

BIOBURDEN INTENSITY

An Integrated Approach to EM Data Trending

Lilly

Conventional Data Analysis

SEVERITY

DEFINITION:

The measured **magnitude** of an event.

Ex: CFU recovered from an environmental monitoring sample.

- ◇ CFU
- ◇ # ≥ Alert Limit
- ◇ # ≥ Action Limit

DEFINITION:

The measured **frequency** of an event over time.

Ex: Positive (non-zero) recoveries, per samples collected, in a month.

- ◇ % Positive (Non-Zero) ◇
- ◇ % ≥ Alert ◇
- ◇ % ≥ Action ◇

DISTRIBUTION

Conventional Data Analysis

SEVERITY

DEFINITION:

The measured **magnitude** of an event.

Ex: CFU recovered from an environmental monitoring sample.

◇ CFU

◇ # ≥ Alert Limit

◇ # ≥ Action Limit

Separating trends vs. "noise"

No surveillance of results that are "below the line"

CHALLENGES

DEFINITION:

The measured **frequency** of an event over time.

Ex: Positive (non-zero) recoveries, per samples collected, in a month.

% Positive (Non-Zero) ◇

% ≥ Alert ◇

% ≥ Action ◇

DISTRIBUTION

Conventional Data Analysis

SEVERITY

DEFINITION:

The measured magnitude of an event.

Ex: CFU recovered from an environmental monitoring sample.

- ◇ CFU
- ◇ # ≥ Alert Limit
- ◇ # ≥ Action Limit

TREND

How Do We Get Here?

DEFINITION:

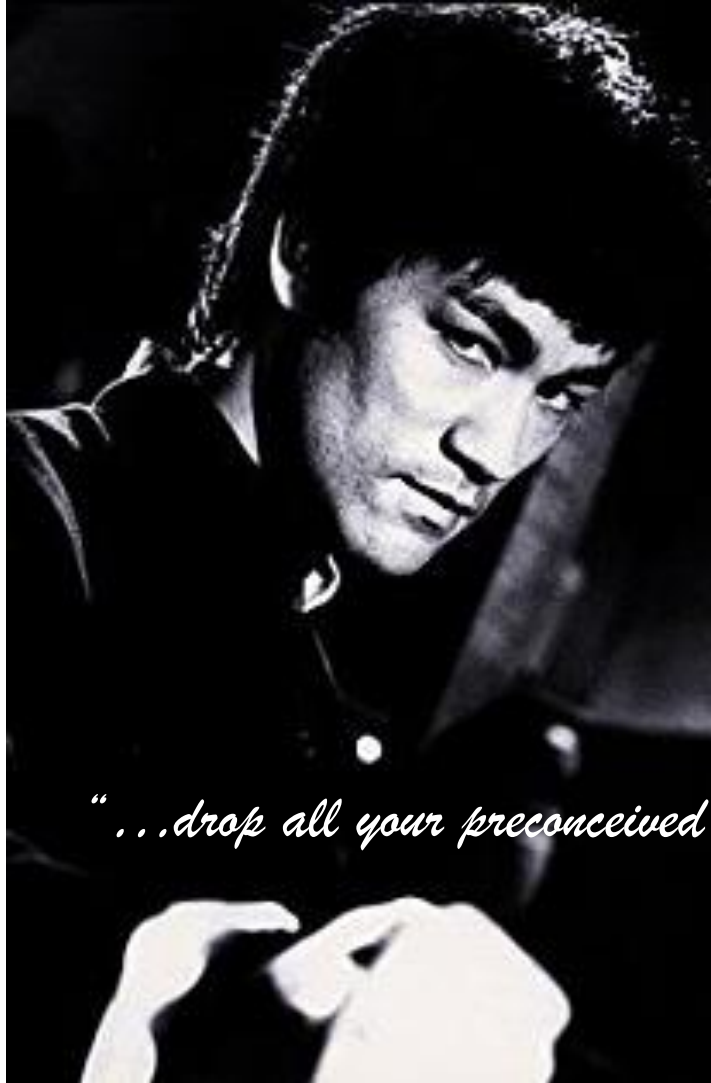
The measured frequency of an event over time.

Ex: Positive (non-zero) recoveries, per samples collected, in a month.

- ◇ % Positive (Non-Zero)
- ◇ % ≥ Alert
- ◇ % ≥ Action

DISTRIBUTION

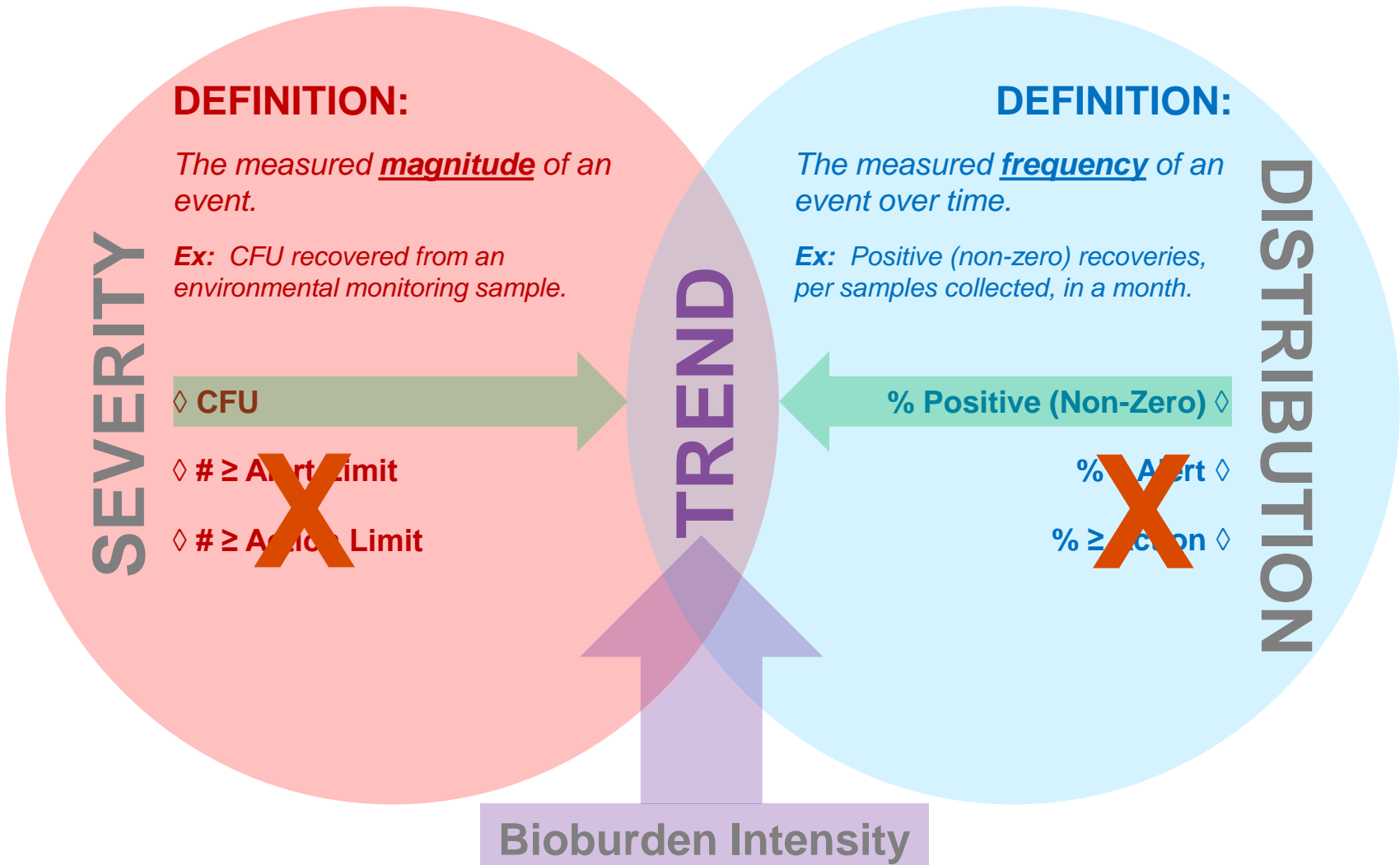
A different perspective....



"...drop all your preconceived and fixed ideas and be neutral."

- Bruce Lee

An Integrated Approach



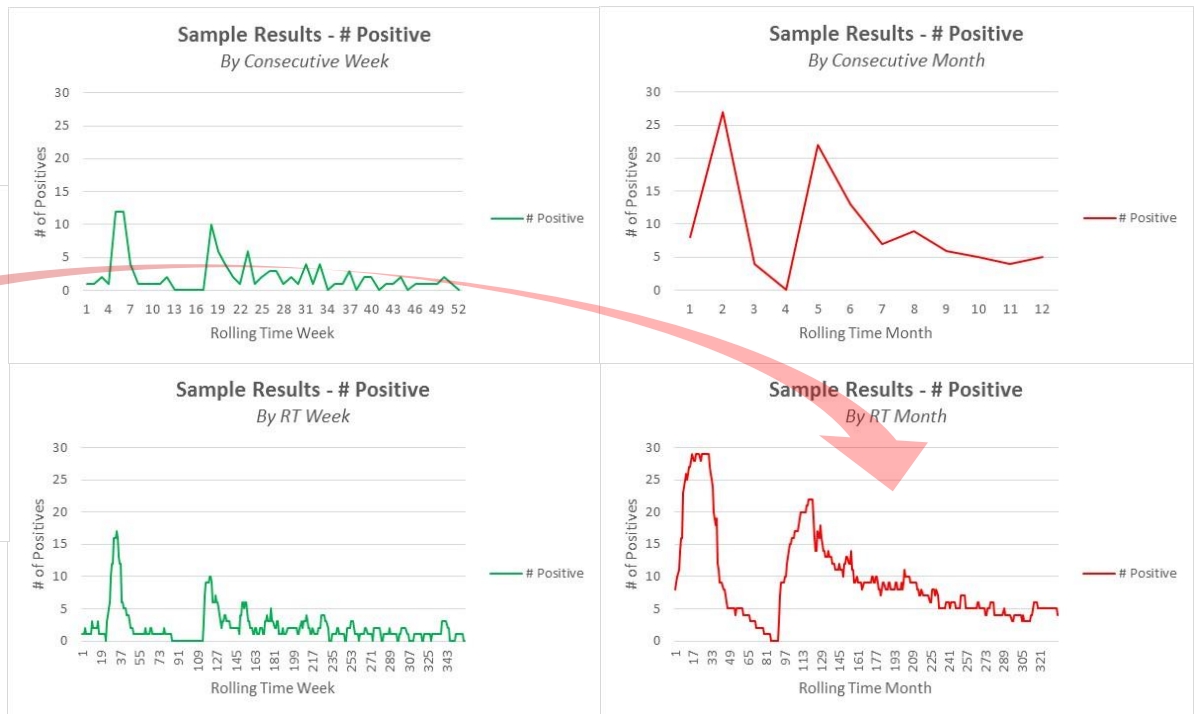
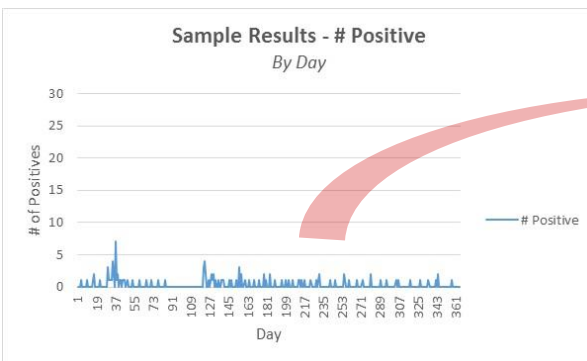
Consecutive vs. Rolling-Time Analysis

SIMULATED EM DATA SET

- ◆ 1 year
- ◆ 347,076 samples
- ◆ 9 out-of-alerts results
- ◆ 13 out-of-action results
- ◆ 110 total positive results

Consecutive Analysis = chronological tabulation of data in equal segments, where each segment begins where the previous ends (e.g., Weekly = Days 1-7, 8-14, 15-21, etc.)

Rolling-Time Analysis = chronological tabulation of data in equal segments, where each segment overlaps the previous segment by equal amounts (e.g., Weekly = Days 1-7, 2-8, 3-9, etc.)



Consecutive → Rolling-Time; resolution improves

Week → Month; “peaks” and “valleys” smooth out – trends more apparent

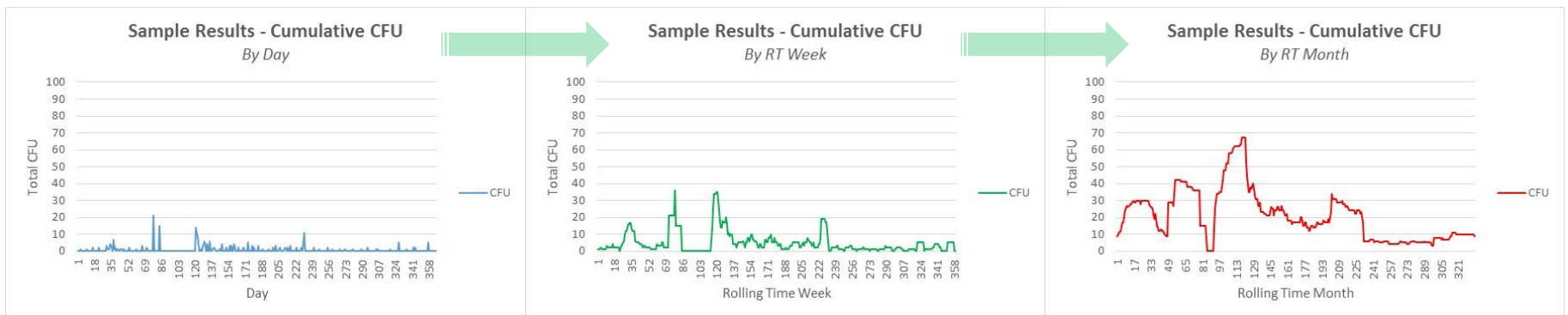
Rolling-Time Cumulative CFU Analysis

SIMULATED EM DATA SET

- ◆ 1 year
- ◆ 347,076 samples
- ◆ 9 out-of-alerts results
- ◆ 13 out-of-action results
- ◆ 110 total positive results

WORKING DEFINITION:

Chronological tabulation of the accumulated CFU in defined rolling-time periods



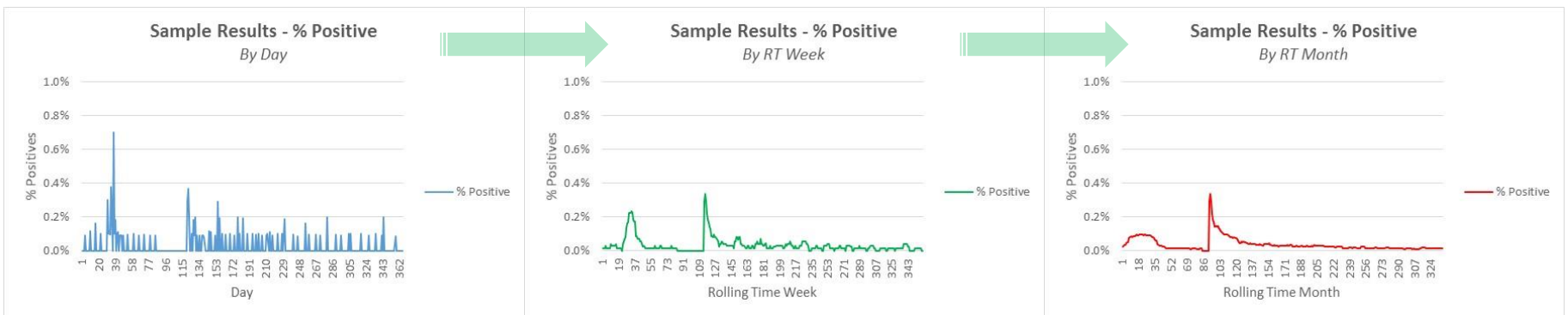
Rolling-Time Percent Recovery Analysis

SIMULATED EM DATA SET

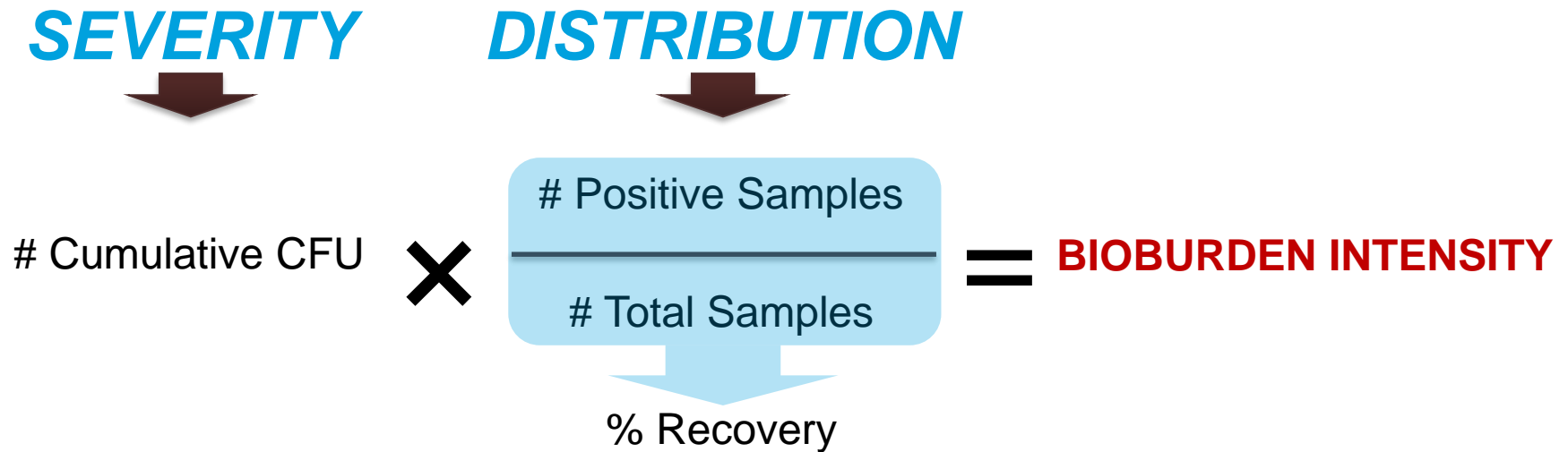
- ◆ 1 year
- ◆ 347,076 samples
- ◆ 9 out-of-alerts results
- ◆ 13 out-of-action results
- ◆ 110 total positive results

WORKING DEFINITION:

Chronological tabulation of the relative frequency of non-zero recoveries in defined rolling-time periods



Bioburden Intensity

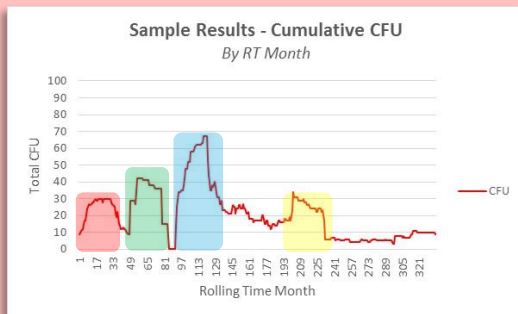


- ◆ **Integrated dual measure of microbiological control in an environment:**
 1. Relative frequency of non-zero recoveries
 2. Cumulative ingress of microbiological contamination
- ◆ **Advantages:**
 - Identify trends in data earlier
 - “Leading indicator” of bioburden ingress into a classified area
- ◆ **Limitations:**
 - Low recovery levels and frequencies in Grade A areas do not lend well to this analysis

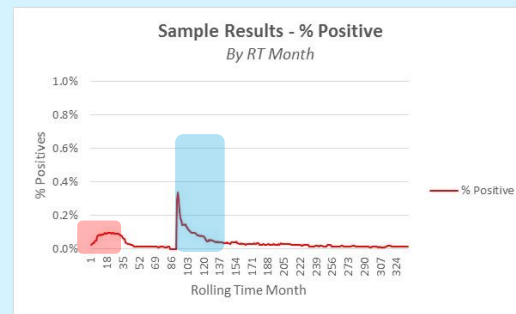
Bioburden Intensity

SEVERITY

HOW MUCH?

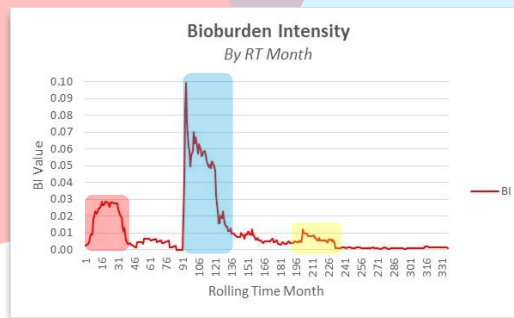


HOW OFTEN?

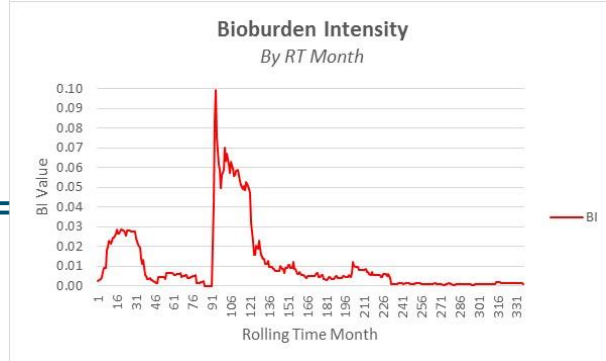
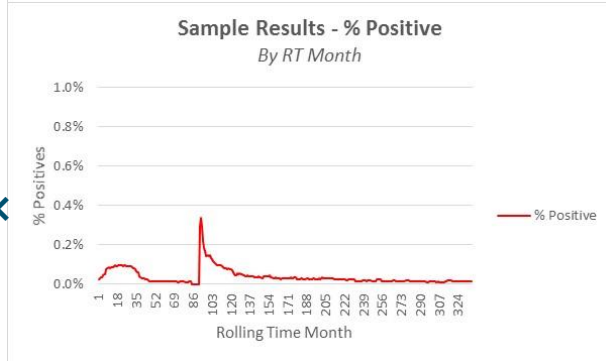
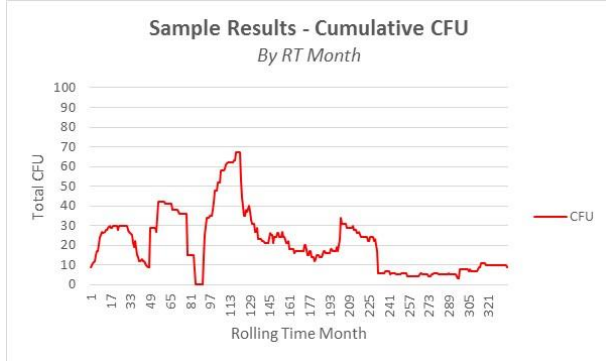
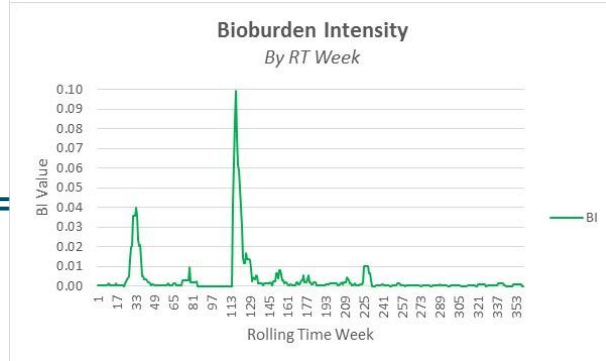
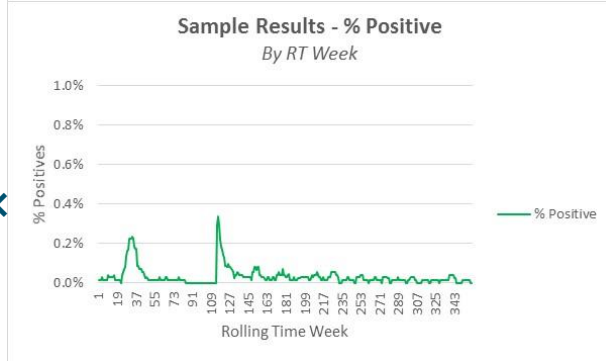
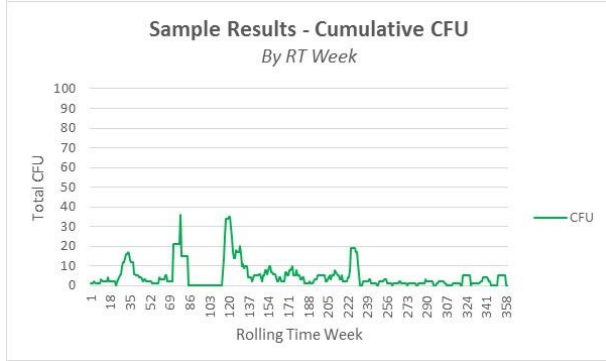
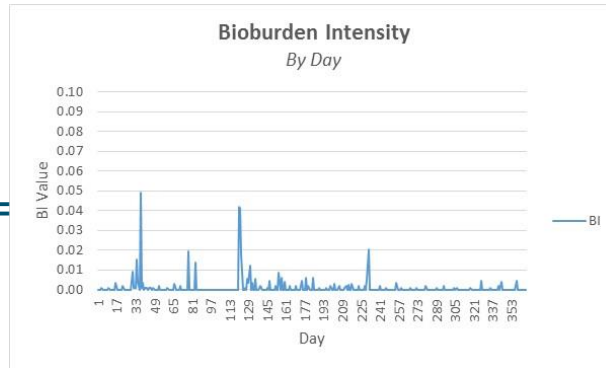
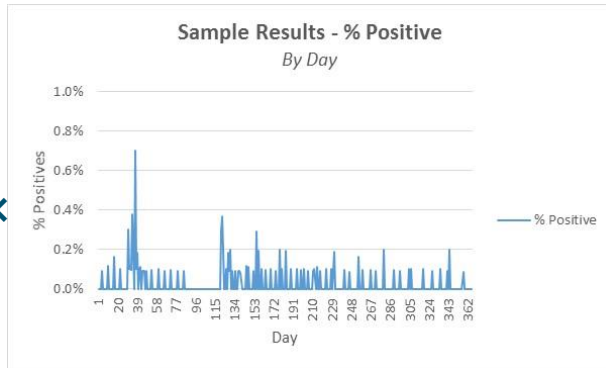
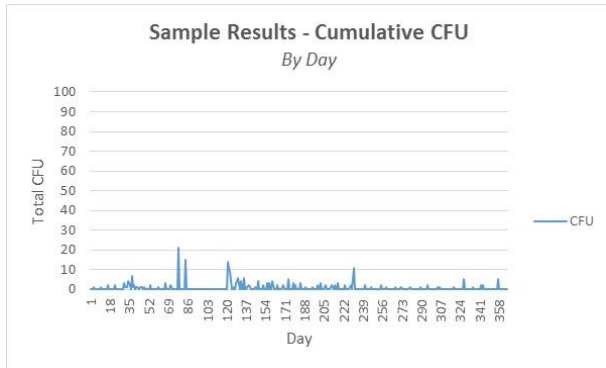


DISTRIBUTION

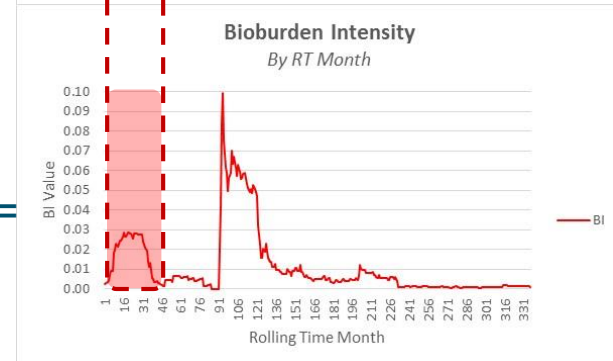
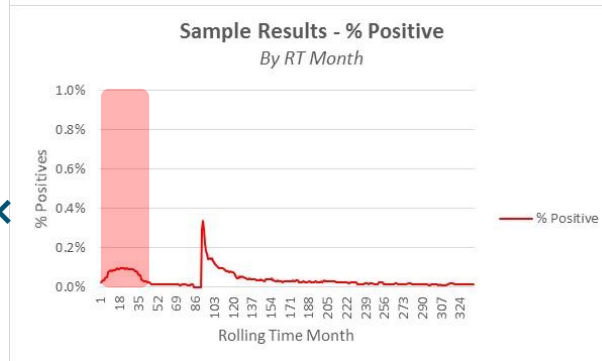
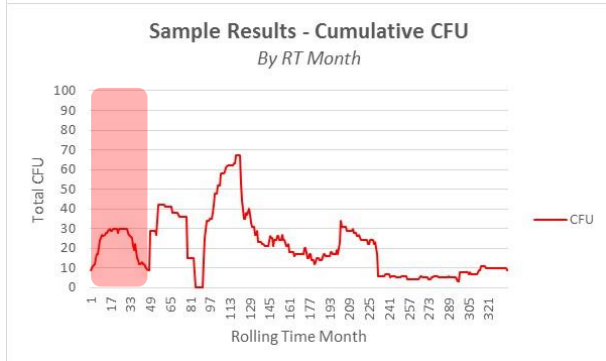
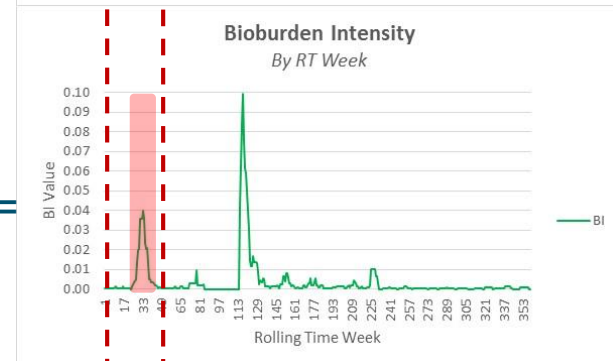
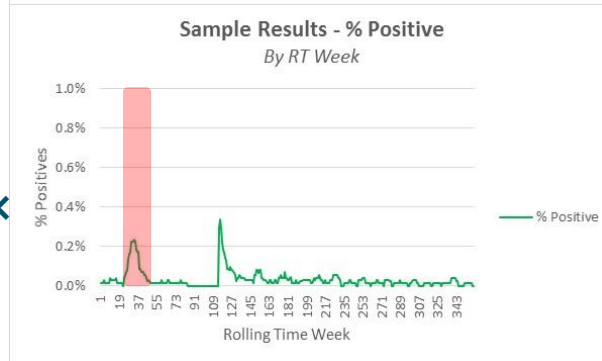
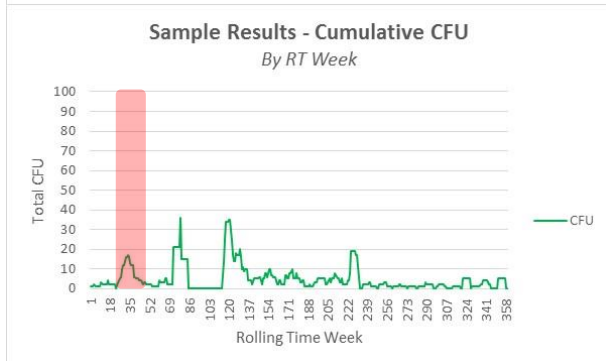
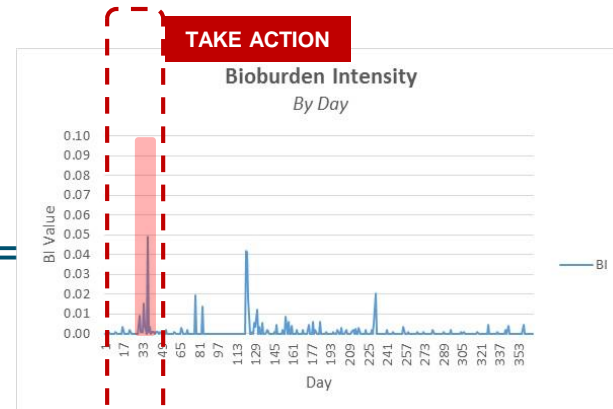
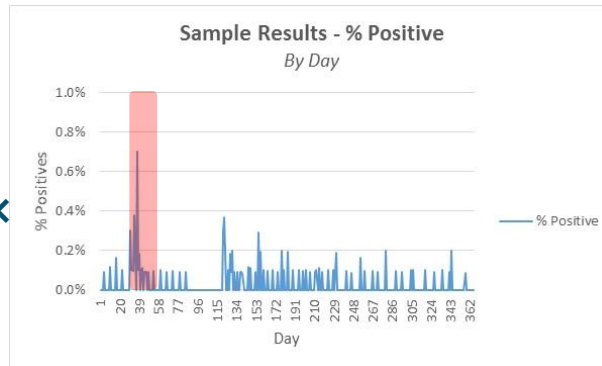
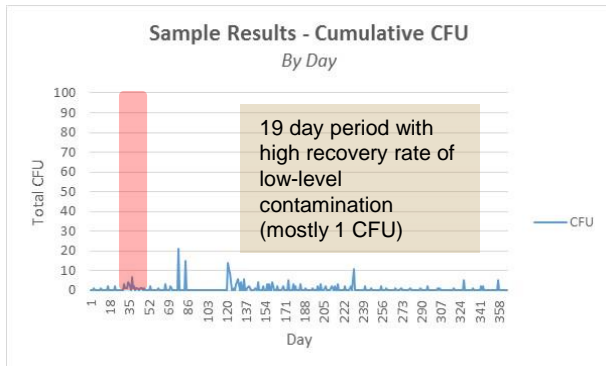
WHEN DO I REACT?



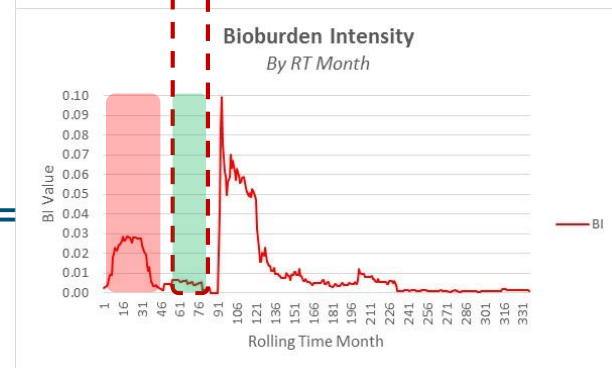
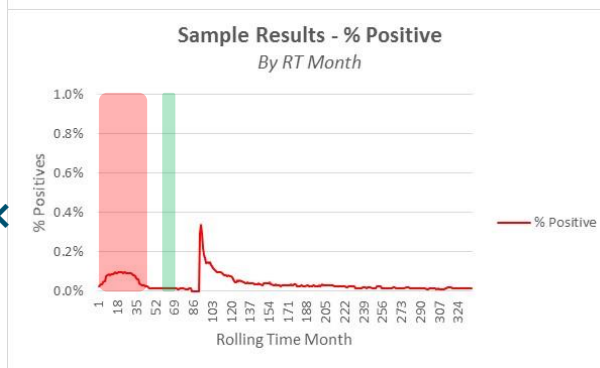
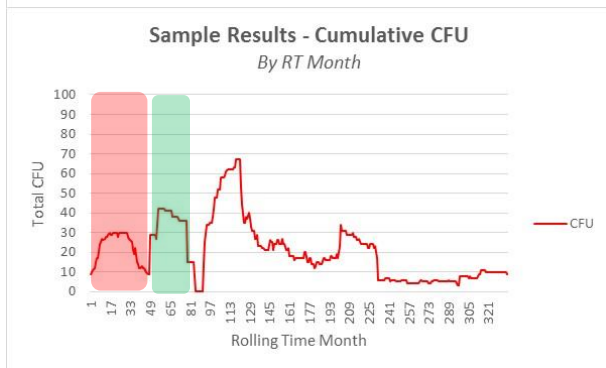
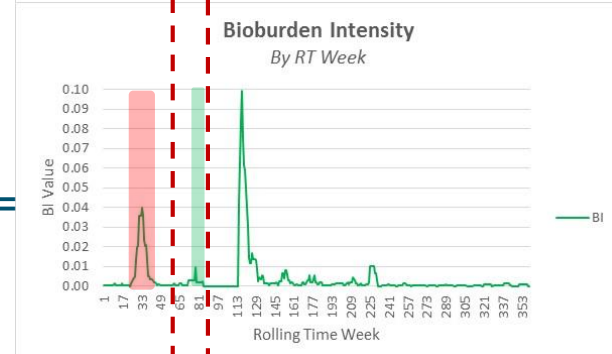
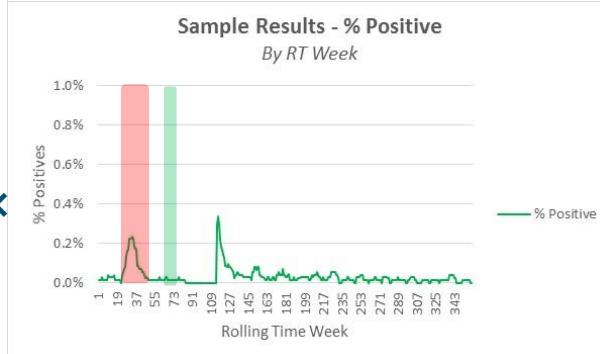
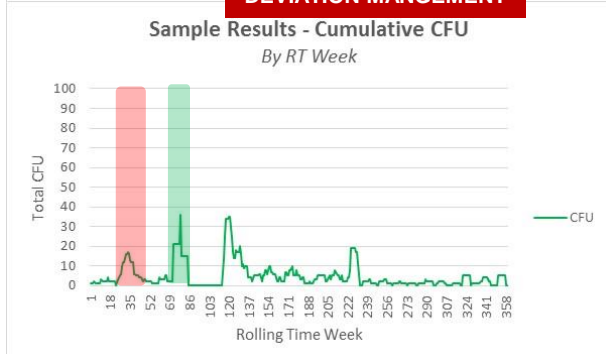
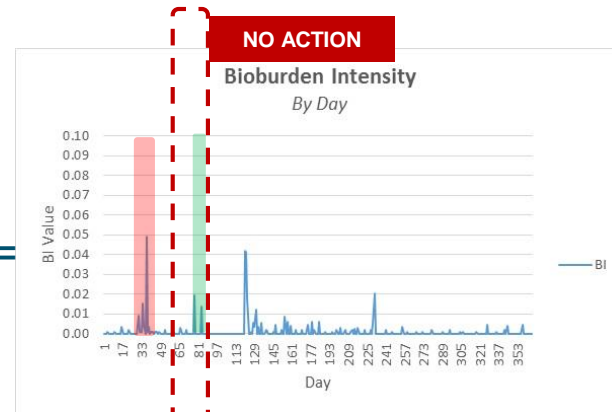
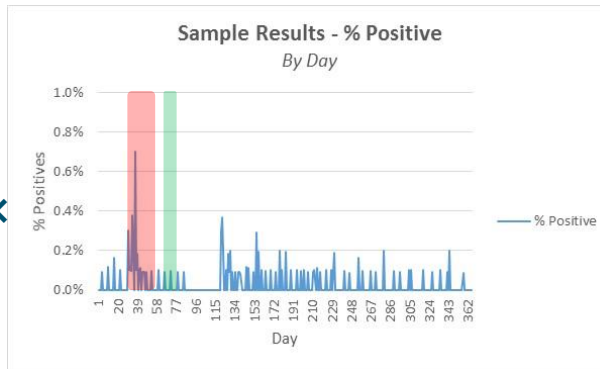
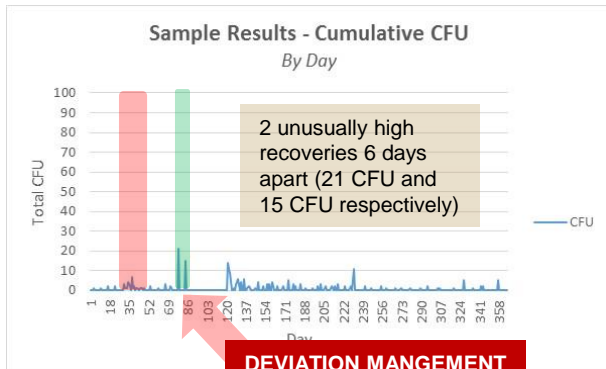
Simulated Case Studies



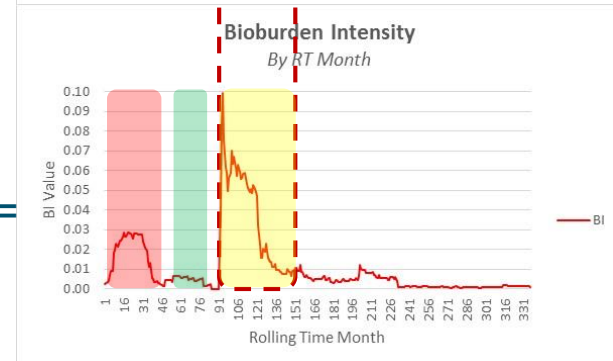
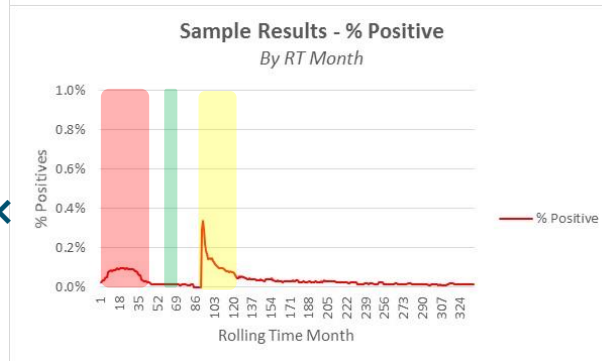
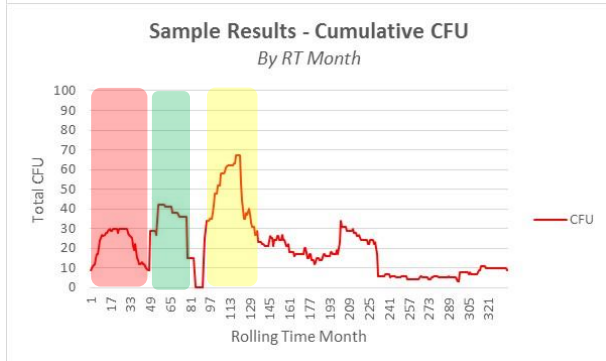
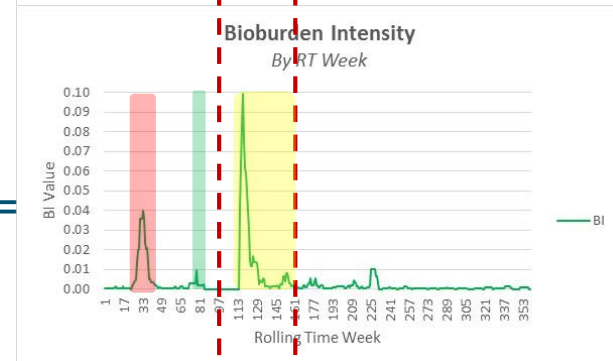
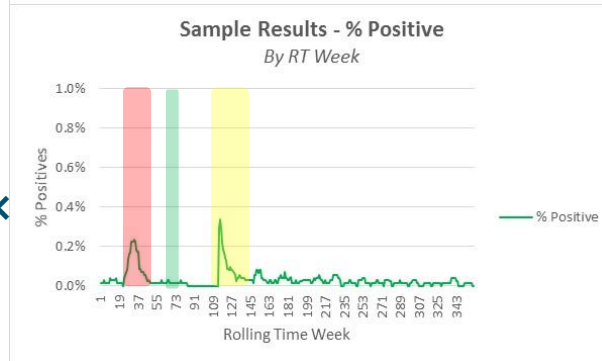
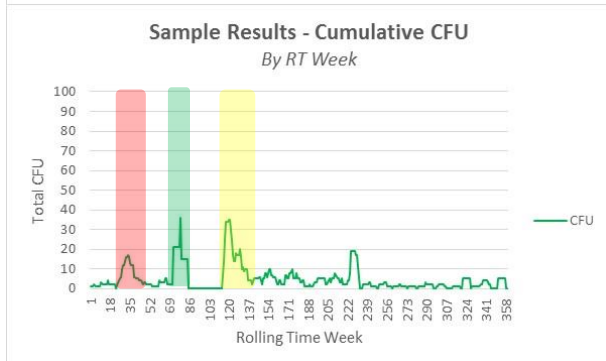
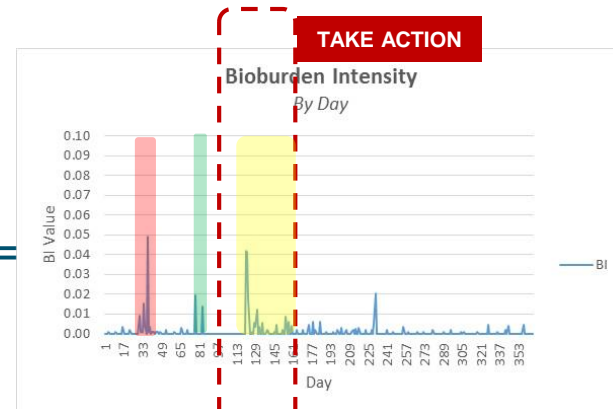
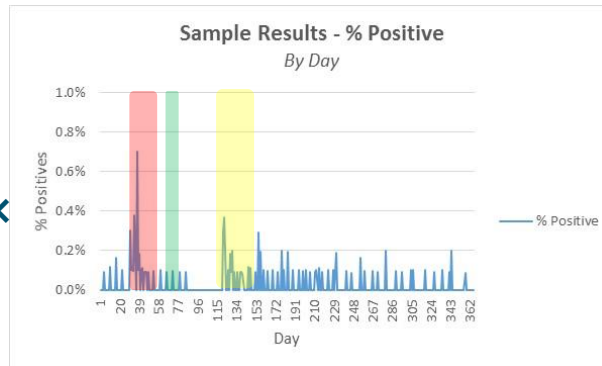
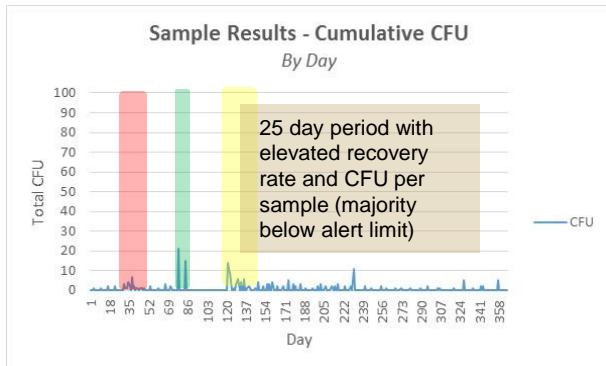
Case Study – Simulation #1



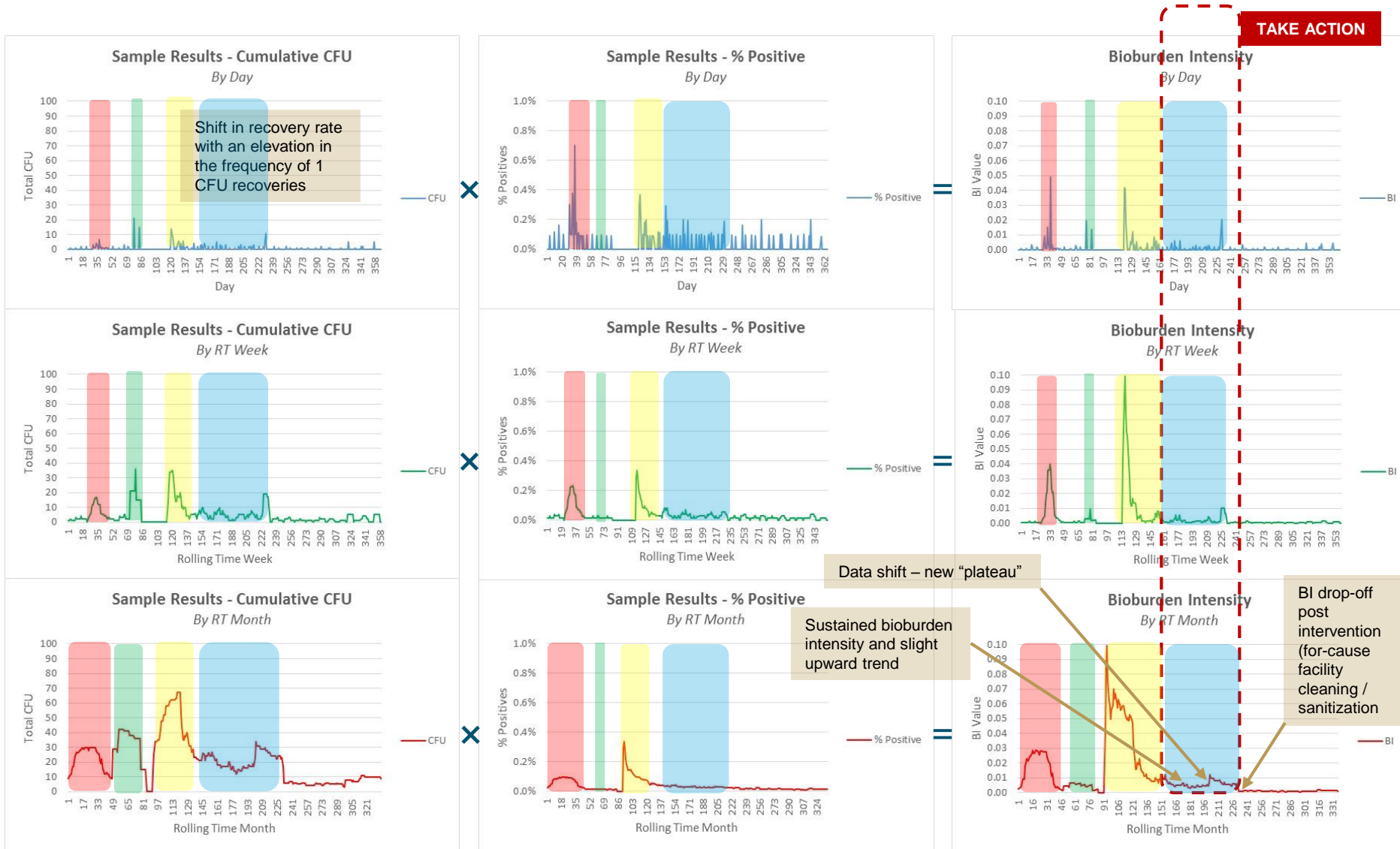
Case Study – Simulation #2



Case Study – Simulation #3



Case Study – Simulation #4



Conclusions

Applications

- Data visualization tool for quickly assessing microbiological control
- Grade B and C classified spaces
- Routine (e.g., daily) trend monitoring
 - Early indicator of shifts in state-of-control
 - Drive proactive mitigation before significant system upsets occur
 - Statistical limits can be established
 - Analysis can be automated

Limitations

- Grade A classified spaces
 - Insufficient recovery severity and frequency
- Grade D classified spaces
 - Insufficient sampling frequency
- **DOES NOT** replace the need to react to individual OOS results
- **DOES NOT** replace the judgement of a qualified microbiologist

Questions & Answers

