

Automated Preparation of Calibration Standards to SANTE Requirements

Hans-Joachim Huebschmann, Titus Breski

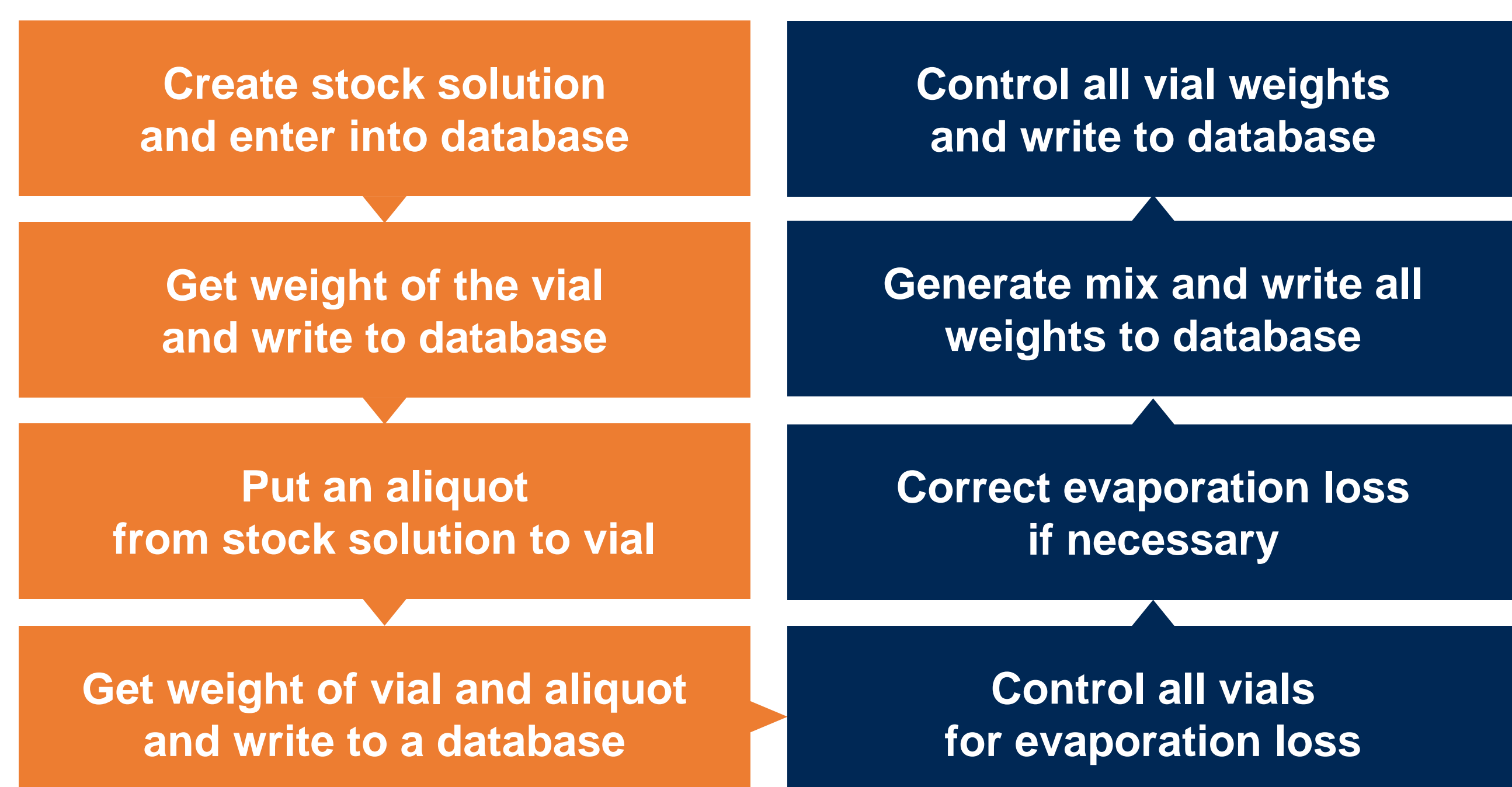
Part of the  TRAJAN Family



Requirements

- The preparation of multi-pesticide stock and working solutions for calibrations is a recurring, labor-intensive, and quality critical task that calls for automation.
- Manual liquid handling steps are often error prone and subject to individual variation, often lacking the required reproducibility.
- The SANTE 2021 analytical quality control document sets the requirements for the preparation of calibration standards:
 - Reference substances and stock solutions should be stored in a cool place away from light and moisture.
 - Standards should equilibrate to room temperature and remixed before use.
 - Punctured septa should be replaced.
 - Standard vials should be permanently labelled.
 - The documentation should ensure full traceability of all steps.
 - Date of preparation, identity, mass and volume of the reference standard and the type and volume of the solvents used must be recorded.
- Automated processing has to comply with above requirements for improved precision, reproducibility, and traceability.

Workflow



Automated MultiMix Features

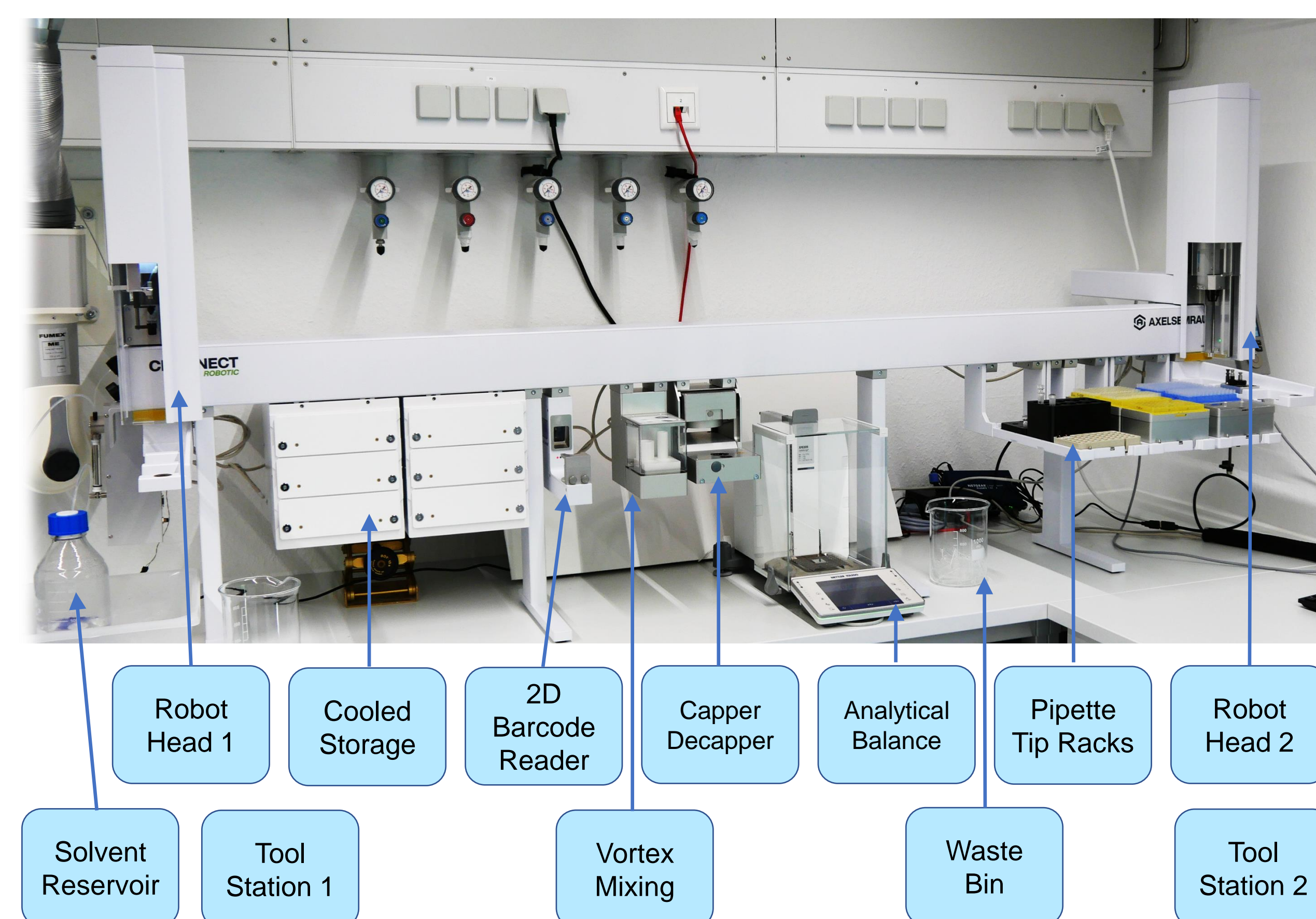
- ◆ Software package with SQL database of >600 pesticide details and certificates.
- ◆ All dosing steps are gravimetrically monitored.
- ◆ Weighing results are transferred to the database.
- ◆ Monitoring potential weight loss of all standards.
- ◆ Correction for evaporation losses.
- ◆ Target volumes are automatically calculated as of analyte concentration.
- ◆ Liquid/solvent class volume correction.
- ◆ Tracking of expiry dates.
- ◆ Compatible with different vial sizes.
- ◆ Pipetting prevents carryover.
- ◆ Printing of solvent resistant barcode labels.
- ◆ Concentration table export to data systems.

Conclusion

- The CHRONECT MultiMix workstation fulfils all SANTE criteria according to SANTE 11312/2021, implemented by 01/01/2022.
- Multi-compound stock solutions from reference materials.
- The automated workflow improves reproducibility and accuracy.
- Individual bias and errors are avoided, evaporation losses controlled.
- Unattended operation leads to significant time savings.
- Routine multilevel calibrations, standard additions and target dilutions are prepared automatically as an additional option.
- The MultiMix workflow can be applied to other types of analytes.

MultiMix System Configuration

The CHRONECT MultiMix Workstation is based on a dual head x,y,z-robotic system of 200 cm rail length. Both heads work simultaneously, using the required tools from two tool stations. Reference and standard vials are placed in cooled drawers. Vials are equilibrated to room temperature and vortexed before use. All vials are 2D barcode labeled and registered by a rotating reader. All vials are gravimetrically controlled using an integrated 5-decimal balance before and after liquid handling. No septa are pierced. Vials get de/capped before and after use. Pipette tips of different volumes are kept ready in dedicated trays.



Advantage Time Saving

Prepare a calibration mix of more than 500 pesticides:

Manual pipetting and documentation: 32 h = 4 working days!

Automated workflow: 5 min planning, 20 h unattended processing including documentation (typically over night operation).