

# Certified Visual Inspection Challenge Sets

*Visual inspection of injectable drugs is required to minimize unintended particles in injectable medications. Each unit of an injectable product must be inspected by a **trained and qualified inspector**.*

Certified Visual Inspection Sets from Micro Measurement Laboratories can be used to train and qualify inspectors or methods whether using manual, semi-automatic, and automatic inspection techniques.



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 manual, semi-automated, or an automated inspection application, the experts at MML will 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 particle identification group can provide FTIR Spectroscopy particle identification services\* to 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**

## Highest Quality & Reliability

- Zero undesired visible particles, guaranteed
- One year guarantee for defect particles, solution stability, and against microbial growth
- Manufactured in a fully-compliant cGMP facility
- Certificate of Conformance includes details for all units (blanks, seeded, or cosmetic 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, or fully automated inspection methods
- Using a *certified* set means a more accurate comparison of particle size and Probability of Detection (POD)

## Highly Customizable Set Configurations

- We have experience with nearly every container type
- We offer the largest variety of particle types and sizes
- We have the instruments and techniques to fabricate custom sized particles from materials utilized in your facility
- We can create a wide variety of cosmetic defects commonly found in production lines
- We will identify virtually any particle\* in a rejected container to address your site-specific particle concerns in inspections

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

- 23 years of experience creating challenge sets
- Our staff is comprised of engineers and scientists who are award-winning authors and regular conference speakers
- Professional organizations use our challenge sets in their training programs
- We continue to participate, contribute, and share information on visual inspection through workshops, forums, presentations, and papers

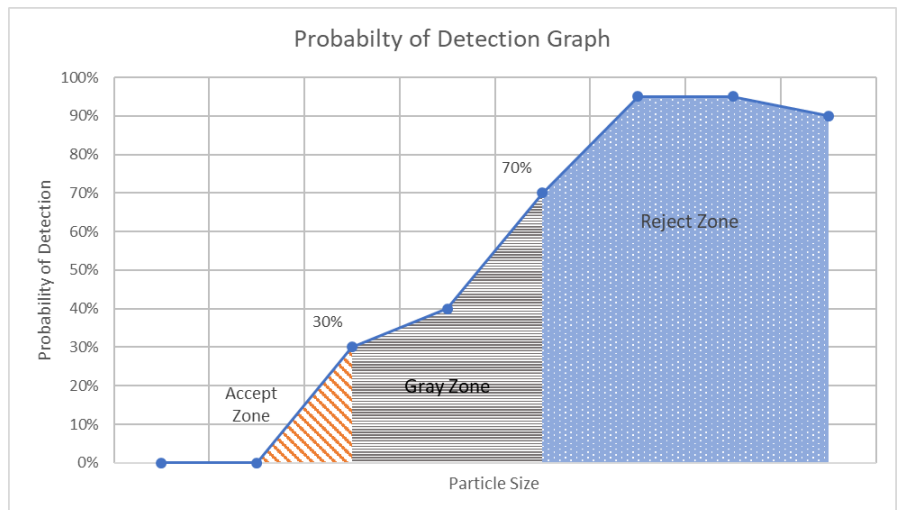
# Designing Your Own *Custom* Certified Visual Inspection Challenge Sets

## First gather some information:

- Type of container – Each container configuration should have its own challenge kit
- Types of particle defects – Gather contaminant information from your own particle or reject library
  - Gather information about the **material** and **size** of contaminants in your facility
    - Intrinsic (glass, steel, gasket, etc.)
    - Extrinsic (wipes, gowns, hair, etc.)
  - No particle library? No Problem! MML offers particle identification services

## Designing your Custom Challenge Kit

- Pick Particle Defects – Each material should include multiple particle sizes
  - Choose from a wide range of MML stock materials or send a sample from your own facility!
- Pick Cosmetic/Attribute Defects –  
Customize to the defects you see!
- Pick “Blank” / Defect Free Units –  
“Blanks” control your results
  - <USP1790> recommends  
90% of challenge kit to be  
“blank” units



## Help

- Not sure what particle sizes to choose?

Starting out can be difficult. If you don't have a particle library, or are designing a challenge kit for a new 'difficult-to-inspect' product, you may need to first determine your visual capabilities. Speak with our representatives about a **Size Determination Set**: these custom kits are small, only feature one or two particle materials and no blank units – but offer a wide size range of particle sizes, so you can determine where *your* visual range is.

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## Defect Menu:

Particle Types Available	
<b>Spheres</b>	<b>Custom Particles</b>
Glass	Glass (Clear or Amber)
Stainless Steel	Stainless Steel Filings
Polystyrene	Aluminum Filings
Polyethylene	Teflon (PFA or ETFE)
<i>Different Colors Available</i>	Rubber
	Tubing (Silicone, Silastic, etc.)
	Plastic (HDPE, PE, etc.)
	Different Colors Available
	<i>Provide your own material!</i>
<b>Fibers</b>	
Silk	
Cotton	
Cellulose	
Polyester	
Polypropylene	
Polyethylene	
Nylon	
Rayon	
<i>Different Colors Available</i>	
<i>Provide your own material!</i>	

**≥50 μm**

**≥100 μm**

**≥250 μm**

**Tip: to ensure Probabilities of Detection (PODs) >> 0, use spheres ≥ 100 μm and fibers ≥ 500 μm**

**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\*!**

Available Cosmetic Defects:			
<b>Crimp Seal Defects</b> <ul style="list-style-type: none"> <li>● Torn</li> <li>● Dented</li> <li>● Scratched</li> <li>● Loose</li> <li>● Misaligned</li> <li>● Missing</li> <li>● Rippled</li> <li>● Incorrect</li> </ul>	<b>Stopper Defects</b> <ul style="list-style-type: none"> <li>● Missing</li> <li>● Incorect</li> <li>● Plunger Defects</li> </ul>	<b>Solution Defects</b> <ul style="list-style-type: none"> <li>● Under / Over Fill</li> <li>● Empty</li> <li>● Turbid / Colored Solution</li> </ul>	<b>Glass Defects</b> <ul style="list-style-type: none"> <li>● Scratch</li> <li>● Scuff</li> <li>● Dirty Body</li> <li>● Crack</li> <li>● Chip</li> <li>● Leaner</li> <li>● Rocker</li> <li>● Malformed Lip</li> </ul>
<b>We can also create custom defects for IV bags, syringes, plastic containers and many more!</b>			
Please Specify Defect Location			

\* Additional Services Billed Separately

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