F.A.Q.

Burst

Price: First 11 Sample's $120, each additional sample is $8.

Taping: Package Size:

< 8 inches=$1 per sample

8-15 inches= $3 per sample

> 15 inches= $5 per sample

Note: All porous samples must be taped.

Standard used: ASTM F1140

Sample number: sample size is a minimum of 11, but we recommended 29 samples for 1 lot or 11 samples for 3 lots. Additional Sample sizes can be determined based on ISO 2859 Sampling procedures for inspection by attributes – Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection. Samples do not include setup samples; please include 2 to 3 extra samples for setups.

Turn around time: 7 days

Bubble

Price: $20 per each sample.

Standard used: ASTM F2096

Sample number: sample size is a minimum of 11, but we recommended 29 samples for 1 lot or 11 samples for 3 lots. Additional Sample sizes can be determined based on ISO 2859 Sampling procedures for inspection by attributes – Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

Turn around time: 7 days

Dye Migration

Price: $20 per each sample if longest side is short than 30 cm additional $1 for packages longer than 30 cm on the longest side.

Standard used: ASTM F1929

Sample number: sample size is a minimum of 11, but we recommended 29 samples for 1 lot or 11 samples for 3 lots. Additional Sample sizes can be determined based on ISO 2859 Sampling procedures for inspection by attributes – Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

Turn around time: 8 days

Seal Peel

Price: Uncut, one side is $20 per each seal/pull.

Uncut, two sides for pouches is $25 per each seal/pull.
Pre-cut and labeled is $10 per each seal/pull.

Standard used: ASTM F88

Sample number: sample size is a minimum of 11, but we recommended 29 samples for 1 lot or 11 samples for 3 lots. Additional Sample sizes can be determined based on ISO 2859 Sampling procedures for inspection by attributes – Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

Turn around time: 10 days

Population Verification

Price: One species BIs, heat shocked is $250 per each set of 3 (pooled).
Dual species BIs, heat shocked is $275 per each set of 3 (pooled).
Additional fee for individual results per BI is $50 (per set of 3).

Standard used: USP 30 <55>

Sample number: minimum of 3 and samples will be pooled into one result.

Turn around time: 7 days

Note: Samples arriving at the lab on Monday or Tuesday will be tested Wednesday. Samples arriving all other days are tested on Monday.

Dye Immersion

Price: $50 per sample (includes uv-vis analysis).

Standard used: ASTM D4991

Sample number: sample size is a minimum of 11, but we recommended 29 samples for 1 lot or 11 samples for 3 lots. This is based on ISO 2859 Sampling procedures for inspection by attributes – Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection. Please also include 5 additional samples for controls.

Turn around time: 14 days

Condom Compatibility

Price: Approximately $1,000 per set tested. Call for a specific price.

Standard used: ASTM D3492

Sample number: 26+ condoms plus one lubricant for one set. It is recommended that three brands of Latex be tested to claim Latex Compatibility.

Turn around time: 21 days

Tear Plastics

Price: $22.50 per each sample

Standard used: ASTM D1004

Sample number: sample size is a minimum of 11, but we recommended 29 samples for 1 lot or 11 samples for 3 lots. Additional Sample

sizes can be determined based on ISO 2859 Sampling procedures for inspection by attributes – Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection

Turn around time: 10 days

Tear Fabrics

Price: $22.50 per each sample
Standard used: ASTM D5587 (woven), ASTM D5733 (non woven)
Sample number: sample size is 10 (5 machine and 5 cross direction).
Turn around time: 10 days
Please make note on fabric what is the machine or the cross direction.

Tensile Plastics

Price: $22.50 per each sample
Standard used: ASTM D638 (dumbbell die cut)
ASTM D882 (thin plastics)
Sample number: sample size is a minimum of 11, but we recommended 29 samples for 1 lot or 11 samples for 3 lots. Additional Sample sizes can be determined based on ISO 2859 Sampling procedures for inspection by attributes – Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection
Turn around time: 10 days

Tensile Fabric

Price: $22.50 per each sample
Standard used: ASTM D5035 (strip method)
ASTM D5034 (grab test)
Sample number: sample size is 13 (5 machine and 8 cross direction).
Turn around time: 10 days
Please make note on fabric what is the machine or the cross direction.

Puncture

Price: $22.50 per each puncture.
Standard used: ASTM F1342
Sample number: sample size is 12 punctures.
Turn around time: 12 days

Microbial Ranking

Price: $650 per each run
Standard used: ASTM F1608
Size: no smaller than a 47mm disk, can process 4 disks per run.

Organism used: Bacillus Atrophaeus
Turn around time:10 days

Accelerated Aging

Price: $22 per day
Add an additional $25 for samples greater than 10 cubic feet.
Standard used: ASTM F1980
Time: 6.5 weeks at 55C is equivalent to 1 year accelerated aged.
Sample number: Depending on the customer's needs.
Turn around time is dependent on how long samples are being accelerated aged (1 year = approximately 6.5 weeks, 2 years = approximately 13 weeks, etc).

Shipping and Distribution Testing

This test method is subcontracted to another facility however we will coordinate all the arrangements.
Price: Dependent on method tested, ranges from ~$1500 to $3,000
Standard used: ASTM 4169, ISTA 2A, 3A
Sample number: Depending on the customers' needs.
Turn around time: 21 days from receipt.

Aerosol Challenge

Price: $2200 initial run, including protocol and report
$1500 for additional runs.
Standard used: None
Sample number: 60 + controls
Turn around time: 28 days from receipt.

Q: Is there a standard for the Microbial Aerosol Challenge Test?
A: No. However, the validated test procedure "has been used to challenge and qualify an estimated 1000+ different products that have been submitted to the US FDA. These submissions have been to CDRH, CBER, and CDER. No post-marketing surveillance issues have been raised since the first use of the test in 1985."
There is a PDA technical monograph #71 and also ISO 11607 par 1: section 5.2 mentions the microbial barrier testing.
Reference: References in the STP.

Q: What is the purpose of the aerosol challenge test?
A: "The whole package microbial challenge procedure was designed to accelerate the microbial exposure process." The test is used to determine the integrity of the whole package-not just the seal. The test represents "a

real world simulation" of packages as they sit on a hospital shelf and collect dust.

Q: What indicator organism do you use, and why?
A: We use *Bacillus atrophaeus* ATCC#9372. We use this challenge organism because of its small size (0.7-0.8µm), high aerosolization efficiency (low aerosol kill), and the spores maintain viability after being deposited onto the surface of the test sample.

Q: How many samples do you recommend?
A: 60 units is a statistically significant sampling and permit a 95% confidence level claim for 60 of 60 sterile units. However, the sponsor will need to determine what level of confidence they would like to achieve based on production, risk, cost, etc.
Reference: Based on AOAC 95% confidence interval disinfection level

Q: Could you explain your monitors for the test?
A: Fallout gauze- quantitates the organism fallout by knowing the surface area of the gauze (tells you how much organism fell on your product).
AGI (all glass impingers) - break up the aerosol particles to determine the challenge level.
Andersen sampler- calibrated so all particles collected can be directly related to the human lung.

GLP (Good Laboratory Practices)

GLP is used for studies that will be submitted to the FDA for review. It adds approximately 3-5 days to the turnaround time.

STAT

Minimum fee is $75 per test otherwise 50% of the total cost of testing. It will usually reduce the turnaround time by approximately 50% of the established turnaround time.