GUIDE TO SAMPLE REQUIREMENTS | PAGE 1

This chart is designed as a convenient quick guide for some of our most commonly ordered tests (and does not list all available tests).

Sample requirements represent the total number of extracts / replicates needed.

	PRODUCT NAME	SAMPLE VOLUME REQUIRED	
ANTIMICROBIAL			
110700.1	AATCC Method 30, Part III — Standard Method — Per Sample	Four (4) 38 mm discs	
110710.1	AATCC Method 100 — Standard method, single replicate — Per Sample	Four (4) sets of 48 mm discs	
110710.2	AATCC Method 100 — Standard method, duplicate — Per Sample	Eight (8) sets of 48 mm discs	
110710.3	AATCC Method 100 — Standard method, triplicate — Per Sample	Twelve (12) sets of 48 mm discs	
110710.F	AATCC Method 100 — Additional time point / organism — Per Sample	One (1) set of 48 mm discs	
110720.1	AATCC Method 147 — Standard method — Per Sample	Two (2) 25 mm x 50 mm pieces	
110730.1	AATCC Method 174, Part 1 — Standard method — Per Sample	Four (4) 25 mm x 50 mm pieces	
110740.1	AATCC Method 174, Part 2 — Standard method, single replicate — Per Sample	Four (4) 48 mm discs	
110740.F	AATCC Method 174, Part 2 — Additional time point / organism — Per Sample	One (1) 48 mm disc	
110750.1	AATCC Method 174, Part 3 — Standard method — Per Sample	Two (2) 38 mm discs	
110760.1	ASTM G—21 — Standard method — Per Sample	Triplicate 50 mm x 50 mm pieces	
110775.1	ASTM E—2180 — Standard method, triplicate — Per Sample	12 untreated & 6 treated 30 mm x 30 mm pieces	
110775.F	ASTM E—2180 — Additional time point/organism, triplicate — Per Sample	3 treated 30 mm x 30 mm or 6 untreated	
110775.F1	ASTM E—2180 — Additional replicate — Per replicate/timepoint/organism	1 treated 30 mm x 30 mm	
110780.1	ASTM E—2149 Dynamic Contact — Standard method, single replicate — Per Sample	1.0 grams — paper, fabric, powder / surface are 4 in. square	
110780.F	ASTM E—2149 Dynamic Contact — Additional time point / organism — Per Sample	1.0 gram per sample, per time point	
110783.1	ASTM E—2196 Rotating Disk Biofilm Reactor — Standard method, single replicate — Per Sample	Varies	
110783.F	ASTM E—2196 Rotating Disk Biofilm Reactor —Additional time point / organism — Per Sample		
110785.1	ASTM E2471—05 — Standard method, duplicate — Per Sample	Six (6) 25 mm x 38 mm	
110786.1	ASTM E2471—05 — Each Additional Organism — Per Sample	Two (2) 25 mm x 38 mm	
110790.1	Zone of Inhibition — Standard method, single replicate — Per Sample	20 mm x 20 mm	
110790.F	Zone of Inhibition — Additional timepoint / organism — Per Sample	Additional Organism 20 mm x 30 mm	
110796.1	ASTM E—2647 Drip Flow Biofilm Reactor — Standard method, single replicate — Per Sample	Varies	
110796.F	ASTM E—2647 Drip Flow Biofilm Reactor — Additional replicate/time point/organism — Per Sample		
110797.1	ASTM E—2562 CDC Biofilm Reactor — Standard method, single replicate — Per Sample		
110797.F	ASTM E—2562 CDC Biofilm Reactor — Additional replicate/time point/organism — Per Sample		
1625510.1	Microbial Barrier / Strike Through Test — Standard method, single replicate — Per Sample	50 mm x 50 mm	
1625510.F	Microbial Barrier / Strike Through Test — Additional time point / organism — Per Sample	12 untreated & 6 treated 50 mm x 50 mm pieces 3 or 6 untreated 50 mm x 50 mm	
190655.1	JIS Z 2801 — Standard method, triplicate — Per Sample		
190655.F	JIS Z 2801 — Additional time point / organism — Per Sample	Per Additional Organism: - 3 treated 50 mm x 50 mm - 6 untreated 50 mm x 50 mm	Per Additional Time Point (Assumes 2 organisms) - 6 untreated 50 mm x 50 mm - 6 treated 50 mm x 50 mm
190662.1	USP Validation of Microbial Recovery — Single Organism Per Sample	10 mL to make 15 aliquots	
190665.1	USP Antimicrobial Effectiveness — Standard method — Per Sample	10 mL to make 5 aliquots	
190670.1	ISO 22196 — Standard method, triplicate — Per Sample	12 untreated & 6 treated 50 mm x 50 mm / 2 org.	
190670.F	ISO 22196 — Additional time point / organism — Per Sample	Additional Organism - 3 treated 50 mm x 50 mm - 6 untreated 50 mm x 50 mm	Additional Time Point - 3 treated 50 mm x 50 mm - 3 untreated 50 mm x 50 mm

GUIDE TO SAMPLE REQUIREMENTS | PAGE 2

	PRODUCT NAME	SAMPLE VOLUME REQUIRED
B&F		
190104.1	USP Bacteriostasis/Fungistasis — Two media, Membrane Filtration (6 samples per test)	6 sterile product samples
190105.1	USP Bacteriostasis/Fungistasis — Two Media, Immersion (6 samples per test)	
190106.1	Bacteriostasis/Fungistasis — SCDM / One Media, Immersion (3 samples per test)	3 sterile product samples
190107.1	Bacteriostasis/Fungistasis — SCDM / One Media, Membrane Filtration (3 samples per test)	
190111.1	Bacteriostasis/Fungistasis — Immersion — Per Organism / Per Medium	1 sterile product sample, per organism, per medium
190112.1	Bacteriostasis/Fungistasis — Membrane Filtration — Per Organism / Per media	
190410.1	Growth Promotion — Per Organism	1 sample per organism
190411.1	USP <71> Growth Promotion for Liquid Media (3 organisms)	3 samples per media type
190412.1	USP <61> Growth Promotion for Solid Media	5 samples per media type
190412.2	USP <61> Growth Promotion for Liquid Media	
BET/LAL		
130200.1	USP Gel Clot LAL Assay Validation — Per Lot	3 Unique Product Lots Required Lot Size - < 30 Units: 2 sample devices - 31 - 100 Units 3 sample devices - 101 Units > 3% of total lot size, maximum 10 devices
130300.1	USP Gel Clot LAL Dilution Assay	Lot Size - < 30 Units: 2 sample devices - 31 - 100 Units 3 sample devices - 101 Units > 3% of total lot size, maximum 10 devices
130300.F	USP Gel Clot LAL Liquid Assay — Additional Dilution Fee	
130501.1	Kinetic Chromogenic LAL Method — Finished Product Testing (1—10 samples) (Composite)	
130501.2	Kinetic Chromogenic LAL Assay — Finished Product Testing (11—20 samples) — Per Composite	
130501.3	Kinetic Chromogenic LAL Assay — Finished Product Testing (21—30 samples) — Per Composite	
130501.4	Kinetic Chromogenic LAL Assay — Finished Product Testing (1—10 samples) — Per Composite (GLP)	
130501.5	Kinetic Chromogenic LAL Limit Assay — Finished Product Testing, Large/Complex Device	
130510.1	Kinetic Chromogenic LAL Assay — Finished Product Testing on Media Bags	
130601.1	Kinetic Chromogenic LAL Assay — Inhibition/Enhancement	
130701.1	Kinetic Chromogenic LAL Assay — Liquid Test	1 mL minimum volume Sample to be delivered in endotoxin free polystyrene or glass container.
130801.2	Kinetic Turbidimetric LAL Assay — Liquid Test	
131701.2	Kinetic Chromogenic LAL Method — Liquid Test (GMP)	
130801.1	Kinetic Turbidimetric LAL Assay — Finished Product Testing	Lot Size - < 30 Units: 2 sample devices - 31 - 100 Units 3 sample devices - 101 Units > 3% of total lot size, maximum 10 devices
130802.1	Kinetic Turbidimetric LAL Assay — Inhibition/Enhancement Assay	3 lot testing required Lot Size - < 30 Units: 2 sample devices - 31 - 100 Units 3 sample devices - 101 Units > 3% of total lot size, maximum 10 devices
131100.1	USP Gel Clot LAL Limit Assay — Finished Product Testing	Lot Size - < 30 Units: 2 sample devices - 31 - 100 Units 3 sample devices - 101 Units > 3% of total lot size, maximum 10 devices
131501.1	Kinetic Chromogenic LAL Method	
131501.2	Kinetic Chromagenic LAL Method (GMP)	
131601.1	Kinetic Chromogenic LAL Test — Validation	
131701.1	Kinetic Chromogenic LAL — Liquid Test	1 mL minimum volume Sample to be delivered in endotoxin free polystyrene or glass container.
BI		
120100.1	Biological Indicator Self—Contained BI	Spore strips. Client—provided positive control recommended
120100.2	Biological Indicator within Product	
120100.3	Biological Indicator Direct Transfer	
120200.1	USP Biological Indicator: Total Viable Spore Count (Suspension)	Varies
190300.1	USP Biological Indicator: Total Viable Spore Count (Composite of 4 BIs)	

GUIDE TO SAMPLE REQUIREMENTS | PAGE 3

	PRODUCT NAME	SAMPLE VOLUME REQUIRED
BIOBURDEN		
1601000.1	Bioburden — Recovery Efficiency — Repetitive Method (5 extractions per sample) — Per sample	5 non—sterile devices
1601000.2	Bioburden — Recovery Efficiency — Repetitive Method (5 extractions per sample) — Per 2—10 Sample Composite	5 sets per number of composite
1602000.1	Bioburden — Recovery Efficiency — Inoculation Method — Per sample	3 non—sterile devices
1602000.2	Bioburden — Recovery Efficiency — Inoculation Method — Per 2—10 Sample Composite	3 sets per number of composite
1603010.2	Aerobic Bioburden Panel — Aerobic / Fungal / Spore Count — Per 2—10 Sample Composite	10 samples total based on composite number for ANSI/AAMI/ISO methods or may be determined by client specific requirements.
1603010.1	Aerobic Bioburden Panel — Aerobic / Fungal / Spore Count — Per sample	10 samples for ANSI/AAMI/ISO methods or may be determined by client specific requirements.
1604000.1	Fungal Bioburden — Per sample	
1604500.1	Aerobic / Spore / Anaerobic Bioburden — Per sample	
1605000.1	Total Bioburden Panel — Aerobic / Fungi / Spore / Anaerobe Count — Per sample	
1605500.1	Spore Bioburden — Per sample	
1605600.1	Anaerobic Bioburden — Per sample	
1606000.1	Aerobic Bioburden — Per sample	
1607000.1	Aerobic and Fungal Bioburden — Per sample	
1607500.1	Aerobic / Fungi / Anaerobic Bioburden — Per sample	
1608000.1	Aerobic and Spore Bioburden — Per sample	
1608100.1	Aerobic and Anaerobic Count — Per sample	
200039.F	Bioburden — Large Device > 500 mL extract — Per Sample	
CHEMISTRY		
195000.1	EO Residual Panel — EO (Headspace), ECH and EG (Water Extraction) — Per Sample	One (1) sample minimum
195000.10	EO (Headspace Extraction) and EC (Water Extraction) — Per Sample	
195000.11	EO Residual Panel (Water Extraction) — EO, ECH, and EB — Per Sample	
195000.12	EG Analysis (Water Extractions)	
195000.2	EO Residual Panel (Water Extraction) — EO, ECH and EG — Per Sample	
195000.3	EO Water Analysis — Per Sample	
195000.4	ECH Water Extraction — Per Sample	
195000.5	EO Headspace Analysis (1 sample, 2 extractions) — Per Sample	
195000.6	EO Water Additional Extraction — Per Sample	
195000.7	EO and ECH (Water Extraction) — Per Sample	
195000.8	EO/EC Additional Extraction — Per Sample	
195000.9	EC Additional Extraction — Per Sample	
20661.1	Residual Moisture — Gravimetric — Per Sample	Varies
20661.2	Karl Fischer Water Titration — Per Sample	0.1 g
400255.1	Turbidity	50 mL
400260.1	pH — Per Sample	Varies
400276.1	USP<661.1> Physicochemical Tests (Absorbance, Acidity/Alkalinity, TOC) — Per Sample	Varies
400280.1	USP <661> Physicochemical Tests — Plastics — Per Sample	600 cm^2
400280.2	USP <381> Physicochemical Tests — Elastomeric Closures for Injections — Per Sample	150 cm^2
400280.3	USP <381> Physicochemical Test — Elastomeric Closures for Injections + Residue on Evaporation — Per Sample	
400290.1	Protein Assay — Per Sample	10 - 20 mL
400360.1	Total Organic Carbon (TOC) — Per Sample	40 mL in certified TOC vial
400360.2	Conductivity — Per Sample	100 mL in plastic bottle
400360.3	Purified Water or WFI— TOC, Conductivity — Per Sample	40 mL in certified TOC vial 100 mL in plastic bottle
400434.1	Calcium (Residual) — Per Sample	Varies
400540.1	USP Sterile Water for Injection — Per Sample	200 mL Minimum
400545.1	USP <30> Sterile Water for Injection — Per Sample	
400828.1	USP<661.2> Physicochemical Tests (Moieties and Glycol) — Per Sample	100 mL Minimum

GUIDE TO SAMPLE REQUIREMENTS | PAGE 4

	PRODUCT NAME	SAMPLE VOLUME REQUIRED
ENVIRONMENTAL		
1701000.1	Environmental Air and Surface Microbial Count — Per Sample	Varies based on client supplied air or surface sample
170300.1	Water System Microbial Counts 100 mL — Per Sample	100 mL Minimum
170300.2	Water System Microbial Counts 1 mL — Per Sample	1 mL Minimum
170300.3	Water System Microbial Counts & Coliform Counts — Per Sample	200 mL Minimum
170300.4	Water System Microbial Counts & Pseudomonas Counts — Per Sample	
170300.5	Water System Microbial Counts, Coliform & Pseudomonas Counts — Per Sample	300 mL Minimum
170300.6	Water System Coliform Counts — Per Sample	100 mL Minimum
170300.7	Water System Pseudomonas Counts — Per Sample	
170300.8	Water System Coliform & Pseudomonas Counts — Per Sample	200 mL Minimum
MICROBIAL EXAMINATION OF NON STERILE PRODUCTS		
161400.1	USP/EP Microbial Enumeration Test — Per Sample	10 gram / 10 mL
161401.1	USP/EP Specified Microorganisms Test — Per Sample	
161402.1	USP/EP Suitability of Counting Method for Microbial Enumeration — Per Sample	
161403.1	USP/EP Suitability of Test Method for Specified Microorganisms — Per Sample	20 gram / 20 mL
PACKAGE		
30778.1	Compression Test [ASTM D642]	One or more shippers
30779.1	Drop Testing [ASTM D5276]	
38052.F	ASTM D4169 — Distribution Simulation Test — Set—up	
38057.F	ISTA Series — Distribution Simulation Test — Set—up	
38030.1	ASTM F88 — Seal Tensile Strength — Per Package	10 (minimum) primary packages per process variable
38039.1	ASTM F1140 — Burst Strength — Per Sample	
38091.1	Liquid Dye Immersion with Vacuum — Per Sample	10 primary packages plus 1 control sample
38051.1	Whole Package Microbial Aerosol Challenge with Sterility Test	12 primary packages recommended (10 test, 1 positive control, 1 negative control)
38059.1	Whole Package Microbial Talc Challenge with Sterility Test	
38038.1	ASTM F1929 — Dye Penetration — Per Sample	30 primary packages recommended
38060.1	Microbial Ingress / Immersion Challenge	
38062.1	Leak Test by Vacuum (30 packages)	
38152.2	FPA — Bubble Emission — Per Sample	
38152.1	ASTM F2096 — Bubble Emission — Per Sample	30 primary packages recommended (At least 1 additional samples is needed for test strip)
STERILITY		
110100.1	AAMI/ANSI/ISO Sterility Immersion <=500 mL	Varies based on method - ISO 11137 Method 1 100 Samples - VDmax 10 Samples
110100.3	AAMI/ANSI/ISO Sterility Immersion 600 — 1000 mL	
110100.5	AAMI/ANSI/ISO Sterility Immersion 1200 — 2500 mL	
122500.1	AAMI/ANSI/ISO Sterility Membrane Filtration	
122900.1	AAMI/ANSI/ISO Sterility Membrane Filtration Fluid Path <= 1000 mL	
122900.3	AAMI/ANSI/ISO Sterility Membrane Filtration Fluid Path 1000 — 2500 mL	
122950.1	Sterility Fluid Path Fill <= 500 mL	
122950.2	Sterility Fluid Path Fill 600 —1000 mL	
122950.3	Sterility Fluid Path Fill 1200 — 2500 mL	
1103040.1	Sterility Test — Media Fill — Incubation Only — Per Sample	Varies
122500.2	USP (2 Media) Membrane Filtration — Single Sample	1 sample
122500.3	USP (2 Media) Membrane Filtration — Up to 10 Samples Pooled	2 — 10 samples
122500.4	USP (2 Media) Membrane Filtration — 11 to 20 Samples Pooled	11 — 20 Samples
1228810.1	Pyronema Screening — 28 Day Incubation required — </= 600 mL (Per 100 Samples)	100 samples
1228810.2	Pyronema Screening — 28 Day Incubation required — >/= 800 mL (Per 100 Samples)	
110100.2	USP Sterility Immersion <=500 mL	Up to 40 samples
110100.4	USP Sterility Immersion 600 — 1000 mL	
110100.6	USP Sterility Immersion 1200 — 2500 mL	
122900.2	USP Sterility Membrane Filtration Fluid Path <= 1000 mL	
122900.4	USP Sterility Membrane Filtration Fluid Path 1000 — 2500 mL	

	PRODUCT NAME	SAMPLE VOLUME REQUIRED
STERILITY continued		
1609100.1	SIP Qualification <=200 mL	20 non sterile samples
1609200.1	SIP Qualification 200—400 mL	
1609400.1	SIP Qualification 800—1000 mL	21 non sterile samples
1609500.1	SIP Qualification >1200 mL	22 non sterile samples
400605.1	AAMI/ISO Method 2, Incremental Dose, Extra Small	20 samples
400610.1	AAMI/ISO Method 2, Incremental Dose, Small	
400615.1	AAMI/ISO Method 2, Incremental Dose, Medium	
400620.1	AAMI/ISO Method 2, Incremental Dose, Large	
400625.1	AAMI/ISO Method 2, Incremental Dose, Extra — Large	