primary Eye	SCX230
Primary Skin (ISO)	SCX240
Bladder	SCX250
Vaginal/Mucosal, direct exposure method for liquids	SCX260
Vaginal, device methos, 2 extracts	SCX265
Oral Mucosal w/ Histo. 2 extracts	SCX270
Oral Mucosal w/ Histo. Direct exposure	SCX275
Systemic Toxicity	
Systemic Injection (ISO)	SCX310
Material Mediated Pyrogen	SCX320
Sub-Acute and Sub-Chronic Toxicity	
Sub-Acute: 14 day and 14 dose (mice)	SCX410
Sub-Acute: 14 day and 14 dose (rat)	SCX420
Sub-Chronic: 28 day and 28 dose (rat)	SCX440
Implantation (ISO)	
1 week surgical intramuscular implant	SCX610
2 week surgical intramuscular implant	SCX620
4 week surgical intramuscular implant	SCX630
8 week surgical intramuscular implant	SCX640
13 week surgical intramuscular implant	SCX650
26 week surgical intramuscular implant	SCX653
1 week subcutaneous implant	SCX615
2 week subcutaneous implant	SCX625
4 week subcutaneous implant	SCX635
8 week subcutaneous implant	SCX645
13 week subcutaneous implant	SCX655
Implantation (USP)	
USP Class III, complete	
Includes intracutaneous irritation and systemic toxicity	SCX810
USP Class VI, complete	
Includes intracutaneous irritation, systemic toxicity, and 7 day implantation	SCX820
Hemocompatibility	See page 11
Genotoxicity	See page 11

Sterilization Validation, Terminal Process for EO – ISO 11135

Ethylene Oxide (EO) Sterilization - Cycle Development

Comparative, Relative, or Bioburden Resistance - Comparative resistance (cycle development) is performed to determine an appropriate process challenge device (PCD) that can be used to monitor EO sterilization cycles. Bioburden resistance is used to demonstrate that the resistance of the PCD is equal to or greater than that of the natural product bioburden. Relative resistance combines the knowledge of the comparative and bioburden resistance studies. For steam sterilization see Page 17.

Test Description	Test Code	
Sterilization Resistance (Comparative, Bioburden, Relative)		
Contact Sales for a device/product evaluation and project estimate.		
Comparative Resistance Study	SCR110	
Relative Resistance Study (Comparative and Biocurden)	SCR210	
Bioburden Resistance Study	SCR310	
Process challenge device preparation (PCD)	PCD110	
PCD preparation & loading		
1–10 samples, each		
11–50 samples, each		
51+ samples, each		
Note: There is a PCD minimum order fee		
Delivery of PCDs to local contract sterilizer in Salt Lake City, if applicable	PCD701	
Product Inoculation for sterilization		
Bacillus atrophaeus inoculation		
Each (10^6 per inoculation site)	SPI110	
Geobacillus stearothermophilus inoculation		
Each (10^6 per inoculation site)	SPI120	
Clostridium sporogenes inoculation		
Each (10^6 per inoculation site)	SPI130	
Wires or non-standard product inoculation, standard organisms		
Each (10^6 per inoculation site)	SPI140	
Other organisms or inoculations	SPI150	
Inoculations for reusable device studies		See page 18
Sterilizer temperature/humidity distribution study		
Per cycle - data compilation and review for third-party probes	TDS120	
Sterilizer temperature/humidity distribution study – probe rental		
Probe rental, per probe	TDS210	
On-site probe placement and study monitoring (per hour)	TDS220	

Ethylene Oxide (EO) Sterilization – Full Validation

EO validations are performed according to ISO 11135 guidelines. Validation studies include process development, coordination with contract sterilizers, and input from Nelson Laboratories Technical Consulting group to help clients define an effective sterilization process.

EO Sterilization Validation – EN ISO 11135: 2014		
Contact Sales for a consultation and project estimate		
EO Validation Study (single use products)	SVE110	
Sterilization validation, on-site		
Nelson Laboratories employees on-site (customer facility or contract sterilizer)	OSV110	

EO Sterilization Batch Release – AAMI/TIR 16

Alternative to a full validation, this study is used to release a single batch of product. It is a convenient option to provide terminally sterilized products for clinical use when the production volume is small, for new product development or when there is only enough product manufactured to complete one sterilization load.

EO Sterilization Batch Release Study – AAMI/TIR 16		
Contact Sales for a consultation and project estimate	SBR110	
Clinical EO use, sterilization batch		

EO Exposure Cycles: 100% EO

Exposure cycles are intended for feasibility, functionality, biocompatibility, etc. If requested, product can be preconditioned up to 24 hours in an environmental chamber. For sterilization, please provide desired temperature, relative humidity (during gas dwell), gas concentration (mg/L), exposure time, heated aeration temperature, heated aeration time, and ambient aeration time (as applicable).

Test Description	Test Code
Pre-conditioning in environmental chamber (optional)	SEC105
Extended aeration (per additional day)	SEC106
EO exposure cycle, 100% EO	
Standard cycle - 1 hour conditioning, 5 hours gas exposure time	SEC110
Standard cycle - 1 hour conditioning, 8 hours gas exposure time	SEC111
Standard cycle - 1 hour conditioning, 12 hours gas exposure time	SEC112
Short cycle - 1 hour conditioning and up to 2 hours gas exposure time	SEC115
Additional exposure or chamber time, per hour	SEC120
Sterilization Exposure Cycles: 100% EO, multiple exposure	SEC130
Sterilization exposure cycle: decontamination/kill load	
Up to 12 hours of exposure	SEC410

EO Residue Analysis, ISO 10993-7

Please provide required extraction dates and date out of the sterilizer. The EO extraction specifics form is recommended when submitting samples for this study. Pricing is per device or pooled set.

Test Description	Test Code
Ethylene oxide residual analysis, ISO 10993-7 – Liquid sample	
EO, ECH & EG for liquid sample (no extraction)	EOR130
Client may indicate on sample submission form which analyte(s) to include in the analysis.	
Ethylene oxide residual analysis, ISO 10993-7 – Device extraction	
Limited use device (<24 hours) exposure	
Pricing is per device or pooled set with extraction in water	
EO & ECH, one extraction only	EOR110
EO, ECH & EG, one extraction only	EOR120
EO Headspace analysis (water ext.), one extraction – limited	EOR500
Prolonged use (24 hours- 30 days) or permanent use (30+ days) exposure	
Exhaustive Extraction: Extraction until the amount of EO or ECH in a subsequent extraction is less than 10% of that detected in the first extraction, or until there is no analytically significant increase in the cumulative residue levels detected.	
Pricing is per device or pooled set with extraction in water	
EO & ECH ISO 10993-7, exhaustive extraction, 1st extraction	EOR310
Each additional extraction	EOR315
EO, ECH & EG, exhaustive extraction, 1st extraction	EOR410
Each additional extraction	EOR415
EO Headspace analysis (water ext.), exhaustive, 1st extraction	EOR510
Each additional extraction	EOR515

Pricing is product dependent, final number of extractions cannot be determined until testing is complete.

Vaporized Hydrogen Peroxide Sterilization Methods

Hydrogen Peroxide Analysis

Nelson Laboratories offers hydrogen peroxide residual analyses for medical devices and related products intended for terminal sterilization or exposure cycles. It is important to note that the exposure levels of hydrogen peroxide vary with processing time, exposure cycle concentration, and manufacturer (STERRAD® 100, 100S, NX, etc. or STERIS® VHP, etc.). If you request exposure cycles, prior to hydrogen peroxide testing, please consult with the lab to ensure your exposure cycles will be representative of intended use.

Test Description	Test Code
Hydrogen peroxide analysis, Devices and Instruments (spectrophotometric method)	
Hydrogen Peroxide (H_2O_2): High Level Assay Only w/ 3 titrations	HPR101
H_2O_2 residue determination, Low level detection extraction and assay: per sample	HPR210

BI – Resistance Performance Tests

Biological indicator performance tests serve as a quality check to ensure the BIs used during sterilization meet the resistance and population specifications highlighted in the Certificate of Analysis provided by the BI manufacturer.

Test Description	Test Code
Biological indicator population verification - USP or ISO	
Paper carriers, viable spores, liquid suspension or sutures	
BI population verification (USP), pooled results, 4 BIs	BPV110
BI population verification (USP), individual results, 4 BIs	BPV120
BI population verification (ISO), pooled results, 4 BIs	BPV125
BI population verification (ISO), individual results, 4 BIs	BPV130
BI population verification – other quantities or methods	BPV150
D-value determinations (up to 10 exposures)	
EO BIER, spore strips: Stumbo method	SDV110
EO BIER, spore strips: Spearman Karber method	SDV120
EO BIER, organism isolate	SDV130
Steam BIER, spore strips: Stumbo method	SDV210
Steam BIER, spore strips: Spearman Karber method	SDV220
Steam BIER, organism isolate, each	SDV230
Product D-value, 100% EO or steam : Stumbo method	SDV310
Product D-value, 100% EO or steam: Spearman Karber method	SDV320
Z-value determination: Steam BIER, spore strips (Spearman-Karber)	SDV400
Spore strip survival time verification (BIs supplied by sponsor, please include manufacturers certificate)	
EO BIER, survival time test	BIT310
Steam BIER, survival time test	BIT320
Other methods or BI quantities	BIT330
Spore strip kill time verification (BIs supplied by sponsor)	
EO BIER, kill time test	BIT410
Steam BIER, kill time test	BIT420
Other methods or BI quantities	BIT430
Spore strip incubation time reduction (RIT) study (BIs supplied by sponsor)	
RIT per CDRH: 100% EO, 6 cycles	RIT110
Additional cycles, each	RIT120

Biological Indicators (BI) Sterility Test

The number of BIs should be based on ISO/EN recommendations regarding usable chamber volume of the sterilizer or product load size (proposed under new revision of ISO 11135).

A minimum report fee applies to BI sterility tests (standard BIs and self-contained BIs).
Additional fees are incurred when testing inoculated product (BIT215, per BI).

Test Description	Test Code
Spore strips test, each in 20 mL soy	BIT210
Self-contained biological indicators test	BIT230

Order Biological Indicators See page 40

Sterilization Validation, Terminal Process for Radiation ISO 11137 & ISO 13004:2013

Nelson Labs provides services for both radiation validation and routine dose audits. Each radiation validation study includes all protocol, dose calculation, and final report fees. An initial bacteriostasis/fungistasis test is required to validate sterility tests (see page 25). For products that are consumed in testing (e.g. powders, gels, liquids), include at least one additional sample for a positive control on all bioburden tests. Recommend bioburden characterization for validations/dose audits using genetic or Vitek characterization.

Dosing for validations and dose audits

Verification dosing can be arranged through Nelson Labs for validations and dose audits. If verification dosing is required, please specify on the sample submission form. Cost depends on choice of contract irradiator, shipping fees, box size, and box quantity.

Substantiation of 25 kGy – VDmax Method:
ANSI/AAMI/ISO 11137-2:2006 & ISO 13004:2013

Test Description	Test Code
VDmax single lot validation	
Bioburden (10), Sterility (10), B/F (3), 3 Gram stains, coordination & summary report	SVR110
VDmax three lot for quarterly release	
Bioburden (30), Sterility (10), B/F (3), 3 Gram stains, coordination & summary report	SVR120
VDmax dose audit	
Bioburden (10), Sterility <1L (10), 3 Gram stains, coordination & summary report	SVR130
Bioburden (10), Sterility >1L (10), 3 Gram stains, coordination & summary report	SVR135
MPN Bioburden (10), Sterility <1L (10), 3 Gram stains, coordination & summary report	SVR140
MPN Bioburden (10), Sterility >1L (10), 3 Gram stains, coordination & summary report	SVR145
VDmax dose audit non-standard method or sample type	SVR760
Method development	

Method 1 – Radiation
ANSI/AAMI/ISO 11137-2:2006

Test Description	Test Code
Method 1 validation	
Bioburden (30), Sterility (100), B/F (6), coordination & summary report	SVR210
Method 1 dose audit	
Bioburden (10), Sterility at <1L (100), 3 Gram stains, coordination & summary report	SVR220
Bioburden (10), Sterility at >1L (100), 3 Gram stains, coordination & summary report	SVR225
Method 1 dose audit non-standard method or sample type	

Alternate Radiation Methods

Test Description	Test Code
Method 2 validation ANSI/AAMI/ISO 11137-2:2006	SVR310
Method 2 dose audit <1L media (10) / >1L media (10)	SVR320/325

Gamma and E-Beam Dosing

Sterilization Service Description	Service Code
Radiation Sterilization: Gamma Dosing Charges	SVR710 or SVR713
Radiation Sterilization: E-Beam Dosing Charges	SVR711 or SVR714
Radiation Sterilization: Custom Dosing Charges	SVR712

Nelson Laboratories can coordinate your quarterly dose audits. Contact Sales at sales@nelsonlabs.com for details and pricing.

Sterilization Validations Reusable Devices, Kits and Trays – ISO 17665, AAMI ST79

Nelson Laboratories offers a range of sterilization validation services for devices and trays. As each product and cycle requirement varies, contact the Sales Department at sales@nelsonlabs.com for a price quote for your specific project. For steam sterilization validations, dry time verification and temperature profiling (specifically with trays/kits) should be performed as described in the AAMI ST77 guidance.

Sterilization Validations

For devices/trays sterilized or reprocessed at a healthcare facility - ISO 17665, AAMI ST79

Test Description	Test Code
Steam sterilization validation of a single device, per cycle type	RVS110
Steam sterilization validation of tray or kit, per cycle type	RVS130
Ethylene oxide sterilization validation of a single device or tray, per cycle type	RVS140
Liquid chemical	RVS150
STERRAD® validation of a single device or tray, per cycle type	RVS180

Functionality (Repeat) Cycles

Functionality cycles should include all aspects of the life of the device including cleaning, disinfection, and/or sterilization.

Test Description	Test Code
Steam cycles only	RSC110
Ethylene oxide cycles (100% EO) only disinfection	RSC120
Chemical immersion	RSC130
Pasteurization cycles	RSC140
Manual cleaning cycles	RSC150
STERRAD® cycles only	RSC160
Automatic washer/disinfector cycles	RSC180
Manual cleaning cycles	RSC185
Steam cycles with cleaning/disinfection	RSC210
EO cycles with cleaning/disinfection	RSC220
STERRAD® cycles with cleaning/disinfection	RSC230

Additional Sterilization Validation Services

For general exposure or hospital cycles intended for functionality, small batch release, or onsite services.

Test Description	Test Code
Steam sterilization validation, on-site	
Consult Nelson Laboratories for on-site sterilization validations	OSV120
Steam sterilization cycle	
Single cycle (1 ½ hours or less per cycle)	SEC150
Sterilization exposure cycles	
EO sterilization, per cycle	SEC160
Steam sterilization for clinical use	SEC170

MEDICAL DEVICE PHARMACEUTICAL TISSUE

Reusable Medical Device – Reprocessing Validations

Reuse Tests for Cleaning Evaluation

Nelson Labs offers a full range of services to validate manufacturers' instructions or directions for use (IFUs / DFUs) for cleaning, disinfection, and sterilization of reusable devices. Recommendations are based on ISO 17664, AAMI TIR 12, AAMI TIR 30, US FDA guidance issued March 2015 for processing/reprocessing of medical devices in healthcare settings, and other current guidance and standards. Validations include simulated use cycling (to achieve used condition and address soil accumulation), worst case clinically relevant contamination, cleaning, disinfection, and post-reprocessing evaluation for targeted quantitative biomarkers. Tests may also include cytotoxicity tests to assess residual cleaning material on devices and bacterial endotoxin tests for devices that may contact cerebral, spinal or neurological fluids. Once validation parameters are set, functionality (repeat) cycle testing can be performed to validate the number of times the product can be reprocessed and reused as outlined in the US FDA guidance document (see pg. 17).

TEST RECOMMENDATIONS ARE BASED ON BODY CONTACT TYPE, DEVICE TYPE, & SIZE.

Cleaning or disinfection following the manufacturer's intended instructions or directions for use (IFUs / DFUs) or internal procedures, will require contamination of the device with test soil to simulate use. The method of contamination is dependent on the clinical procedure that the device will encounter. Clients should consult their FDA reviewer or regulatory consultant on the specific device and test requirements, and to confirm the appropriate test plan especially for novel device types. The use of quantitative biomarkers assessments is required. Disinfectants and detergents used in US and EU healthcare facilities are different and may require separate validations to meet regulatory or market requirements for each region.

Written justification for the selection of test soils, test plan, and acceptance criteria should be included in the product design file or technical file. Nelson Technical Consultants are available to assist with these written elements to satisfy regulatory requirements.

For a product-specific consultation for **US FDA 510(k)** or **EU CE Mark**, contact Nelson Labs at sales@nelsonlabs.com.

Cleaning Validation for Reprocessing of Reusable Devices

Test Description	Test Code
Protocol Development & Initial Consult	RVC105
Cleaning Validation – Reusable or Reprocessed Devices	RVC110
Cleaning Validation – Automated Reprocessing	RVC120
Cleaning Validation – Simulated Use-Sub Test	RVC130

Sample test plan shown below. Final recommendations based on surgical procedure.

Bio Markers	Cleaning Parameters	Disinfection Parameters	Sterilization Parameters
Recommended Validation	**Simulated Use / Pre-test**	**Low Level**	**Sterilization Cycle Types**
Based on clinical procedure	[ ] Biofilm, # cycles _____	*4 veg., 6 log reduction*	[ ] EO
[ ] Protein	[ ] Functionality, # cycles ___	**Intermediate Level**	[ ] Steam 121C/132C
[ ] Hemoglobin	**Used condition devices*	*4 veg., 6 log reduction*	[ ] Sterrad® or VHP®
[ ] Bacterial Endotoxin		*M. terrae, 3 log reduction*	[ ] Thermal/Chemical *(CE mark)*
[ ] Bioburden: Spore *(CE mark)*	**Organisms & Soils**	**High Level**	[ ] Chemical *(510k)*
	Based on clinical procedure	*M. terrae, 6 log reduction*	
Optional Validation	[ ] Organic/Mucous soil	**Thermal**	
[ ] Carbohydrates	[ ] Organic/Blood soil	*[ ] A_0*	
[ ] MEM or Det. Residual	[ ] Other: _____	*[ ] Direct inoculation*	
[ ] Bioburden: Vegetative		**Optional Validation**	
		[ ] Cytotoxicity: MEM Elution	

Disinfection for Reprocessing of Reusable Devices

Disinfection study prices are per device area or component evaluated to simulate manufacturer cleaning instructions.

Test Description	Test Code
Protocol Development & Initial Consult	RHL105
Disinfection Validation – HLD	RHL110
Disinfection Validation – ILD	RHL120
Disinfection Validation – LLD	RHL130
Thermal Disinfection: Inoculation	RTD110
Thermal Disinfection: A_0	RTD120

Cleaning Validation for Reprocessing Flexible Endoscopes

Nelson Laboratories specializes in reprocessing flexible endoscopes. Due to the complexity in comparison to a standard reusable medical device, specified pricing and considerations are applied to these unique reusable medical devices. All testing recommendations are based on AAMI ST 91, AAMI TIR 12, AAMI TIR 30, US FDA guidance issued March 2015 for processing of medical devices in healthcare settings, ISO 17664, ISO 15883, and other current industry trends specifically for flexible endoscopes. Automated endoscope reprocessors (AERs) are also validated per US FDA guidance and industry trends. Clients should consult with their regulatory reviewer or notified body on the test requirements and confirmation of an appropriate test plan.

Test Description	Test Code
Protocol Development & Initial Consult	SVC105
Cleaning Validation – Reusable or Reprocessed Devices	SVC110
Cleaning Validation – Reusable or Reprocessed Devices, additional test articles *Final recommendations based on surgical procedure.*	SVC130

Disinfection and Liquid Chemical Sterilization for Reprocessing Flexible Endoscopes

Disinfection study prices are per device area on the endoscope or AER and validation in accordance with the manufacturer instructions for use.

Test Description	Test Code
Protocol Development & Initial Consult	SHL105
Disinfection Validation – High Level Disinfection (HLD)	SHL110
Disinfection Validation – Liquid Chemical Sterilization	SHL120
Disinfection Validation – HLD, additional test articles	SHL130

Flexible Endoscope Sampling Kit

Healthmark Industries and Nelson Labs have partnered to create an endoscope sampling kit for use with flexible endoscopes with a purpose of monitoring and reporting objective microbiological results from reprocessed clinical scopes.

The Flexible Endoscope Sampling Kit is sold by Healthmark Industries and test services are provided by Nelson Laboratories as a full-service kit.

Test Description	Test Code
Healthmark Clinical Scope Surveillance Study (Micro)	HMS110
Healthmark Clinical Scope Surveillance Study (IDs)	HMS115

MEDICAL DEVICE PHARMACEUTICAL TISSUE

Cleaning Validations for Newly Manufactured Devices & Implants

Validation of the cleaning processes used to remove residual manufacturing materials (RMM) from newly manufactured devices is an important assessment of the manufacturing process. This assessment provides documentation that the cleaning process is effective. This documentation can be useful in support of a regulatory submission or in the event of a US FDA or notified body audit. Nelson Labs offers a full range of testing to assess cleanliness throughout the manufacturing process.

There are several standards regarding the cleaning validation of newly manufactured devices and implants, including ASTM F2459 and ASTM F2847. Our scientists are available to consult about your specific device and manufacturing process. Please contact Sales for additional information or to set up a consultation and a project estimate.

Test Description **Test Code** **Price**

Simplified Test Matrix for Newly Manufactured Devices

Purpose	Test Options	RMM105	Quote
Manufacturing Residues	Quantification of extractable residue, gravimetric, ASTM F2459 Soap/Detergent residuals by UV/Vis spectroscopy Fourier Transform Infrared Analysis (FTIR) Cytotoxicity: MEM Elution, ISO 10993-5, USP87 Particulates: Automatic counter method, USP 788	Contact Sales for a device evaluation and project estimate.	
Environmental & Microbiological Residues	Bioburden, ISO 11737, ISO 11135 LAL: Kinetic Turbidimetric method, USP 85 TOC: Total organic carbon – O.I., USP 643		

*** Additional tests may be required depending on your device, manufacturing process and end use application.*

Equipment/Test	Polymer	Metals	Targets
USP <661> - QN & pass/fail	X	N/A	**Organics & Inorganics** - Buffering Capacity, Nonvolatile Residue, Residue on Ignition, Heavy Metals
FTIR - QL	X	X*	**Organics** - Chemical structure and ID of polymers, plasticizers, materials
DSC - QL	X	N/A	**Organics** - Thermal properties of polymer
ASTM F2459 - QN	X	X	**Organics & Inorganics** -Gravimetric for high molecular weight species i.e., mineral oil, lubricants, detergents, silicone oil, mold release agents
GC/MS - QL & QN	X	X	**Organics** - Volatile and Semi-Volatile organic compounds (VOCs/SVOCs)
LC/MS - QL & QN	X	X	**Organics** - Non-volatile organic compounds (NVOCs)
ICP/MS- QL & QN	X	X	**Inorganics** - Metal compounds from surface or Leachable
SEM/EDS - QL	X	X	**Inorganics** - Gives surface picture and elemental analysis
IC/MS - QL & QN	X	X	**Inorganics & Organics** - Specific screening for Anions & Cations
TOC - QN	X	X	**Organics** - Carbon containing compounds
Particulates - QN	X	X	**Organics & Inorganics**
Bacterial Endotoxins - QN	X	X	**Biologics -** assess contamination; typically from water sources
Bioburden - QN	X	X	**Biologics -** assess bioburden (organisms) present on product
MEM Elution - pass/fail	X	X	**Biologics -** cytotoxicity gives sensitive biocompatibility reaction data

QL = Qualitative; QN = Quantitative **Residue from Gravimetric ASTM F2459 analyzed by FTIR*

Packaging Validation and Testing - ISO 11607

Package Validations

A Packaging Validation is a way to test your sterile barrier system (SBS) and show that it can be maintained over time. Thus, ultimately establishing a shelf-life and expiration date for your product. In order to meet the requirements outlined in ISO 11607-1 for validating a SBS, we recommend the following packaging validation testing based on SBS type. Five year shelf life is an example that is used for the recommendations listed below. Actual aging periods depend on product shelf life label claims.

The purpose of testing is to demonstrate the strength, integrity and microbial barrier properties. Different configurations and situations may require slight variation to the following recommendations. To discuss your specific needs or to receive a quote and information about any of the offered tests please contact Sales at sales@nelsonlabs.com.

Packaging Validations

Interim return shipments for aging studies, priced per set

Test Description	Test Code
Non-Porous Pouches	PKG620

Transportation & Distribution: ASTM D4169 (US FDA's consensus standard)

Time points: Baseline or T=0, post ship or distribution testing
Accelerated Aged 1 year, 3 year, 5 year
Real Time 5 year

Sterile Barrier Assessment: *We recommend performing the following tests at each of the time points listed above*:
Strength: ASTM F1140 Internal Pressurization Failure Resistance of Packages (Burst)
Integrity: ASTM F2096 Detecting Gross Leaks by Internal Pressurization (Bubble emission)
Microbial: ASTM 2981 Nonporous Material Resistance to Air Passage (Gurley)

Porous Pouches PKG620

Transportation and Distribution: ASTM D4169 (US FDA's consensus standard)

Time points: Baseline or T=0, post ship or distribution testing
Accelerated Aged 1 year, 3 year, 5 year
Real Time 5 year

Sterile Barrier Assessment: *We recommend performing the following tests at each of the time points listed above*:
Strength: ASTM F88 Seal Strength of Flexible Materials (Seal Peel)
Integrity: ASTM F1929 Detecting Leaks in Porous Medical Packaging by Dye (Dye Migration)
Microbial: ASTM F1608 Microbial Ranking of Porous Materials (Exposure Chamber Method)

Trays PKG620

Transportation and Distribution: ASTM D4169 (US FDA's consensus standard)

Time points: Baseline or T=0, post ship or distribution testing
Accelerated Aged 1 year, 3 year, 5 year
Real Time 5 year

Sterile Barrier Assessment: *We recommend performing the following tests at each of the time points listed above:*
Strength: ASTM F1140 Internal Pressurization Failure Resistance of Packages (Burst)
Integrity: ASTM F2096 Detecting Gross Leaks by Internal Pressurization (Bubble emission)
Microbial: ASTM F1608 Microbial Ranking of Porous Materials (Exposure Chamber Method)

Header Bag PKG620

Transportation and Distribution: ASTM D4169 (US FDA's consensus standard)

Time points: Baseline or T=0, post ship or distribution testing
Accelerated Aged 1 year, 3 year, 5 year
Real Time 5 year

We recommend performing the following tests at each of the time points listed above:
Strength: ASTM F88 Seal Strength of Flexible Materials (Seal Peel)
Integrity: ASTM F1929 Detecting Leaks in Porous Medical Packaging by Dye (Dye Migration)
Microbial: ASTM F1608 Microbial Ranking of Porous Materials (Exposure Chamber Method)

Time Aging, Accelerated Aging, Stability, and Distribution (ISO 11607 Section 5.5)

Accelerated Aging

One year of accelerated aging is 6 ½ weeks at 55°C using 25°C ambient temperature. Alternate temperatures are available. Contact the Sales Department at sales@nelsonlabs.com for a specific quote.

Real-Time Aging

Clients should store samples for real-time aging in simulated use conditions for temperature, humidity and handling. Nelson Labs offers real-time aging storage options. Contact the Sales Department at sales@nelsonlabs.com for a specific quote.

Test Description	Test Code
Visual inspection (channels only) ASTM F1886	PKG105
Visual inspection (annex and labels) ASTM F1886	PKG106
Accelerated Aging in chamber, per day	PKG115
Thermal profiling (temperature and relative humidity per time point)	PKG118
Real-Time Aging in storage, per day	PKG150
Thermal profiling (temperature and relative humidity per time point)	PKG118
Additional fee if >10 cubic feet, per week	PKG120

Distribution Studies

Transportation of these packages can provide exposure to situations that result in product failure before delivery to its final destination. Simulation tests may include: conditioning, swing arm drop test, compression test, loose load testing, and vibration testing.

Nelson Lbas offers transportation and distribution test services. Contact the Sales Department at sales@nelsonlabs.com for a project quote.

Test Description	Test Code
ASTM D4169 – Performance Testing of Shipping Containers and Systems	PKG125

This test provides a uniform basis of evaluating the ability of shipping units to withstand the distribution environment. This is accomplished by subjecting them to a test plan consisting of a sequence of anticipated hazard elements encountered in various distribution cycles. This practice is not intended to supplant material specifications or existing pre-shipment test procedures.

ISTA 3A – General Simulation Performance Test	PKG130

This procedure is a general simulation test for individual packaged-products shipped through a parcel delivery system. The test is appropriate for four different types of packages commonly distributed as individual packages, either by air or ground.

Thermal Cycling	PKG140
Preconditioning Fee (Applies to each study denoted with **)	PKG720

Strength Tests

ISO 11607 Section 5.1.9

Test Description	Test Code
Packaging: Burst Test, ASTM F1140 - per pouch	PKG215**
1-11 samples, each	
12+ samples, each	
Packaging: Seal peel test (pouches), ASTM F88 – prep & pull, one side, per pouch	PKG230**
1-11 samples, each	
12-49 samples, each	
50+ samples, each	
Packaging: Seal peel test (trays), ASTM F88, prep & pull, one side, per package	PKG240**
1-11 samples, each	
12-49 samples, each	
50+ samples, each	

Integrity Tests

ISO 11607 Section 6.3.2 – There is a test set up fee plus cost of test, per study

Test Description	Test Code
Dye migration test for packaging, ASTM F1929 – per pouch	PKG250**
Bubble emission test for packaging, ASTM F2096 – per pouch	PKG260

Microbial Barrier Tests
ISO 11607 Section 5.2

Whole package integrity (microbial aerosol challenge for packaging)

This test is intended to challenge the whole package in order to determine package integrity of a finished product package. Chamber size is 3 cubic feet with a single layer of product, configured for appropriate challenge flow. The test includes the whole package microbial challenge, subsequent sterility testing on the packaged product to determine penetration of the indicator organism used, test controls, digital pictures of chamber testing, and all protocol & test report fees. The digital pictures will be a visual representation of the sample distribution in the chamber.

Test Description	Test Code
Initial chamber run	PKG315
Each additional chamber run (same set up to 60)	PKG320
Each additional sterility unit (for >60 units per set)	PKG330
Microbial ranking (exposure chamber method), ASTM F1608	
Per chamber run (4 samples)	PKG350
Aerosol filtration for porous material, ASTM F2638	
Includes testing up to 5 flow rates per set	
Set up and initial sample set (5)	PKG360
additional samples, each	PKG365
Nonporous flexible barrier material resistance to the passage of air, ASTM F2981	
Recommended sample size 3	PKG200
Determination of air permeance and air resistance, ISO 5636 Part 5: Gurley	
Recommended sample size 10	PKG270

Packaging Tests – Pharmaceutical

Test Description	Test Code
Container closure/integrity	
PDA TR 27. FDA Docket 980-0021	
Bacterial immersion	PKG410
Bacterial immersion sensivity	PKG411
Dye immersion with UV/Vis analysis and limit of detection (LOD), each	PKG420
Dye immersion with visual analysis only, each	PKG430
Dye immersion test for autoinjectors	
Dye immersion test sample manipulation (shake/immerse/etc.), per hour	PKG446
Mass extraction for pharmaceutical vials	PKG510/520

Sterilant Penetration and Shelf Life Studies

Sterilant penetration and shelf life studies should always include a predicate device that has a current 510(k) approval. Without justifiable reason predicate testing should always be included. Contact the Sales Department at sales@nelsonlabs.com for a quote on your project.

Test Description	Test Code
Steam penetration studies	SPV110-135
Ethylene oxide penetration studies	SPV210-235
Ethylene oxide residual for sterilant penetration studies	SPV240-245
STERRAD® penetration studies	SPV310-335

Event Related Sterility Assurance

General testing is per material type, 30 packs and 8 sites with environmental counts.

Test Description	Test Code
30 days up to 365 days or custom intervals, no predicate	ERS110-150
30 days up to 365 days or custom interval, with predicate (recommended)	ERS210-250

Product Validation and Lot Release Testing

Bioburden

ANSI/AAMI/ISO 11737, ISO 11135, EN 1174

For products that are consumed in testing (e.g. powders, gels, liquids), please include at least one additional sample for a positive control on all bioburden tests.

Bioburden Recovery Efficiency

Recovery efficiency is an important factor in calculating total bioburden. Nelson Laboratories recommends a minimum of 3 units for recovery efficiency validation tests. Consult with lab on when to perform recovery studies should be performed.

Test Description	Test Code
Bioburden – exhaustive rinse method, per unit	BIO910
Bioburden – inoculated product method, per additional unit	BIO920
Bioburden – recovery qualification with multiple organisms, per unit	BIO930
Bioburden – Pooling fee for small/medium products, per pooled unit *Pooling = There is are Initial unit test fees*	BIO710
Bioburden – Packaging pooling fee, per pooled unit w/ concurrent product test	BIO715
Bioburden – Sample item portion or preparation fee, per hour (small/medium product)	BIO720
Bioburden – Method development, per hour	BIO750
Bioburden – Most Probably Number (MPN) method, per unit for device or solution	BIO815
Bioburden – Most Probably Number (MPN) method, per unit for tissue	BTS815

Additional reads may be requested for an extra fee.

Bioburden – One Category

Test Codes	
BIO110	Aerobic bacteria only
BIO120	Anaerobic bacteria only
BIO130	Fungi only
BIO140	Spores only

Bioburden – Two Categories

Test Codes	
BIO210	Aerobic & anaerobic bacteria
BIO220	Aerobic bacteria & fungi
BIO230	Aerobic bacteria & spores

Bioburden – Three Categories

Test	
BIO310	Aerobic & anaerobic bacteria, and fungi
BIO320	Aerobic bacteria, spores and fungi

Bioburden – Four Categories

Test	
BIO410	Aerobic & anaerobic bacteria, spores and fungi

Bioburden (Tissue) – One Category

Test	
BTS120	Anaerobic bacteria only
BTS130	Fungi only
BTS140	Spores only

Bioburden (Tissue) – Two Categories

Test	
BTS210	Aerobic & anaerobic bacteria
BTS220	Aerobic bacteria & fungi
BTS230	Aerobic bacteria & spores

Bioburden (Tissue) – Three Categories

Test	
BTS310	Aerobic & anaerobic bacteria, and fungi
BTS320	Aerobic bacteria, spores and fungi

Bioburden (Tissue) – Four Categories

Test	
BTS410	Aerobic & anaerobic bacteria, spores and fungi

For test options on radiation sterilization (validations and dose audits) See page 16

Product Sterility Tests

USP 71, USP 161, USP 797 EP 2.6.1, JP14 54, ANSI/AAMI/ISO 1137-2 – 2006, AAMI TIR 33

Large or complex devices may require a product-specific quote.

Sterility Suitability

Bacteriostasis and fungistasis (B/F) testing is an essential part of sterility testing and is a USP requirement. All products being tested for sterility should be initially validated with a B/F test. USP is the default method unless specified.

Test Description	Test Code
Suitability test for USP <71> Sterility – Bacteriostasis / Fungistasis	
USP method (filtration): Two media types, 6 organisms (USP/EP/JP)	BFS110
USP method (standard): Two media types, 6 organisms (USP/EP/JP)	BFS120
Bacteriostasis/Fungistasis requiring neutralization medium	BFS125
Bacteriostasis/Fungistasis with Growth Promotion, up to 6 organisms	BFS126
Isolator facility: Two media types, 6 organisms (USP/EP/JP)	BFS130
AAMI method: One medium type, 3 organisms	BFS140
Sterility B/F Validation: (Tissue) w/ 6 org.	BFS145
Sterility B/F Validation: Non-Standard Organism Culture and Maintenance, per organism	BFS150
Sterility B/F Validation for Re-Challenge Test: per organism	BFS160
Package validation for isolator sterility test	
Required once per product/package	PSI701
Sterility test of filter systems – cleanroom test includes sterile set up and supplies	
<2L PEPT flush and assay, per filter	PSC830
>2L PEPT flush and assay, per filter	PSC831

Two reads are included in sterility test prices. Additional daily reads may be requested for an additional fee.
Isolator tests requiring more than one sterilization run will incur additional charges.
Tests utilizing EMD Millipore SteriTest™ canisters include one canister per set tested; ***each additional canister billed as incurred****.*

Cleanroom Facility

Class 100, ISO Class 5

Immersion	Immersion	Filtration
Test Code PSC110	**Test Code PSC120**	**Test Codes PSC155**
<1L media volume	>1L media volume	Closed Membrane SteriTest

Isolator Facility

Immersion	Filtration
Test Code PSI110	**Test Code PSI150**
<1L media volume	Closed Membrane SteriTest

If sample amounts for sterility tests are different than above, please contact the Sales Department at sales@nelsonlabs.com

Bacterial Endotoxin Test
USP 85, USP 161, USP 797, AAMI ST72:2002, EP 2.6.14

BET Validation testing (Bacterial Endotoxin/Pyrogen):

- The first three lot release reports constitute a validation for this test method.
- A device test generally represents 3 to 10 devices pooled for extraction, pooling fee applies.
- Additional fees apply to non-standard materials, extensive sample manipulation, and additional dilutions.
- Minimum order fee applies for BET services

Test Description	Test Code
Kinetic Turbidimetric method	
Device immersion, device flush, or liquid/powder (routine 24 – 48 hour results), per test	LAL110
Expedited Kinetic methods (same-day results), per test	LAL610
Water sample, per test	LAL140
Kinetic Chromogenic method, per test	LAL150
Suitability Assay (sample prep, 5 dilutions)	LAL155
Gel Clot method, per test	LAL210

Water samples for endotoxin tests
Water samples should be collected into polystyrene tubes that are pyrogen-free or low pyrogen containers. Normally 5 mL volumes are sufficient. Samples should be shipped cold to prevent growth.

To order BET sampling bottles for proper liquid sample collection See page 40

Particulate Analysis

Particulates: Automatic Counter Method (HIAC ROYCO) – USP 788

Test Description	Test Code
Particulates: Automatic counter method (devices)	PAR110
Product w/ non-standard extraction or preparation, each	PAR115
Particulates: Automatic counter method (solutions)	PAR120

Particulates: Microscopic Method – USP 788

Test Description	Test Code
Particulates: Microscopic method	
Devices, each	PAR210
Solutions, each	PAR220
Particulate microscopic photographs, per sample	PAR215
Product w/ non-standard extraction or preparation, each	PAR225
Particulates: Recovery Validation Study	
Device or Solution, each	PAR750

Particulates: Other methods

Test Description	Test Code
Particulates: ISO protocols	
USP <789> Opthalmic solution	PAR140
USP <787> Theraputic protein injection	PAR150/155
ISO 14708/ EN 45502, particulate analysis (active implantables)	PAR320
ISO 1135-4 for devices, per 10 devices (infusion sets)	PAR330
ISO 8536-4 for devices, per 10 devices (infusion sets)	PAR335

If non-standard sample preparation or additional extractions are required for particulates a separate quote should be requested.

Microbial Identification

Which identification system is right for your isolate?
There are several options available for organism identification at Nelson Labs. Choosing the right system depends on the type of information you need and the type of organism.

Organism identifications USP 71, ISO 11737:

Gram Stain – Stain with colony and microscopic morphology
MicroSeq®Genetic ID – DNA sequencing and MicroSeq® library search
Correlation of Organisms – Visual correlation of colony morphology

Volume price breaks are available for organism identifications. Please consult Sales at sales@nelsonlabs.com.

MicroSeq® Genetic Organism Identification

Available for both bacterial and fungal organisms.

Test Description	Test Code
MicroSeq® Genetic Organism Identification w/ Gram Stain - **mixed cultures**	IDG105
1-10 isolates, each	
11+ isolates, each	
Pricing is per isolate.	
MicroSeq® Genetic Organism Identification w/ Gram Stain – **pure cultures**	
1 business day service – per isolate	IDG200
3 business day service – per isolate	IDG205
5 business day service – per isolate	IDG215
Pricing is per isolate.	
Guaranteed business day turnaround time service.	

NOTE: Organisms submitted for identification should bein the form of colonies on a plate of agar or other growth media. Other types of samples (e.g. liquid cultures, sterility positives, biological indicators, etc.) will require a subculture fee as described below.

Other Organism Identification Methods

Test Description	Test Code
Mold Identifications – Classical Method	
Classic morphological to genus level, per isolate	IDS210
Microscopic and morphological w/digital picture, per isolate	IDS220
Note: For mold ientifications, it is highly recommended to use the Genetic Organism Identification above	
Gram stain	
Per stain	IDS510
Preparation and Culturing	
Subculture fee, per sample	IDS710
(Required for liquid cultures, sterility positives, biological indicators, etc.)	
Isolate preparation, per isolate or culture	IDS720

Microbiological Analysis

USP <61> Harmonized Microbial Enumeration

The harmonized USP <61> section describes the microbial enumeration tests. This portion of the USP outlines new plate count procedures for bacteria, fungi, and yeasts.

USP <62> Harmonized Absence of Specified Organisms

The harmonized USP <62> describes requirements for growth and recovery of specific organisms which include: Bile-tolerant Gram negative bacteria, *Escherichia coli*, *Salmonella*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Clostridium*, *Candida albicans*.

For both USP <61> and <62> tests the pharmacopeia requires that a one-time validation (suitability test) be performed prior to routine testing. Contact the Sales Department at sales@nelsonlabs.com for more information.

*** Products requiring extensive preparation / manipulation prior to testing or extensive time for testing may incur additional fees.*

Test Description	Test Code
Suitability test for USP <61>	
Suitability test, required once per product, per dilution with < 1 hr preparation	MEP115
Suitability retest fee, per organism	MEP120
Suitability test for USP <62>	
Suitability test, required once per product, per dilution – per organism	MEP110
Routine Test for USP <61>	
Total Aerobic Microbial Count (TAMC) or Total Yeasts and Molds Count (TYMC)	
USP <61> - TAMC and TYMC	MEP250
1-5 samples, each	
6 + samples, each	
USP <61> - TAMC or TYMC (one method only)	MEP265
Routine Test for USP <62>	
USP <62> - per organism	MEP235
Routine Test for USP <61/62>, per sample	
Total Aerobic Microbial Count (TAMC) or Total Yeasts and Molds Count (TYMC)	
Transdermal patches	MEP215
TAMC and TYMC, 1 org. screen	MEP310
TAMC and TYMC, 2 org. screen	MEP320
TAMC and TYMC, 3 org. screen	MEP330
TAMC and TYMC, 4 org. screen	MEP340
TAMC and TYMC, 5 org. screen	MEP350
TAMC and TYMC, 6 org. screen	MEP360
TAMC and TYMC, 7 org. screen	MEP370

USP Plate Count Validation, Routine Plate Counts

Test Description	Test Code	
Standard plate counts – filtration, spread or pour plate method		
NOTE: Standard plate count is not intended to determine the titer of individual types of microorganisms within a product.		
Aerobic bacteria only	SPC110	
1-5 samples		
6-10 samples		
Aerobic bacteria & fungi	SPC120	
1-5 samples		
6+ samples		
Fungal only (molds and yeast)	SPC130	
1-5 samples		
6-10 samples		
Anaerobic bacteria	SPC140	
1-5 samples		
6+ samples		
Optional: Additional plated dilutions (plate counts)	SPC701	
Standard plate counts – membrane filtration (environmental water samples)		See page 31
Total coliform counts – membrane filtration		See page 31

Pharmaceutical Services

Bioequivalence Studies

Bioequivalence Studies are i*n vitro* microbial kill rate validations. Sample retention may be required.
Consultation is required prior to study initiation for study design, protocol development and product assessment.

Filter Sterilization Validations, ASTM

Consultation required to ensure proper test, challenge organism or chemical and process run time.
Please contact the Sales Department at sales@nelsonlabs.com for specific product and method/test requirements.

Test Description	Test Code
Sterilization filtration validations, PDA Technical Report 26	FSV210
Filter extractables testing	
NVR and FTIR analysis only	FSV220
Contact Nelson Laboratories for other extractables analysis	
Integrity test value validation, filters	
Product wet integrity validation	FSV230
Compatibility testing, filters	
Product wet integrity validation	FSV240

Filter Testing

Test Description	Test Code
***Brevundimonas diminuta* challenge**	
10” cartridge filter, each	FSV110
142 mm disk, each	FSV115
47 mm disk, each	FSV120
IV/syringe filters, each filter	FSV125
IV/syringe filters, additional filters, concurrent test	FSV126
Filter Prep: Hydrophobic filters requiring wetting (IPA added), additional charge	FSV720
Bubble point/integrity test/diffusion, filters	
Each filter	FSV130
***Serratia marcescens* challenge, filters**	
10” cartridge filter, each	FSV140
Other organism challenge, filters	
Each filter	FSV170

Antimicrobial Preservative Efficacy (APE)

NLI follows the USP APE protocol and uses five organisms which represent a broad spectrum of species (gram positive, gram negative, yeast, mold, etc.). USP requires minimum testing of one product replicate, plated in duplicate. To minimize variability in plate count estimates, Nelson Laboratories performs plating in triplicate.
Additional fees may apply if initial test methods are not appropriate and further validation testing is required

Test Description	Test Code
United States Pharmacopeia, USP <51> protocol APE (4 time points)	
Qualification of neutralization for plate count method	APE105
Five organisms (one product replicate, plated in triplicate)	APE110
Five organisms (two product replicates, each plated in triplicate)	APE115
Additional organisms, each	APE120
USP-EP protocol APE (7 time points)	
Qualification of neutralization for plate count method	APE205
Five organisms (one product replicate, plated in triplicate)	APE210
Five organisms (two product replicates, each plated in triplicate)	APE215
Additional organisms, each	APE220

Antibiotic Potency Assay

The organism depends on the antibiotic type, per USP specification. Nelson Laboratories has validated Gentamicin and Vancomycin for antibiotic potency assay testing. Other requests require a price quote and a validation before tests are submitted.

Test Description	Test Code
Antibiotic potency assay, USP 81	
First sample	APA110
Each additional sample (same set)	APA115

Tissue Services

BIOLOGICAL TESTING (non-clinical)
Nelson Labs offers a variety of tests to screen harvested and processed tissue for bacterial content, dependent on the tissue type and application. In addition we offer a full range of services for facilities, process validation, routine screening and assessment of sterilization using radiation. We also offer technical advisory services for these services and establishment of acceptance criteria.

CLINICAL TESTING
All tissue samples should be screened for viral pathogens and certified to be blood borne pathogen-free prior to shipping samples to Nelson Labs for analysis. Please contact the Sales Department at sales@nelsonlabs.com for more information.

Facilities

Monitoring the processing, storage and handling of tissues is important. Common environmental contributors to contamination include equipment, water systems, staff processing tissue, and adequacy of line clearance disinfection or cleaning between donor processing. Nelson can assist with establishing initial alert and action levels, validation of equipment and water systems, and assessment of cleaning practices.

Routine Tissue Screening

Routine screening depends on tissue and process type. Each processor is responsible to determine the appropriate tests and acceptance criteria for their unique tissue processes. Nelson can assist with establishment of acceptable limits and routine tests to monitor for objectionable organisms, non-tissue particulate matter, endotoxin and moisture content.

Product Validation

Environmental and Water System Monitoring

Environmental Water Samples - Standard Plate Count By Membrane Filtration

Environmental report fee applies per order plus cost of test

Water samples collected for environmental water analysis should be labled with the sample ID, collection date/time, and shipped to the lab in cool pack containers (but not frozen) to minimize microbial change. Additional dilutions will incur additional charges. If applicable, samples received in the laboratory after the requested hold time will be tested, noting the exceeded hold time in the final report.

Test Description	Test Code
Membrane Filtration, Aerobic bacteria only	ENV210
Membrane Filtration, Fungal (sel. plates)	ENV230
Membrane Filtration, Aerobic and Fungal (sel. plates)	ENV240
Membrane Filtration, Total Coliforms, 2 replicates	MCC130

USP/EP Water Tests

Nelson Labs offers a full range of USP/EP compendia water tests. The current USP and EP both have multiple categories and requirements for different types of water. Contact the Sales Department at sales@nelsonlabs.com for an abbreviated test set or specific water category quote.

If your product requires testing for Sterility, LAL or Particulates, please send a separate sample/container for these tests to preserve sample integrity.

Test Description	Test Code
Includes compendia testing and summary report	
USP Water Analysis - Purified water study: *TOC/Conductivity/pH* 1-10 samples, each 11+ samples, each *Individual USP water monograph tests available. Call for quote.*	PWA305
USP Water Analysis - Water for injection, monograph 1-10 samples, each 11+ samples, each *Individual USP water monograph tests available. Call for quote.*	PWA320
EP Water Analysis - Sterilized water for injection, monograph	PWA500
USP/EP Purified Water Test: *TOC/Conductivity/EP nitrates/heavy metals*	PWA120
USP/EP Purified Water Test: *EP nitrates and heavy metals only*	PWA125

Environmental Monitoring – Incubation and enumeration

Environmental report fee applies per study plus cost of test

Air and surface sample analysis: Slit-to-Agar, Andersen, HYCON (RCS), membrane cassettes, fallout plates, surface sampler.

Test Description	Test Code
Aerobic bacteria & fungal counts, single plate w/ extended incubation	ENV110
Swab samples	
Swab Samples, Aerobic bacterial counts only	ENV120
Swab Samples, Fungal counts only	ENV125
Swab Samples, Aerobic Bacteria & Fungi	ENV130

Disinfectant and Antimicrobial Efficacy Studies

The effectiveness of sanitizers and disinfectants used in cleaning and disinfectant regimens for manufacturing cleanrooms or controlled environments should be confirmed with validation data. It is an area of increasing concern for both manufacturers and regulatory agencies to show that these agents are effective against the organisms that may be present in the aseptic processing or controlled production environment.

Disinfectant efficacy must be established in order for a product to have a general label claim as a sanitizer or disinfectant or for specific claims against organisms. These products include household and industry disinfectants, sporicides, fungicides, and hand sanitizers.

The disinfectant testing at Nelson Labs follow many of the guidelines established in USP general chapter 1072, DIS/TSS-10, AOAC Chapter 6, ASTM E2614, ASTM E2315. We are highly experienced in performing general disinfectant efficacy tests with a large variety of organisms and products.

Disinfectant Studies

Test Description	Test Code
Time kill test, ASTM E2315 (modified)	
Per variable or product dependency	DIS115
Disinfectant surface efficacy, USP <1072>, DIS/TSS-10 (coupon test)	
Per variable or product dependency	DCT110
Disinfection, AOAC tests for EPA/FDA submissions on liquid or sterilant claims	
Use dilution test	DIS310
Fungicidal test	DIS410
Sporicidal test	DIS510
Germicidal spray test	DIS610
Confirmation testing	DIS710
ISO-FDA regimen test for disinfection of contact lens solutions	DIS850
ISO-FDA stand-alone test for disinfection of contact lens solutions	DIS860
MIS105 minimum inhibition concentration (MIC) study	MIS105
MIS110 minimum lethal concentration (MLC) study	MIS110

Antimicrobial Studies

The antimicrobial tests were developed primarily to determine the percent or log reduction of a target organism when exposed to an antimicrobial that was placed in or on a textile or material. The method can also be modified to include different materials, time points and test organisms. Please contact the Sales Department at sales@nelsonlabs.com for specific product requirements.

Test Description	Test Code
Time kill test, ASTM E2315 for antimicrobial efficacy of liquids	
Per variable or product dependency	DIS115
Antimicrobials on plastics and other non-porous surfaces	
ASTM E2149, non-leaching antimicrobials under dynamic contact	AME210
ISO 22196/JIS Z 2801, plastics and other non-porous surfaces	AME210
ASTM E2180, agar slurry for polymeric or hydrophobic materials	AME210
Antimicrobials on devices	AME410
Antimicrobials on textiles	
AATCC Method 100	AME210
AATCC Method 147, Parallel Streak	AME310
Zone of inhibition for liquids or solids	ZHT110
Set up fee, per organism	
Per sample/time point fee	

Disinfectant and Antimicrobial Study Disclaimer: It is the responsibility of the client to contact their FDA/EPA reviewer to confirm the appropriate test plan for their disinfectant or antimicrobial product 510(k) or other regulatory submission. Tests required for EPA submissions are product dependent and the client should consult with the EPA prior to testing.
Important information and requirements for all disinfectant and antimicrobial tests: Additional organisms may be tested upon request. Organisms which require different media for growth and/or neutralization may require additional charges. A **disposal fee** will be added for all chemicals that are not returned to the sponsor which cannot be disposed of in municipal drain systems. **MSDS, or equivalent information, is required for all disinfectant submissions prior to testing.** Please contact the Sales Department at sales@nelsonlabs.com for specific product and method/test requirements.

MEDICAL DEVICE PHARMACEUTICAL TISSUE

Barrier Material Performance Tests

For wovens, nonwovens, and barrier material manufacturers (masks, gowns, gloves), Nelson Laboratories offers a wide range of tests for bacterial and viral filtration efficiency and other barrier qualities in compliance with ASTM F2100, AAMI PB70, EN14683, and other U.S. and international standards.

General Use, Medical Masks, Surgical Masks, Flat Stock Filter Media & Housed Filters

For US submissions, follow testing requirements outlined in ASTM F2100. For CE marking, follow testing requirements outlined in EN14683. For CE marking submissions, additional tests may be required for surgical face masks.

If >20 samples per material type, please contact Sales for a custom quote.

Test Description	Test Code
Bacterial Filtration Efficiency (BFE) only Per sample	BFE 101
Bacterial Filtration Efficiency, (BFE) with differential pressure Per sample	BFE 110
Differential pressure only Per sample	DPT 110
Flammability test – 16 CFR Part 1610 Per material type (up to 10 replicates may be required)	FTS 101
Particle Filtration Efficiency: Latex particle challenge Per sample	PFE 115
Synthetic blood fluid penetration resistance for face masks Set of 32 masks, per set	SBP 210
Microbial cleanliness for face masks	
One mask type, set of 5	MCM 100
Additional masks, same mask type	MCM 105

Tests For Face Masks With Alternate Organisms

Test Description	Test Code
Virus Filtration Efficiency (VFE) w/ Bacteriophage 1-4 samples, each 5 or more samples, each	VFE 110

Mask Certification Program

Face mask performance summary letter available for a fee by our Consulting group.
Please contact the Sales Department at sales@nelsonlabs.com for more information.

Alternate Filter & Mask Filtration Efficiency Tests

Test Description	Test Code
Filtration Efficiency: Sodium chloride (NaCl) aerosol challenge	SCL110
For flat sheet media and filters	
Load, conditioning, or sample preparation (for first time test), per sample	
Filtration Efficiency: Dioctyl phthalate (DOP)	DOP110
For flat sheet media and filters	
Load, conditioning, or sample preparation (for first time test)	

Tests for Filter Systems and Housed Filters

BFE/VFE increased challenge test minimum 3 samples required.

Test Description	Test Code
Bacterial Filtration Efficiency (BFE) Increased Challenge for Housed Filters	BFE125
1-4 samples	
5+ samples	
Virus Filtration Efficiency (VFE) Increased Challenge for Housed Filters	VFE125
1-4 samples	
5+ samples	
Respiratory Breathing Circuit Filter Efficiency – BS EN ISO 23328-1	RBC110
Per sample	
Conditioning of filters, each	RBC701

NIOSH 95 and Respirator Pre-Certification Tests

Nelson Laboratories provides pre-qualification tests to support NIOSH submission for masks/respirators.
Contact the Sales Department at sales@nelsonlabs.com for a specific quote on your NIOSH project.

Test Description	Test Code
NIOSH Respirator Certification: 42 CFR Part 84	
NIOSH respirator certification: Sodium Chloride (NaCl) – 42 CFR Part 84.181	NRC110
NIOSH respirator certification: Dioctyl Phthalate (DOP) – 42 CFR Part 84.181	NRC115
NIOSH respirator certification: inhalation/exhalation – 42 CFR Part 84.180	NRC120
NIOSH respirator certification: valve leak test – 42 CFR Part 84.182	NRC125

Surgical Drapes and Gowns

AAMI PB70 – Liquid Barrier Performance
ISO 16603 and ISO 16604- Gowns/Drapes

The requirements for AAMI PB70 are to follow the ASTM, AATCC, and other standards issued to classify surgical drapes and gowns. The number of test sites and product classification determine the type of test to be performed. The requirements for ISO 16603 (Synthetic Blood Penetration) and 16604 (Viral Penetration) are similar to the ASTM standards; however, there are specific requirements for time points and classification.

Based on the guidance document compatibility assessment should occur for each material and for each site, if different.

Test Description *If >20 samples per material type, please contact Sales for a project-specific quote* **Pricing is per material per sample for each test site**	**Test Code** **AAMI PB70**	 **ISO 16603** **ISO 16604**
Hydrostatic pressure test, INDA, AATCC 127, ISO Per sample, each site	HPT110	
Spray impact test, INDA, AATCC 42, ISO Per sample, each site	SIT110	
Synthetic blood penetration, ASTM F1670 or ISO 16603 Set up and preparation (cutting) Per sample, each site	SBP110	SBP120
Viral penetration, ASTM F1671 or ISO 16604 Set up and preparation (cutting) Compatibility test, per material type Penetration test 1-9 samples, each site 10+ samples, each site	VPT110	VPT120

EN 13795 - Gowns/Drapes

For CE marking submissions, additional tests may be required for surgical gowns and drapes. Manufacturers should consider the microbial cleanliness of the gown following EN ISO 11737-1 using the bioburden test method as described on page 24.

Contact the Sales Department at sales@nelsonlabs.com for a quote on testing in compliance with these standards.

Test Description	Test Code
Resistance to Liquid Penetration, EN 20811 Per sample, each	HPT110
Resistance to Wet Bacterial Penetration, ISO 22610 Per product (set of 5)	HPT210
Resistance to Dry Microbial Penetration, ISO 22612 Per product (set of 5)	HPT220
Evaluation of Bursting Strength in Dry State, ISO 13938-1 Per product (set of 5)	HPT230
Evaluation of Bursting Strength in Wet State, ISO 13938-1 Per product (set of 5)	HPT235
Tensile Test (Dry), EN 29073-3 Minimum per product type/lot is I0 samples – sponsor provides directionality, each	PHY150
Tensile Test (Wet), EN 29073-3 Minimum per product type/lot is I0 samples – sponsor provides directionality, each	PHY155
Particle shed analysis or linting: Gelbo flex test , ISO 9073-10 Per sample (first 10 replicates included, five samples each side)	PSA120

Additional Tests for Drapes and Gowns

Test Description	Test Code
Particle shed analysis: Helmke drum particle counts, IEST RP-CC003.4 Per sample, each	PSA115

General Physical Tests

Test Description	Test Code
Basis weight (weight uniformity), ASTM D3776 Sample quantity 1 to 11 samples	WUT101

Glove Tests

Test Description	Test Code
Glove Test: Evaluation of Leakage in Gloves Sample quantity based on lot size - contact lab for sampling plan according to ISO 2859	GLV220
Glove tensile test ASTM D3578, D3577, D5250, D6319; unaged Each sample 13 samples per lot	GLV110
Glove tensile test ASTM D3578, D3577, D5250, D6319; aged Each sample 13 samples per lot	GLV115
Glove physical dimensions ASTM D3578 Each sample 13 samples per lot	GLV120
Glove test, residual powder, ASTM D6124 method; unaged (5 powder-free gloves or 2 powdered gloves), per test	GLV130
Glove test, residual powder, ASTM D6124 method; aged (5 powder-free gloves or 2 powdered gloves), per test	GLV135
Glove puncture resistance, ASTM F1342 Each sample (minimum per product type/lot is 12 samples)	GLV140
Glove test: Whole glove viral barrier study Per sample	GLV410
Glove viral penetration, ASTM F1671 Set up and preparation (cutting), per set of 32 Compatibility test, once per material 1-9 specimens to test, each 10-19 specimens to test, each	VPT110
Latex ELISA for Antigenic Protein (LEAP©) test for gloves* **Nelson Laboratories,LLC offers this test on a subcontract or referral basis.*	

Tear Resistance

Test Description	Test Code
Tear resistance of fabrics, ASTM D5587	
Each sample	PHY220
Minimum per product type/lot is 10 samples – sponsor provides directionality	
Tear resistance of rubber and elastomerics	
Each sample	PHY225
Minimum per product type/lot is 10 samples	

Tensile Tests

Test Description	Test Code
General tensile	PHY110
Elastomeric materials, ASTM D882, D638	
Each sample	PHY115
Minimum per product type/lot is 10 samples – sponsor provides directionality	
Disposable fabric (Grab Test), ASTM D5034, D5035	
Each sample	PHY120
Minimum per product type/lot is 13 samples – sponsor provides directionality	
Tensile Test (Wet or Dry), EN 29073-3	See page 36
Heat seal (seal peal) pre cut & labeled	See page 22
Special physical test projects	
Contact Nelson Laboratories to discuss specific product and test requirements	PHY901

General Analytical Tests

Gas Chromatography (GC)

Test Description	Test Code
Alcohol determination	
Methanol or Ethanol, each	GCS110
Isopropyl alcohol (IPA)	
Per sample	GCS130
Solvent purity: IPA, MEK, MC, THF, CH	
Per sample	GCS150
Order sampling bottles	See page 40

Other Analytical Tests

Test Description	Test Code
Total organic carbon (TOC) – O.I., USP 643, EP 2.2.44	
TOC dilution or preparation fee, each	TOC701
TOC sample analysis (water or liquid), each	TOC101
TOC sample analysis (device extractions), each	TOC105
Volume price breaks available, please consult Sales.	
Conductivity, USP 645	
Per sample	CTA101
Glutaraldehyde Determination (UV/Vis)	
Quantitation	CTA310
Analysis, per sample	CTA320
Oxidizable substances	
Per sample	CHM120
pH analysis	
Per sample	CHM110
pH reported with other test	
Per sample	CHM115
Protein assays	
Micro BCA protein assay, each	PAB110
Micro BCA protein assay with device extraction, each	PAB115
Sodium or chloride identification	
Per sample	SCA101
Sodium or chloride assay	
Up to 3 titrations per sample, each sample	SCA110
Specific gravity	
Per sample	SGA101
UV/visible spectrophotometer scan	UVV110
Quantitation and first sample	
Each additional sample, UV/visible only	

Water Content Determination in Product

Test Description	Test Code
Moisture residue (gravimetric)	
Per sample	MRT101
Water content by Karl Fischer titration, USP 921 method 1C	
Normal reagents (3 replicates)	KFT110
Ketone reagents, 1st sample	KFT115
Ketone reagents, each additional sample	KFT120

Test Supplies

You may order BIs, PCDs, or sampling supplies by calling Nelson Laboratories at +1 (801) 290-7500

Minimum order fee BIT800 applies to all BI orders.

Biological Indicators (BIs) to Purchase

Description	Order Code
Biological indicators, single species (BI only)	
STERIS® *Bacillus atrophaeus* and *Geobacillus stearothermophilus*, each	BIT802

Sampling Bottles

Description	Order Code
Bottles for TOC sampling, pack of 10	ENV860
Bottles for Conductivity sampling, pack of 10	ENV870
Polystyrene bottles for LAL sampling, pack 25	ENV880
Bottle with thiosulfate pill (chlorinated water), pack of 10	ENV890
Bottle w/o thiosulfate pill (non-chlorinated water), pack of 10	ENV895

Commercially Prepared Media

Description	Order Code
Agar plates or liquid media	Varies

Growth Promotion Verification of Commercially Prepared Media

Test Description	Test Code
Growth Promotion: Agar Media	
RODAC® or Agar Plate growth promotion, each *Typically includes up to 5 organisms tested in duplicate*	MIC210
Airstrips or Hygicult ® growth promotion, each *Typically includes up to 5 organisms tested in duplicate*	MIC220
Sterility Media, USP growth promotion, per lot or product set *Typically tested in duplicate, 3 soy and 3 thio plus negative controls*	MIC230
Additional replicates, each	MIC235

General Fees and Policies

Visit www.nelsonlabs.com/our-company/general-pricing-and-fee-policies/

INDEX OF TEST SERVICES

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