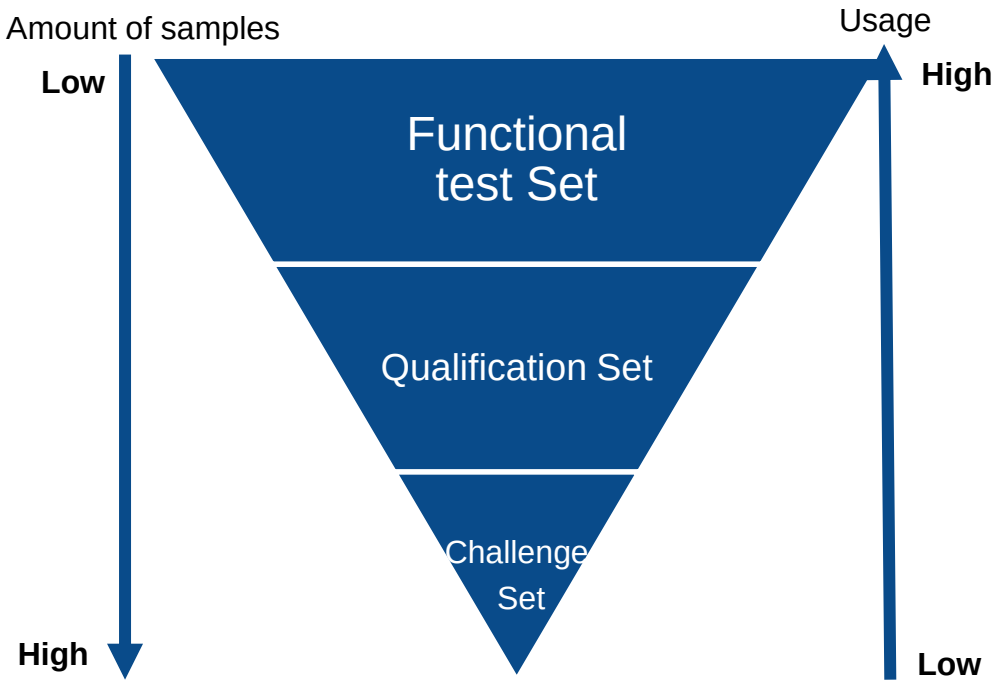
Introduction into test set handling for automated visual inspection

PDA Parenteral Drug Association

PDA TRAINING

Test sets overview

- **Functional test Set**
  - Equipment verification
  - daily use
- **Qualification test Set**
  - Equipment & Process Qualification
- **Challenge Set**
  - Deep Insight
  - „Research“



Function test Set

- **Small amount of Samples**
- **Easy to replace (enough spares)**
- **Can consist out of Qualification samples. Better if not.**
- **Should be close to the AVI**
- **Clear Instructions necessary!**
- **The test result should be stable and very reliable!**

Annex 1 8.32 P.25
open the discussion for the interpretation of

„The performance of the equipment should be challenged using representative defects prior to start up and at regular intervals throughout the batch“

Qualification Set

- **For initial and re-qualification**
- **Represents all required defect category's**
  - Knapp test is often listed as one category
- **Spare samples should be present and documented ahead of time**
  - Spares are not used for the qualification
  - Some Category's require a lot of spares
    (broken finger grip, big cracks get easily destroyed by repeated use)
- **Defect documentation and detection rates should be placed together with the samples**
  - List of defects and detection rate is the first question from any technician.

Challenge Set

- **Not that common**
  - Due to the amount of work
  - Due to the specific content of the information
- **Only internal use to get the capability's of the AVI**
  - Usually not used for the qualification
  - Due to the goal to get the AVI to the limit / „to Fail“
- **Often the qualification set is also called „challenge set“**
- **Wide range of defects**
  - To get the limits of the AVI
- **Might be used for evaluations of new or existing machines.**

Storage / Handling

- **Glass to glass contact should be avoided**
- **For Vials and Bottles, trays with pockets for each samples is preferred**
- **For syringes trays or nests are preferred**
  - Trays provide a better visibility.
  - Nests are better for handling larger amount of samples
- **Test sets can last for several years**
  - A stable product is required
  - Clear documentation and numbering on the samples is necessary.

Labeling

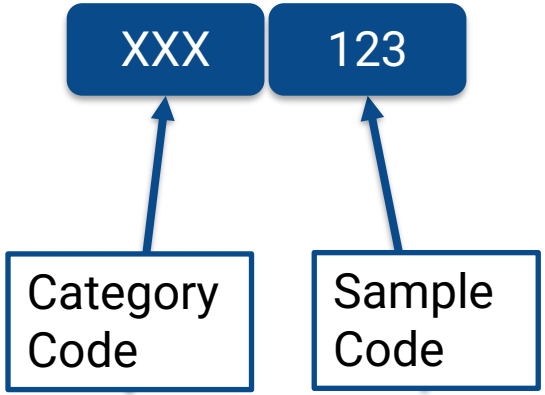
- **Good visible / readable**
- **Never cover defects**
- **Never put it in the expected defect area**
- **Top of the vial or needleshield recommended**
- **Label should not be permanent**

Labeling

For any defects
not at the cap / needleshield

For any defects
at the cap / needleshield

Labeling example coding



Description	Number	
Scratch Sidewall	12345	1234
Cap Color	1243	1243
Crimp Cut	1324	1324
Fiber Particle 500µm	2134	2134
Glass Particle 250µm	4231	4231

Example set packaging

+ No glass to glass contact
+ Clear overview
+ Easy to use

- Needs a lot of space
- Loose fit
- Special case

+ Easy to get
+ Compact size
+ Secure fit

- Gets easily damaged
- Very dirty

Example Numbering/ Sorting

Category	Description	Severity (m/ M/ C)	Sample Number / Name	Required PoD	Current PoD
Scratch	Scratch Sidewall	m (minor)	12345	>90%	95%
Cap Defects	Cap Color	M (Major)	1243	>95%	>99%
Crimp Defects	Crimp Cut	C (Critical)	1324	>98%	>99%
Particle Defects	Fiber Particle 500µm	Knapp Test	2134	>92%	95%
Particle Defects	Glass Particle 250µm	Knapp Test	4231	>92%	97%

Knapp Test (Procedere)

- **Sufficient amount of defect samples are mixed in good samples**
  - Usually around 200 good samples
  - 50 defect samples
  - Exact numbers can be adjusted / vary
- **The samples are labeled in such a way that the operator cannot tell what is a defect and what is a good sample**
  - Defect samples are mixed randomly into the good samples
- **The whole test is tested by operators**
  - Usually 10 times
    → Sometimes 30 times
  - At best with different operators at different times to catch all the variations of the human
- **The evaluation of the result is not performed by the operators who inspect the test set**
- **Only samples with a detection rate >=70% are important**

Knapp test

Avoid this

Testing in a rush	The knapp test needs time!
Defects clustered together	The defects should be spread equally inside of the knapp test
Hints about the defects	The defects should have no marks or anything to identify them
Sample to sample comparison	NEVER compare the results on a sample to sample basis