

# Certified Standard Challenge Sets



Certified Standard Challenge Sets provide sterile injectable product manufacturers with a durable, precision-manufactured challenge set that can be used to train and qualify inspectors and automated inspection machines. Certified sets means higher confidence in POD data.

Whether it's a human, semi-automated, or automated inspection application, the experts at MML are here to help you select the best choices for your challenge sets for each drug product and container combination you manufacture.

If your particle defect library isn't fully characterized, MML's analytical testing group can provide Raman and FTIR Spectroscopy particle identification services\* ensure the correct mix of particle defects are designed into the set.

More information is available: please download from the PDA our award-winning paper "Considerations for Design and Use of Container Challenge Sets for Qualification and Validation of Visible Particulate Inspection", James A. Melchore and Dan Berdovich; PDA Journal of Pharmaceutical Science and Technology 2012, 66 273-284.

**Call us at (847)459-6540**

**We Will Help You Design Your Set**

\* Additional services billed separately

## Benefits

### Highest Quality & Reliability

- Zero undesired visible particles, guaranteed
- One year guarantee for defect particle and solution stability and against microbial growth
- Manufactured in a fully-compliant cGMP facility
- Certificate of Analysis includes details for all units (blanks, seeded, or attribute defect containers)

### Manual, Semi- & Fully Automated Inspections

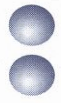
- Determine a manual (Knapp) performance baseline and qualify your inspection system's detection capabilities
- Train, qualify, and re-qualify manual, semi-automated, and fully automated inspectors
- Using a *certified* set means a more exact comparison of particle size and Probability of Detection (POD)

### Highly Customizable Set Configurations

- The largest variety of standard particle types and sizes available in the industry
- We will identify virtually any particle in a rejected container to address your site-specific particle concerns in inspections
- We have the instruments, techniques, and procedures in place to meet your exacting particle type and size requirements with tight tolerances accurately
- Examples and some specifications on reverse

### When the Regulators Come...You Will Be Ready

- 18 years of experience creating challenge sets
- Our staff is comprised of engineers and scientists who are award-winning authors and subject matter experts on visual inspection and regular conference speakers
- Professional organizations use our challenge sets in their training programs
- A smooth start-up to your program: our experience means we've eliminated or designed around many common problems with challenge sets



# Certified Standard Challenge Sets

## capabilities menu

Particle Types					
Spheres:			Natural Fibers:		
Material	Description	Size (µm)	Material	Description	Size (µm)
Glass	Solid/Clear	≥ 50	Silk	Black	250 µm & Up
Stainless Steel		≥ 50		White	250 µm & Up
Polystyrene Latex	White/Clear	≥ 50	Cotton	Black	250 µm & Up
	Black	≥ 100		White	250 µm & Up
	Red	≥ 200	Cellulose	White	250 µm & Up
<p><b>Tip: to ensure Probabilities of Detection (PODs) &gt;&gt; 0, use spheres ≥ 80 µm and fibers ≥ 400 µm</b></p>			Synthetic Fibers:		
Polyethylene	White	≥ 50	Polyester	Black	250 µm & Up
	Black	≥ 50		White	250 µm & Up
	Red	≥ 200		Blue	250 µm & Up
	Green	≥ 200	Polypropylene	Clear	250 µm & Up
<p><b>We can also create particles of desired sizes from most any material in your plant or process, even if you don't know what it is - we'll ID it for you*!</b></p>			Polyethylene	Yellow	250 µm & Up
<p><small>* Additional services billed separately</small></p>			Nylon	Black	250 µm & Up
				White	250 µm & Up
			Rayon	Black	250 µm & Up
				White	250 µm & Up
Custom Made Materials:					
Glass	Shards	80 µm & Up	Plastic	Dark	100 µm & Up
Stainless Steel		100 µm & Up		Light	100 µm & Up
Aluminum		100 µm & Up		Colored	100 µm & Up
Teflon	PFA or ETFE	100 µm & Up	Rubber	Gray	100 µm & Up
Cardboard	Corrugated	150 µm & Up		Black	100 µm & Up
Wood / Cork		150 µm & Up		Red	100 µm & Up
Hair	(color varies)	500 µm & Up		Blue	100 µm & Up
Gasket Material	Black	100 µm & Up			
Tubing	Specify Type	100 µm & Up			
Available Cosmetic Defects:					
Defect Type	Detailed Description	Examples			
Solution Defect	High or low fill volume, empty container, colored or turbid solutions				
Glass Defects (A)	Crack <sup>†</sup> , check <sup>†</sup> , bent neck <sup>†</sup> , foreign matter/particles, leaner, Lehr sticker, malformed seal, rippled shoulder, rocker, stone				
Glass Defects (B)	Scratch <sup>†</sup> , scuff <sup>†</sup> , bruise <sup>†</sup> , dirty body <sup>†</sup> , bulls eye, Chip <sup>†</sup> , pressure surface mark				
Aluminum Seal Defects	Damaged crimp, dented/bruised/scratched seal, loose crimp, misaligned crimp, missing crimp, rippled crimp, wrong color cap, foreign particle deposit				
Stopper Defects	Incorrect / misaligned / missing / or stained stopper, protrusion				
<p><sup>†</sup> Indicates customer must specify defect location</p>			<p>Note: specifications may change without notice</p>		

Don't forget to ask your MML account rep about our sub-visible particle testing capabilities\*