

Microbial EM Trending using 3P[®] Connect and 3P[®] Enterprise

August 2026 – Wylie Armstrong



THEN AND NOW..

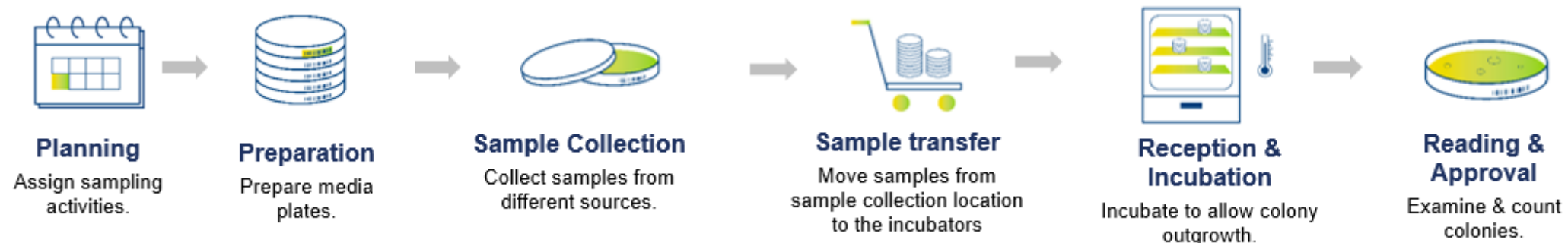
The Legacy Approach

- Isolated EM testing
- Static numerical limits
- Periodic manual checks
- Reactive error handling

Annex 1 Mandate

- **Integrated Contamination Control Strategy (CCS)**
- Dynamic, risk-based trending & **root cause analysis**
- Continuous monitoring & Implementation of **advanced technologies**
- **Proactive** personnel hygiene and behavioural control

TRADITIONAL EM WORKFLOWS CREATE OPERATIONAL AND COMPLIANCE CHALLENGES



PROCESS VARIABILITY
PLATE IDENTIFICATION
STOCK CONTROL PAPER RECORDS
RABS IMPLEMENTATION AUDIT TRAIL REVIEW BURDEN
DATA RECONCILIATION ANNEX 1 21 CFR PART 11
AUDIT READINESS TRACEABILITY RELIABILITY
MISSING PLATES
COSTS MANUAL TASKS DOUBLE-CHECKING
TREND ANALYSIS TIME-CONSUMING
EXPIRY CONTROL DATA INTEGRITY SAMPLE MIX-UPS
RESOURCE-INTENSIVE DIGITALISATION WORKLOAD
KNOWLEDGE GAPS
REPETITIVE TASKS HUMAN ERROR DOCUMENTATION
TRANSCRIPTION ERRORS
MANUAL CHECKS INVESTIGATIONS
REGULATORY SCRUTINY

➤ RESOURCE-INTENSIVE PROCESS

➤ ERROR-PRONE WORKFLOWS

➤ ECONOMIC & PRODUCTIVITY
IMPACT

➤ COMPLIANCE & DATA INTEGRITY
RISK

EM GENERATES LARGE VOLUMES OF DATA, BUT INSIGHT REMAINS SLOW

FRAGMENTED DATA

Multiple systems, forms, and manual records



RETROSPECTIVE TRENDING

Signals may be identified only after escalation



DATA INTEGRITY & COMPLIANCE BURDEN

Significant effort to verify, reconcile, and report data.



WHAT SHOULD GOOD TRENDING ANSWER?

- 1 Frequency** Are alert or action events becoming more frequent in a particular room, line or sample point?
- 2 Location** Is the same area repeatedly showing low-level recoveries or limit breaches?
- 3 Organism** Are we seeing recurring organisms, a shift in flora, or organisms that are more difficult to control?
- 4 Activity** Do results correlate with maintenance, line clearance, or other interventions?
- 5 Response** Did the corrective action return the area to its expected baseline?



THE DIGITAL FOUNDATION FOR EFFECTIVE TRENDING

A range of digital approaches can support the same goal: less time assembling data, more time interpreting risk.

THE BROADER DIGITAL EM LANDSCAPE

Different architectures, common objectives

DEDICATED EM PLATFORMS

NOVATEK • Lonza MODA-EM • BioTrends • SherpaPharma

LIMS-EM MODULES

LabWare • LabVantage

SHARED INDUSTRY AIM

Traceability • Data integrity • Trending • Faster review

Within this broader landscape, the 3P[®] ecosystem connects the microbial EM workflow from sample to insight.

3P[®] CONNECT

DIGITISE & STRUCTURE

- Guided environmental monitoring workflows
- Media and sample traceability
- Context captured with the result
- Centralised records and reporting



Creates trusted, structured EM data



EXTENDS TO
AUTOMATION

3P[®] ENTERPRISE

3P CONNECT + SMART PLATES + 3P STATION

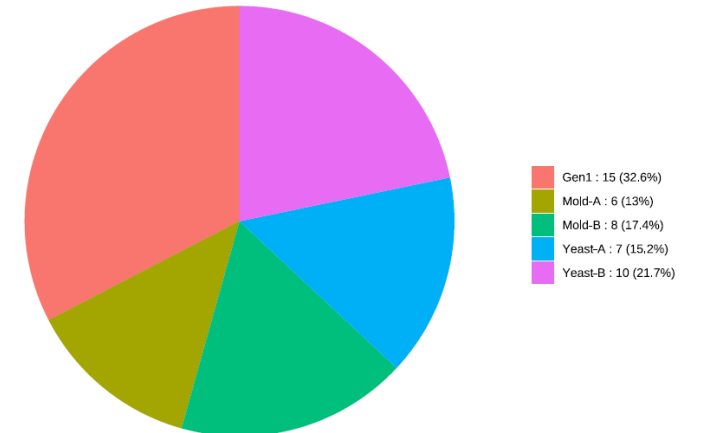
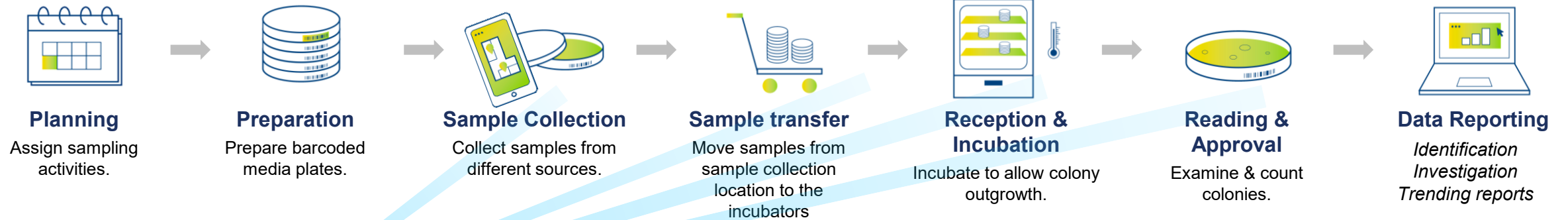
- Connected plate identity and lifecycle data
- Automated incubation, imaging and reading inputs
- Earlier availability of structured results
- Centralised visibility, reporting and trend analysis



Turns workflow data into actionable insight

THE POINT IS NOT MORE DATA. IT IS LESS MANUAL ASSEMBLY, EARLIER VISIBILITY AND MORE TIME FOR INTERPRETATION.

3P[®] CONNECT



BARCODED MEDIA : BUILDING QUALITY BEFORE TRENDING BEGINS

Reducing risk at the sample collection stage

- ✓ **Right media used**
Barcode verifies the correct media type for each sampling location.
- ✓ **Expiry control**
Prevents use of expired plates and improves compliance.
- ✓ **Plate traceability**
Each plate is uniquely identifiable from preparation to result.
- ✓ **No manual labelling**
Eliminates handwriting, relabelling and transcription steps.
- ✓ **Prevents plate mix-ups**
Reduces risk of swapping samples during collection and incubation.
- ✓ **Stronger data integrity**
Improves confidence in trending by ensuring reliable source data.

Traditional Process

Manual plate labelling
Manual media verification
Risk of transcription errors
Potential sample mix-ups



3P[®] Connect + Barcoded Media

Automatic verification
Electronic traceability
Controlled workflow
Data ready for analysis



Barcode example : (01)0357302632036(17)210201(10)1005481260(21)000476

01	0357302632036	17	210201	10	1005481260	21	000476
ID GTIN	GTIN	ID Expiration date	Expiration date YY/MM/DD	ID Batch number	Batch number	ID Serial number	Serial number
2	14	2	6	2	10	2	6
Total length: 44							

3P[®] STATION: FROM PLATE READING TO DIGITAL INSIGHT

Standardising the point where a microbiology observation becomes usable data



AUTOMATED KINETIC READING

Image capture, enumeration and electronic result handling



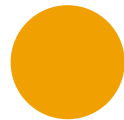
STANDARDISE

Consistent reading methodology helps reduce operator-to-operator variability.



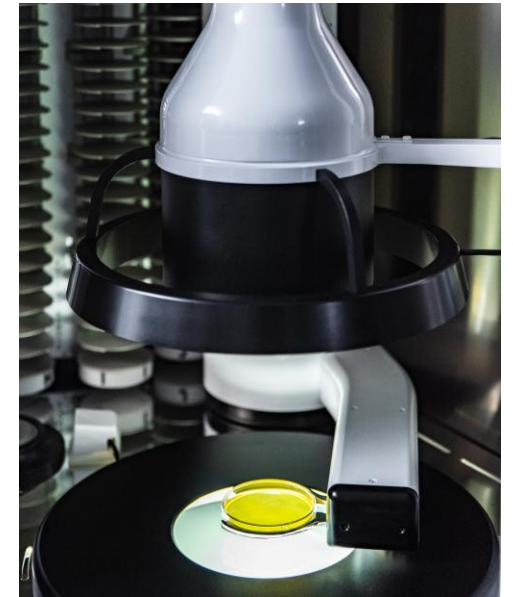
DIGITISE

Plate images, results and review status become traceable electronic records.



INVESTIGATE

Stored images and results support faster review, comparison and follow-up.



AUTOMATED IMAGE ACQUISITION



DATA TRENDING - ACTIONABLE INSIGHTS

Microbio traceability

Period type

Custom range

01/16/2025

09:34 AM

02/12/2025

09:34 AM

Sampling plan

Sampling plan Building 1 ...

Location

ROOT , bioMérieux Site , ...

Sampling location

Sampling U , Sampling V ...

Type

Person , Air sampler , Se...

Person(s)

Grade

A , B , C , D , None

Incubator

Batch number

Product name

Organism type

None , Bacteria , Mold , ...

Organism name

None , Bacillus subtilis , ...

Sample status *

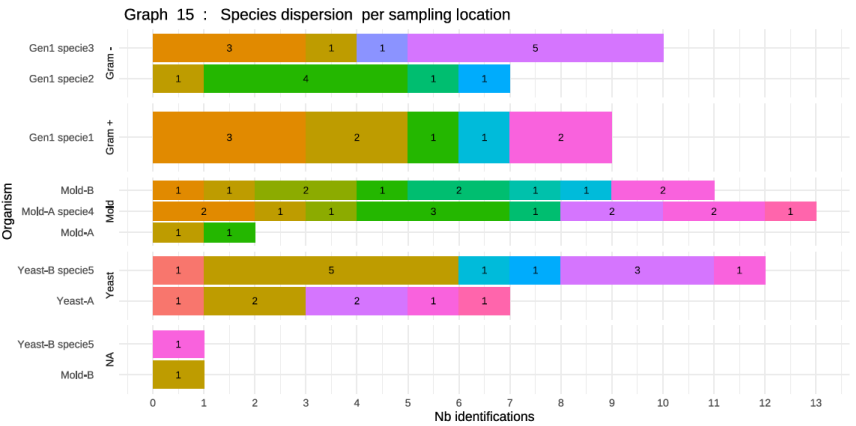
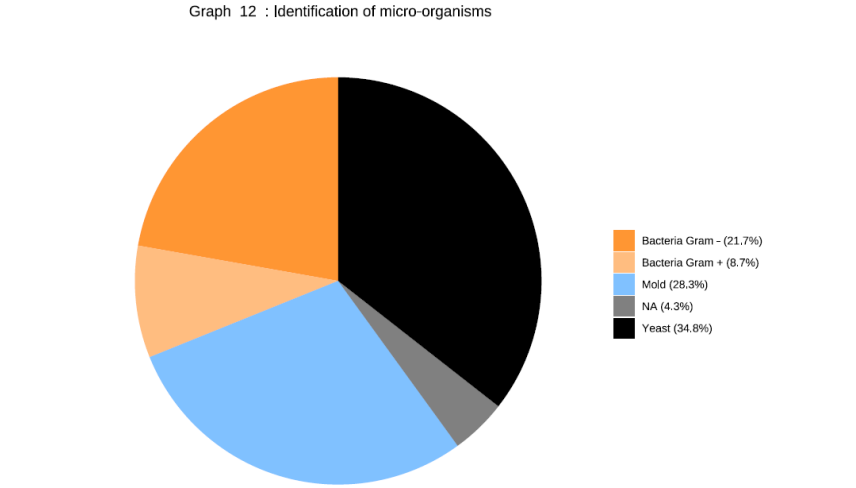
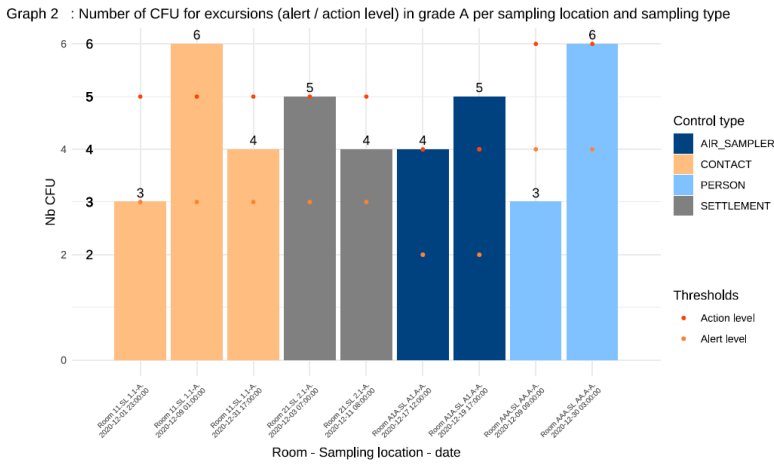
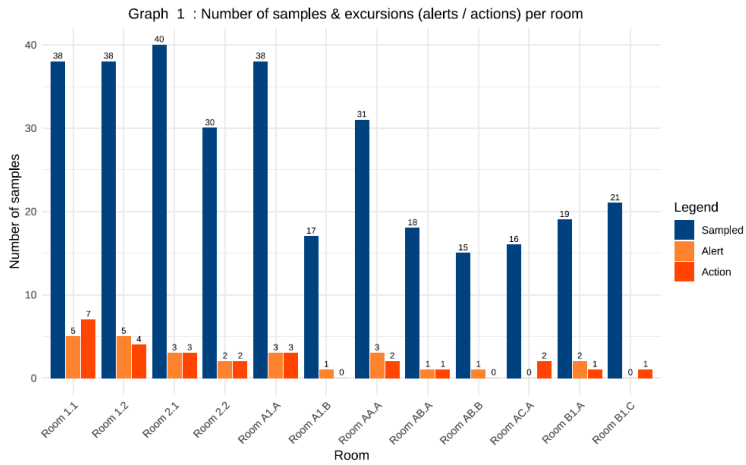
Ready , Sampling , Sam...

Alert / Action level...

None , Alert level , ...

Mold suspicion

Has mold(s) , Has n...



CONFIDENCE IN TRENDING STARTS WITH CONFIDENCE IN RESULTS

Capturing and trending results adds value only when the underlying microbiology is scientifically sound and controlled.

1 MEDIA SELECTION

Fit-for-purpose media and recovery of relevant microorganisms

2 INCUBATION STRATEGY

Defined temperature range and sufficient incubation duration

3 GROWTH PROMOTION

Demonstrated recovery performance and ongoing suitability

4 QUALIFIED SUPPLIERS

Approved sources, quality oversight and supply consistency

5 STANDARDISED METHODS

Consistent sampling, handling, reading and interpretation

6 DATA INTEGRITY

Accurate, complete, attributable and traceable records



ASSURED INPUTS

MEANINGFUL TRENDS

BETTER DECISIONS

THREE PRINCIPLES FOR EFFECTIVE EM TRENDING

From scientifically sound results to earlier, risk-based action



RELIABLE RESULTS COME FIRST

Sound media selection, incubation, growth promotion and controlled methods create data that can be trusted.

DIGITALISATION STRENGTHENS THE PROCESS

Connected workflows improve traceability, reduce manual handling and make information available for analysis.

INSIGHT DRIVES ACTION

Meaningful trending helps recognise emerging risk earlier and supports more confident contamination-control decisions.



PIONEERING DIAGNOSTICS