CLEAN VALIDATED

FIELD NOTES / 03 • CLEANING VALIDATION

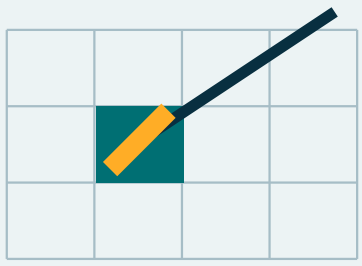
SWAB OR RINSE?

The sample only tells the story of what it can recover.



Illustration · Clean Validated

SWAB / LOCAL SURFACE



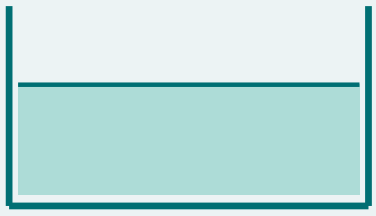
Defined area.
Defined location.
Defined technique.

Useful for accessible problem spots and local residue loading. Limited access and patch selection constrain what the result represents.

THE BLIND SPOT

One clean patch does not prove every surface is clean.

RINSE / CONTACTED SYSTEM



Defined contact.
Defined volume.
Defined recovery.

Can reach internal paths. A clear rinse does not show that an insoluble or trapped residue was removed.

THE BLIND SPOT

A larger rinse volume can dilute the same residue mass.

A NON-DETECT IS NOT A ZERO

Interpret it against detection capability, sampling recovery and the area or system actually represented.

Same signal. Different interpretation.

AREA CHANGES THE MEANING

5 µg / 25 cm² = 0.20 µg/cm²

Spread the same recovered mass over 100 cm² and the result becomes 0.05 µg/cm². Record the area with the result.

SAME MASS / 4× AREA / ¼ SURFACE LOADING

VOLUME CHANGES THE MEANING

0.1 µg/mL × 1,000 mL = 100 µg

At the same concentration, a 10 L rinse represents 1,000 µg. Multiplication alone does not prove recovery or full coverage.

SAME CONCENTRATION / 10× VOLUME / 10× MASS

Illustrative arithmetic only; these examples do not define acceptance limits or recovery corrections.

BEFORE YOU SAMPLE

1. **Map the difficult locations**
   Choose sites by risk and cleanability; document access and geometry.
2. **Demonstrate method recovery**
   Link the surface, residue, sampling material and extraction method.
3. **Control the procedure**
   Specify area or volume, contact, handling, timing and sample storage.

WHEN YOU READ THE RESULT

1. **Keep blanks in view**
   Sampling materials and solvents can contribute background.
2. **Keep the units attached**
   Concentration, recovered mass and surface loading are different quantities.
3. **State the boundary**
   Swab and rinse may complement each other. Neither covers every uncertainty.

SOURCE & SCOPE

FDA · Validation of Cleaning Processes (7/93), analytical methods and sampling. Historical inspection guide; use alongside applicable current GMP requirements. Arithmetic examples by Clean Validated.

Educational field guide
Examples are illustrative.
Apply site-specific assessment.