

Different types of test sets throughout a visual inspection project lifecycle:

From vendor selection to visual inspection in production

There are multiple defect testkits that can be used throughout a visual inspection project timeline. This poster summarizes all possible types of testkits, from initial defect kit for treshhold study for the manual baseline, to the final functional kit & requalification kit when in production.

Different strategies are possible regarding the number of testkits + it's composition. It's possible to reduce the testkit effort by combining kits at some stage. Also bracketing can be considered, in case of multiple products.

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PoD kit for manual baseline

- Using all defects from the defect library.
- Consisting both of particle defects, (for Knapp test) as of other defects
- Particles spread across size ranges, multiple defects per size range
- Consisting of 10% defects, 90 % good units to not bias manual operators

Feasibility Study kit

- For challenging AVI vendors
- One of vendor selection criteria
- With real product, if possible. If not possible, with mimicking solution (e.g. placebo)
- A certain number of good units could be useful for already evaluating the FRR (20-100 units)
- Not always necessary to include obvious to see defects (e.g. missing flip off)

Evaluation Study kit

- Requested by AVI vendor
- Used for initial vision configuration
- For confirming the performance expected in the URS
- For finalizing vision lay out (e.g. if an extra camera station is required to see a certain defect)

Mechanical Test Kit

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- For testing mechanical components (e.g. grippers & format pieces) of the equipment
- No need to use real product (e.g. not even needed to use sterile vials/WFI, as you will just use them for mechanical testing)
- No need to contain defects

FAT/SAT kit

- For challenging initial vision configuration during commissioning, while taking PQ requirements into account
- Also Evaluation Study kit can be used for this, but could be good for challenging vendor to have a complete new kit
- Kit will be used during FAT, after confirming quality of testkit by MVI, kit should be used again during SAT to prove that shipment & installation has not impacted the vision system. Strategy with Knapp and/or Fixed AC possible.
- Plenty of good vials to challenge FRR (500-10 0000)

ER Kit

- Finetuning of vision recipe (PQ ready)
- For confirming the performance expected in the URS (Knapp and/or Fixed AC)
- As many different samples as possible, to really challenge vision software. (including various lots of primary containers & batch variation)
- Goal is to reach acceptable PoD for all defects, while maintaining the FRR at a low level = Acceptance criteria for PQ

PQ Kit

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- Used for qualifying vision system
- Acceptance criteria is dependent on the strategy (fixed, Knapp, per defect category, ...)
- Vision configuration should be finalized, before using this kit (change control applies)
- Ran multiple times on the AVI equipment (e,g, 15 times), possible to use loop/knapp mode
- Goal is to reach acceptable PoD for all defects, while maintaining the FRR at a low level = Acceptance criteria for PQ

Functional Test Kit

- Used to test correct installation of format pieces
 & correct positioning of vision components
- Not to challenge vision recipe, but with easy to see defects.
- Limited amount of defects
- Easy to replace defects (spares), in case of container breakage due to wrong set up

(Re)qualification Kit/Training Kit

• AVI

- Possible to reuse PQ kit (correctly maintained & verified)
- MVI
- Operator Trainings kit should contain all types of defects, with challenging particle sizes.
- Operator Qualification kit should contain 10% Defects & 90% goods, only including particles that were rejected >70%