Real-time Microbiological Air Sampling in Cleanrooms

Fluorescence-based viable particle detection

TSI Inc. Model 9510-BD
BioTrak® Real-time viable particle counter

Simon Tebb
TSI Instruments

UNDERSTANDING, ACCELERATED

Laser Induced Fluorescence:
What is fluorescence?

Glowing Gin and Tonic…

Laser Induced Fluorescence:
What is fluorescence?

Glowing Gin and Tonic…

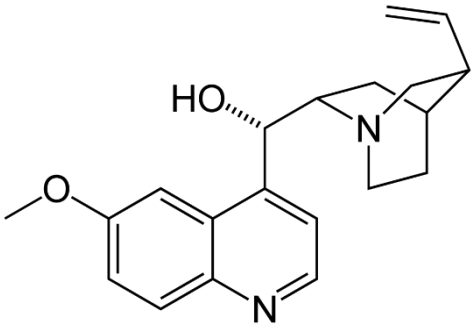
Tonic

Laser Induced Fluorescence:
What is fluorescence?

Glowing Gin and Tonic…

Tonic

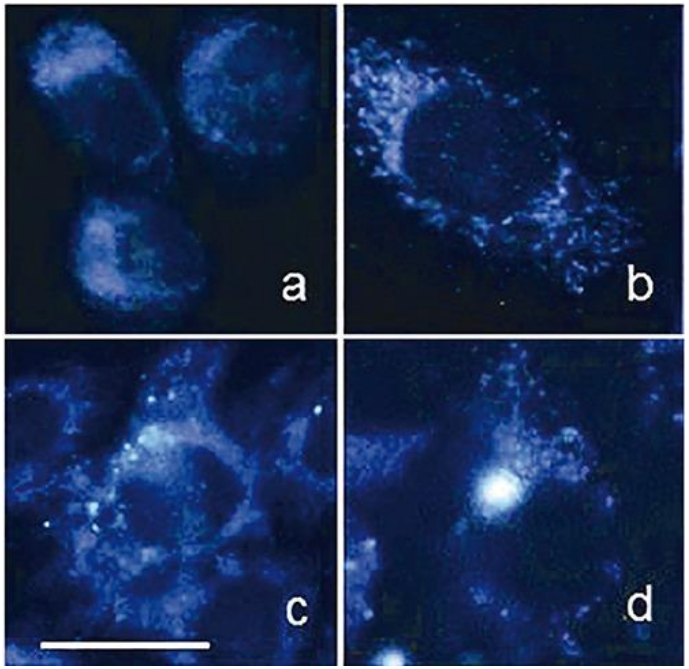
Quinine



Specific molecules fluoresce

Laser Induced Fluorescence:
What is Auto-fluorescence?

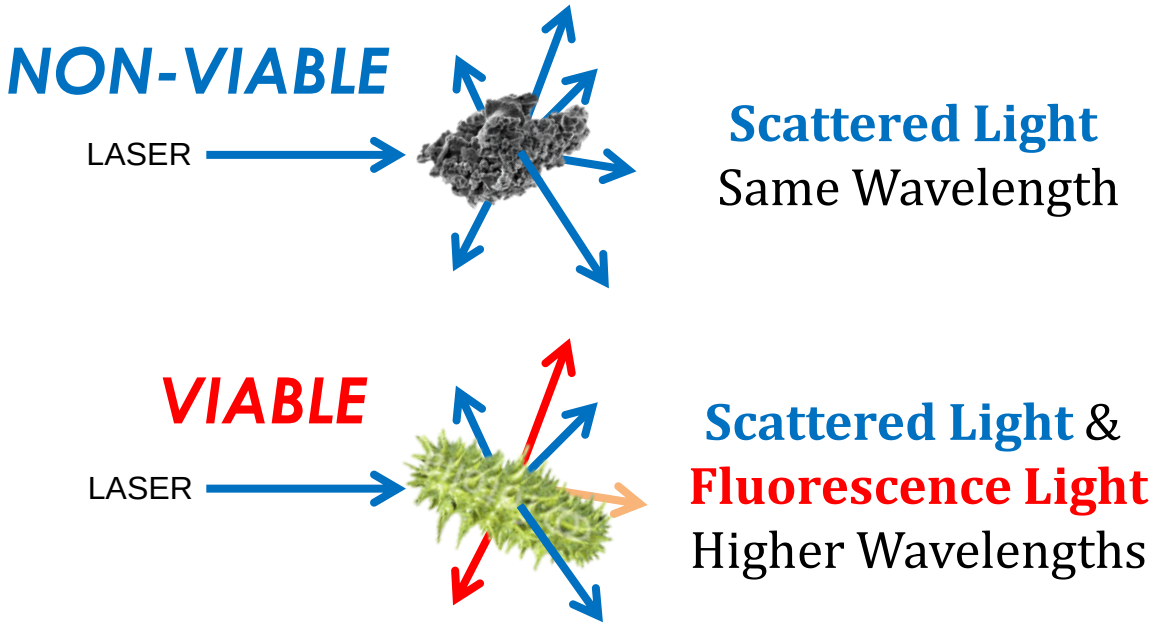
Cells naturally fluoresce!



Contain many fluorescent molecules!

Molecule	Approximate Peak Fluorescence (nm)
NAD(P)H	450
Retinol	500
Riboflavin	550
Folic acid	450
Pyridoxine	400
Tyrosine	305
Tryptophan	325
Flavin	540

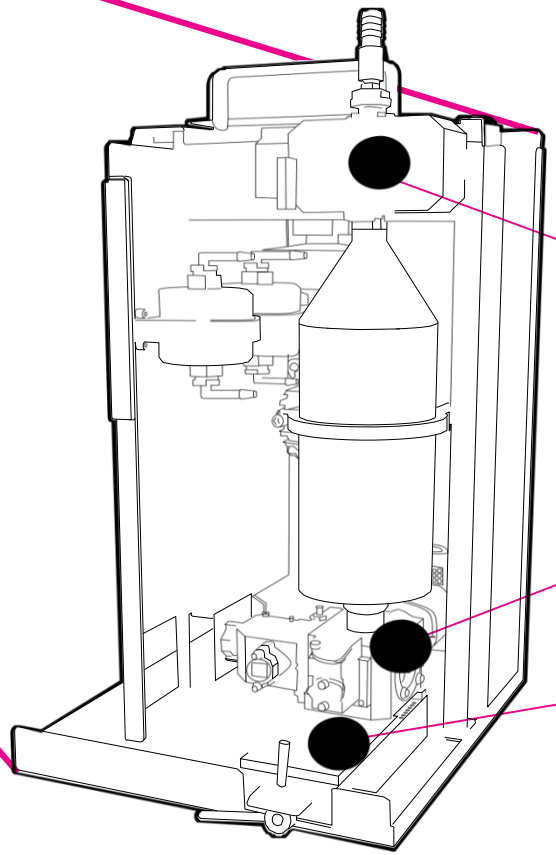
Laser Induced Fluorescence:
Third Component: Size



Each particle:

- Scattered light intensity (size)
- Fluorescent light intensity (2 bands)

BIOTRAK®: Features & Operation



THREE INSTRUMENTS IN ONE

TOTAL PARTICLES
VIABLE PARTILCES
MICROBIAL COLLECTION

Airborne Particle Counter (LSAPC)

Viability Detector

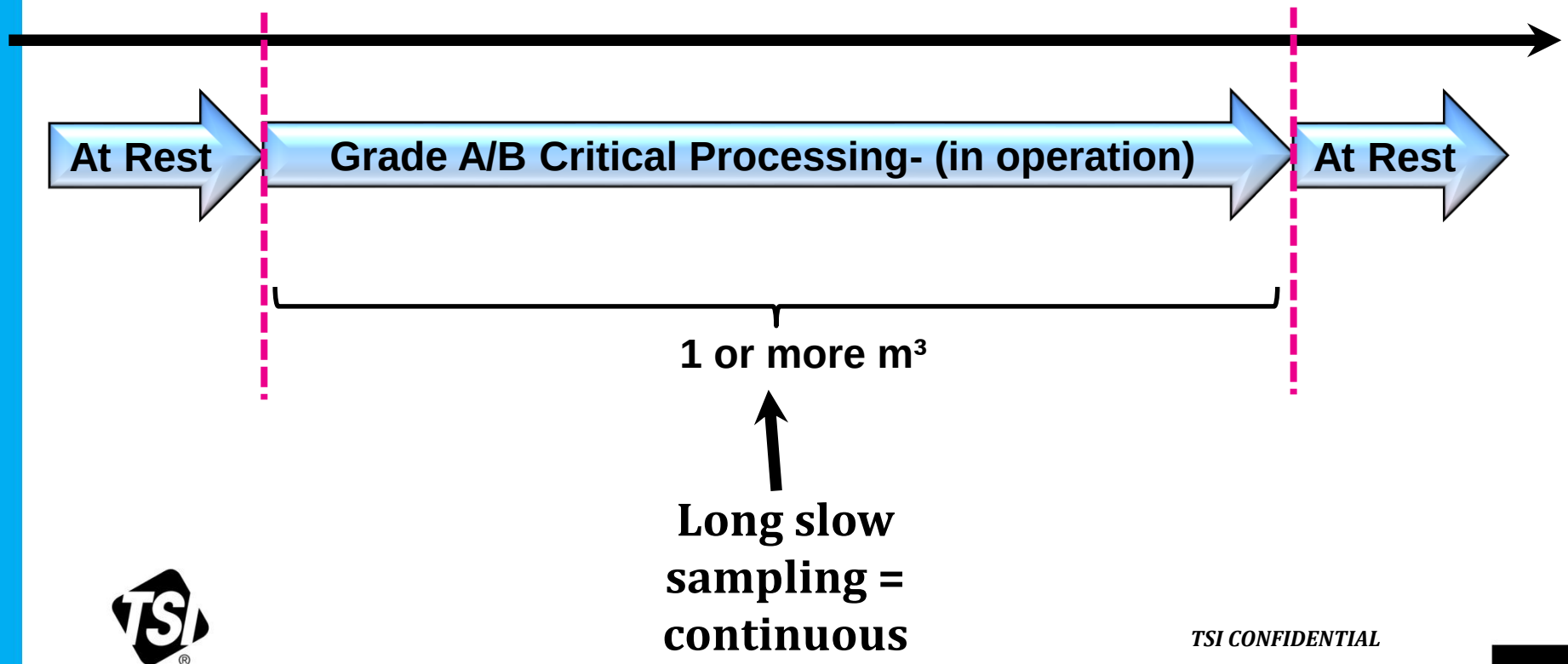
Particle Collection

Laser Induced Fluorescence: Fundamental Truths

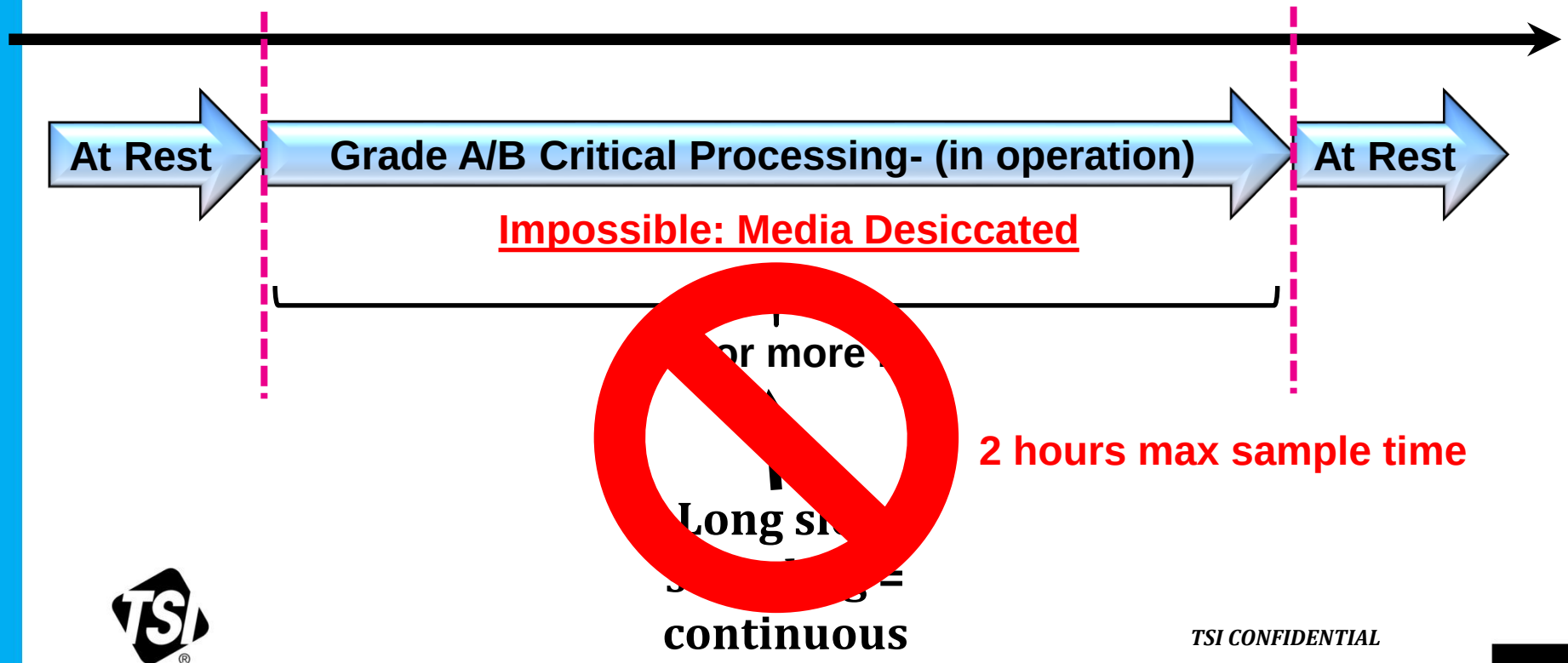
+ Laser Induced Fluorescence detects particles that have optical characteristics consistent with a microorganism.

+ Laser Induced Fluorescence:
  - Does not always correlate with CFU
  - More sensitive than CFU
  - Detects more viable but not cultureable
  - Detects some interferents

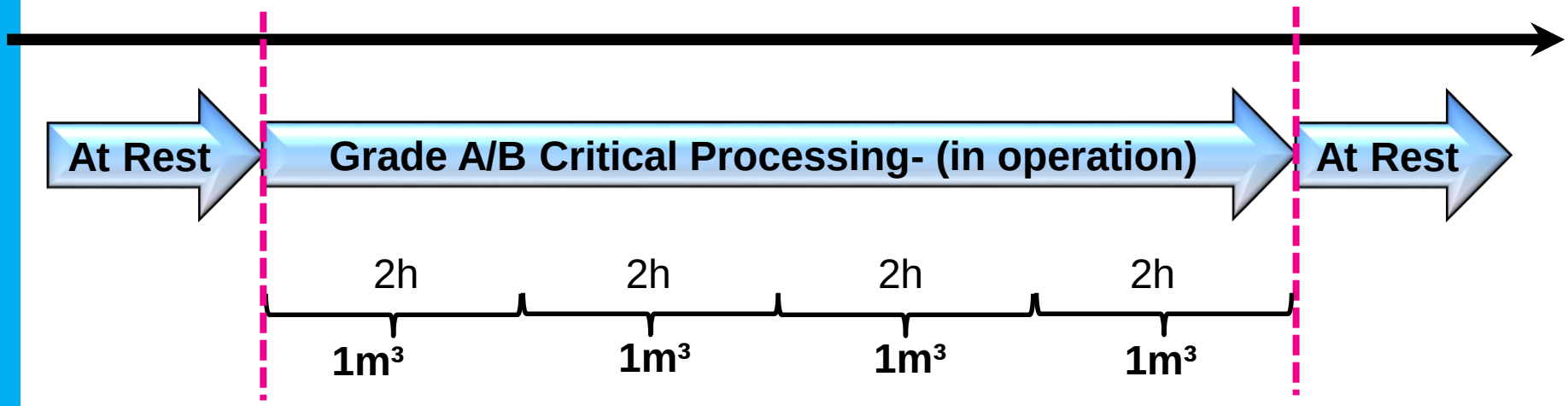
Microbial sampling:
Continuous throughout process



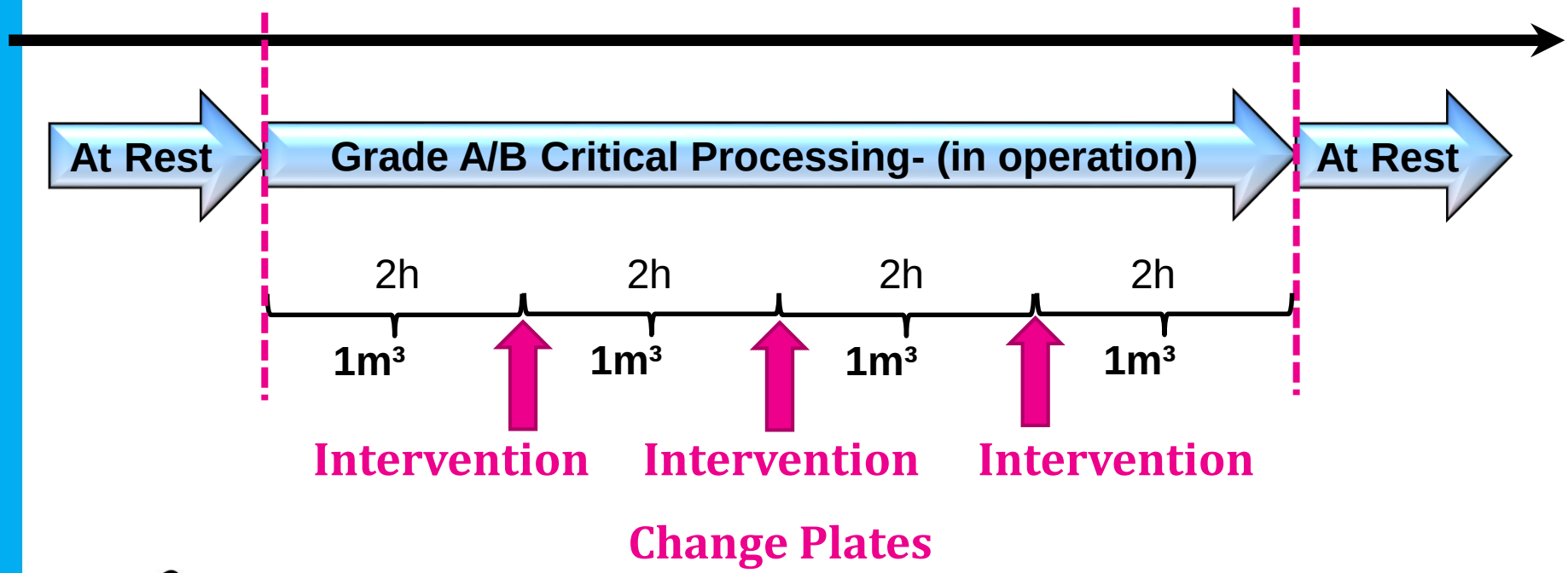
Microbial sampling:
Continuous throughout process



Microbial sampling:
Continuous throughout process



Microbial sampling:
Continuous throughout process



Intervention Costs

Project in NA: 2 lines, 12 points

+ Every 2 hours (run 24hrs Mon-Fri)
  - 20 min downtime (stopped the line)
  - 100 open vials wasted
  - 1 liter product flushed to mitigate needle clogging

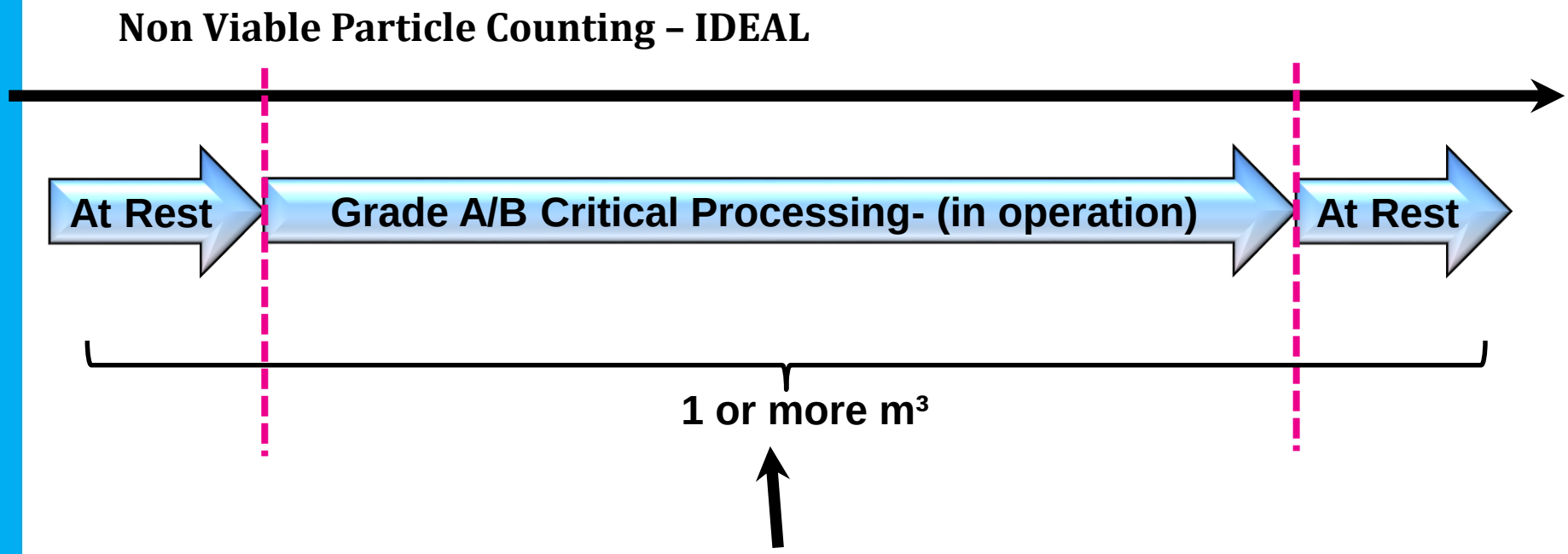
Intervention Costs

Project in NA: 2 lines, 12 points

+ Every 2 hours (run 24hrs Mon-Fri)
  - 20 min downtime (stopped the line)
  - 100 open vials wasted
  - 1 liter product flushed to mitigate needle clogging

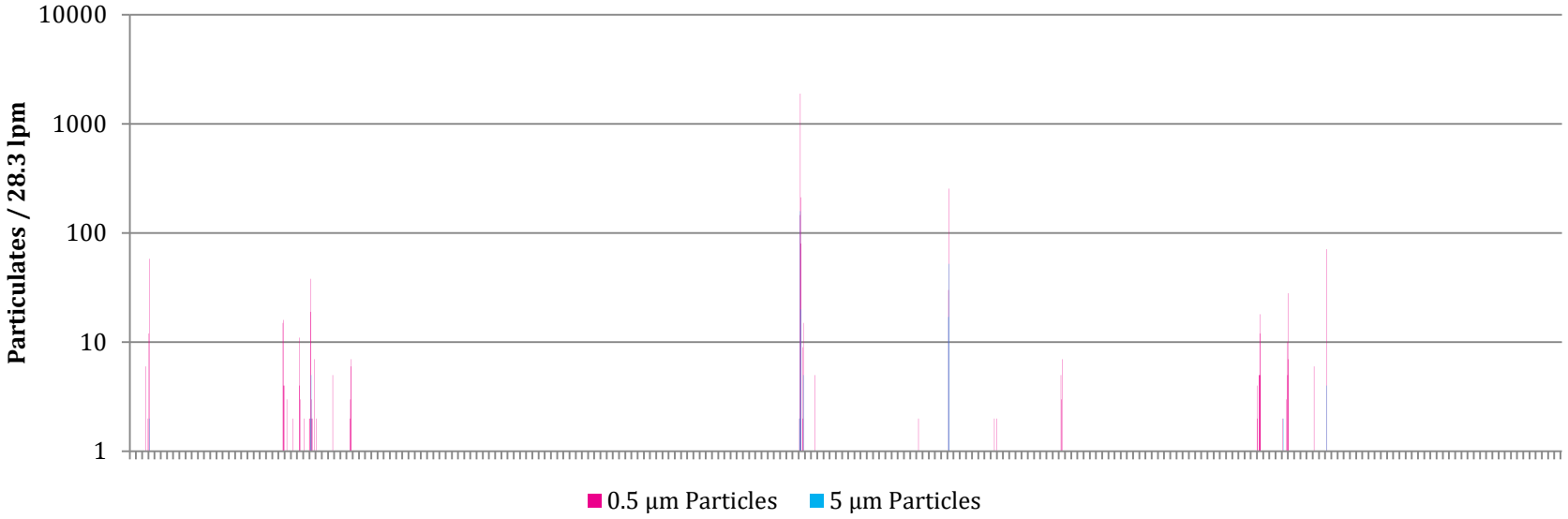
+ Every year (2 lines)
  - 6,240 interventions
  - 37,440 agar plates processed
  - 86 **days** of downtime
  - 6.8 million vials of product wasted

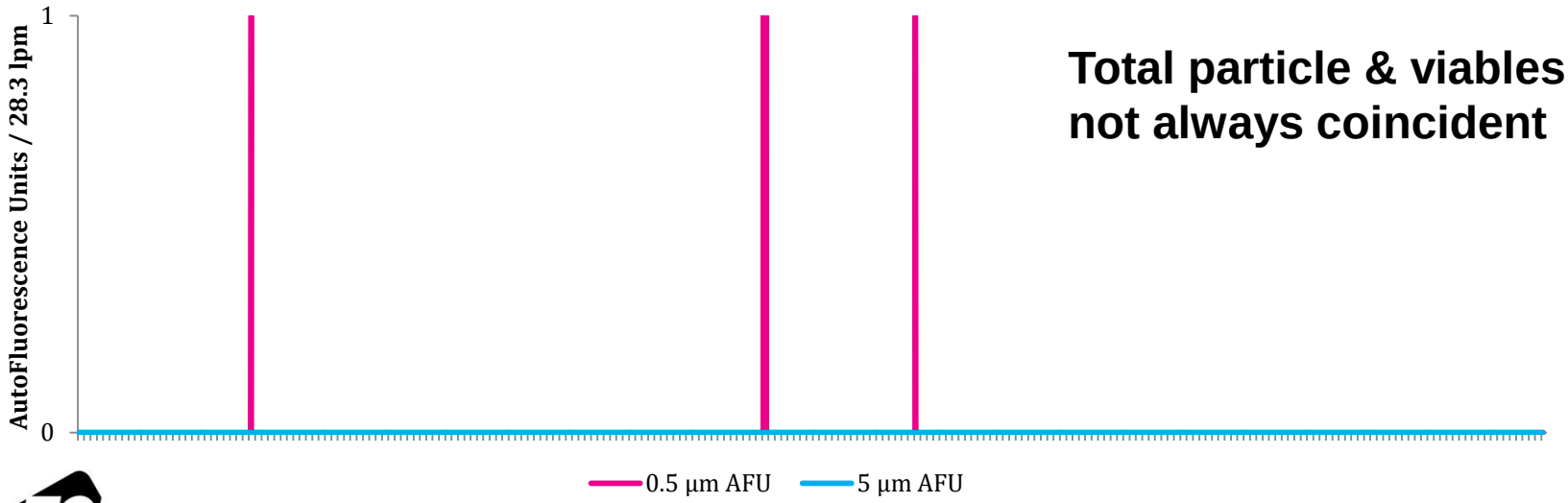
Microbial sampling:
Continuous throughout process



LIF allows continuous monitoring with
ZERO INTERVENTIONS
****Proactive risk mitigation****

Inert Particles
(Traditional active air particle counting)





Total particle & viables not always coincident

Adapted from: Jeff Weber, Pfizer

Thank you

PMT
www.pmt-ag.ch