Environmental Monitoring Airborne Testing Equipment

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Airborne Microbiological Testing Equipment

- **Active Viable Air Monitoring**
  - Methods for sampling air in production areas for microbial content
  - Samples a defined volume of air with units in cubic feet, cubic meters or liters
  - Results defined as CFU/Volume of air
  - Samples represent overall filling operations
  - Required by all Regulatory Agencies

Airborne Microbiological Testing Equipment

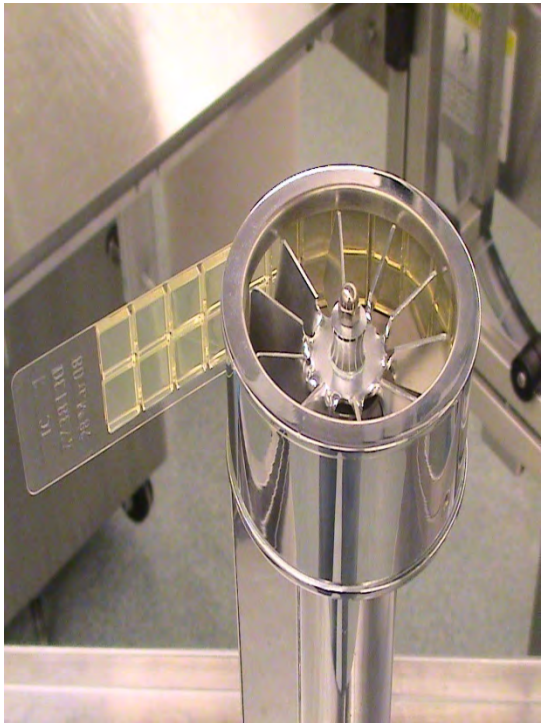
- **Types Active Air Monitoring Systems**
  - Centrifugal
  - Slit to Agar
  - Sieve Samplers
  - Filtration
  - Liquid Impingement

Airborne Microbiological Testing Equipment

- **Centrifugal Impaction Samplers**
  - A agar strip is fed into the sampling head
  - Air is drawn into the top of the unite by means of an impeller
  - The air is rotated around the sampling head and the organisms are deposited onto a agar strip by centrifugal force
  - Results are defined in liters or ft^3

Airborne Microbiological Centrifugal Impaction Sampler

- **Centrifugal Impaction Samplers**



Standard RCS

Airborne Microbiological Centrifugal Impaction Sampler

- **Centrifugal Impaction Samplers**

RSC High Flow

Airborne Microbiological Centrifugal Impaction Sampler

- **Advantages**
  - Light weight, easy to use and fast.
  - Self-contained power supply.
  - Remote start/stop.
  - Head assembly can be sterilized
  - Can measure a large volume of air.
  - Various sampling configurations

- **Disadvantages**
  - A fixed calibrated vacuum source is required at each site
  - Not recommended for areas with high microbial concentrations
  - System must be manually started and stopped
  - Vacuum tubing should be autoclaved and changed periodically

Active Viable Air Monitoring Centrifugal Impaction Sampler

- **Centrifugal Impaction Manufacturers**
  - BioTest: Reuters Centrifugal Sampler, RCS

Active Viable Air Monitoring Slit to Agar Sampler

- **Slit Slit-To-Agar (STA)**
  - Composed of a stationary sampling head and a revolving base which the agar plate is placed
  - As the sample plate rotates, the air is pulled through the slit and microorganisms are deposited on the agar surface
  - Distance from the sample head slit to the agar surface is a defined distance

Active Viable Air Monitoring Slit to Agar Sampler

- Organism distribution is time/concentration dependent
- Time to complete a full rotation of the plate is typically 60 minutes
- May have a detachable sample head for remote sampling
- Uses a 100 mm or 150 mm plate
- Sample volume is usually measured in ft^3/minute

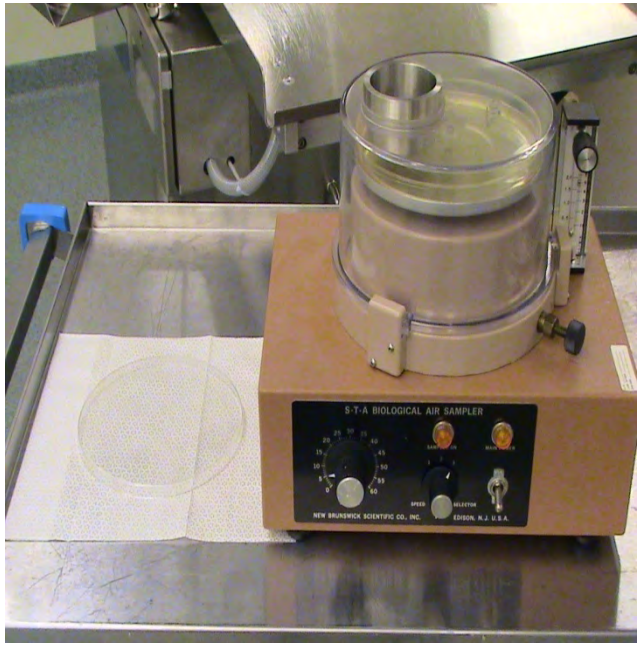
Active Viable Air Monitoring Slit to Agar Sampler

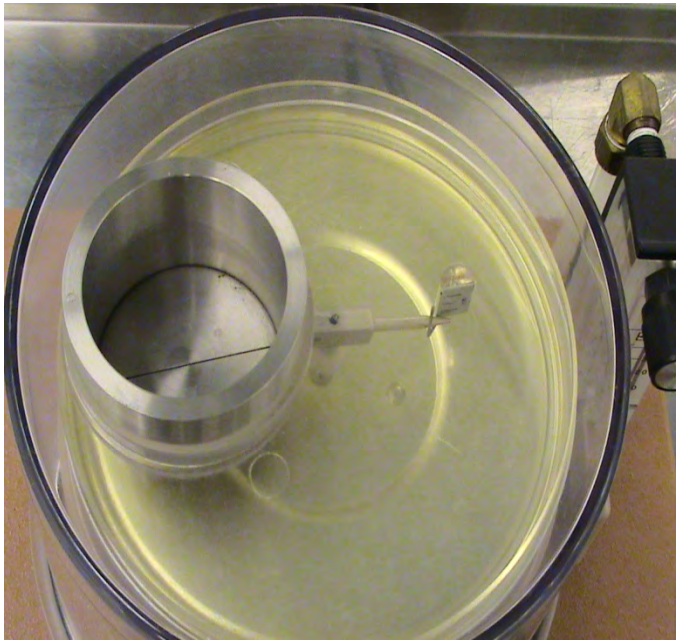
- **Slit Slit-To-Agar (STA)**

Matson Garvin

Active Viable Air Monitoring Slit to Agar Sampler

- **Slit Slit-To-Agar (STA)**

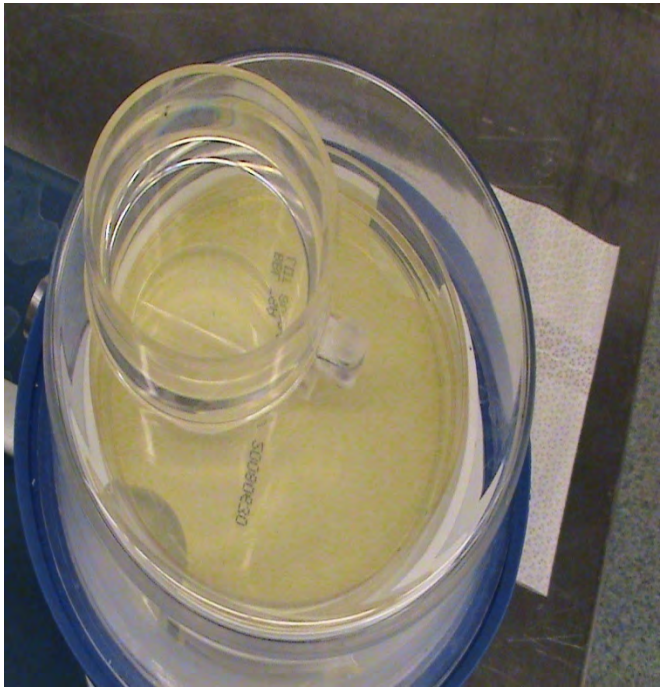




New Brunswick

Active Viable Air Monitoring Slit to Agar Sampler

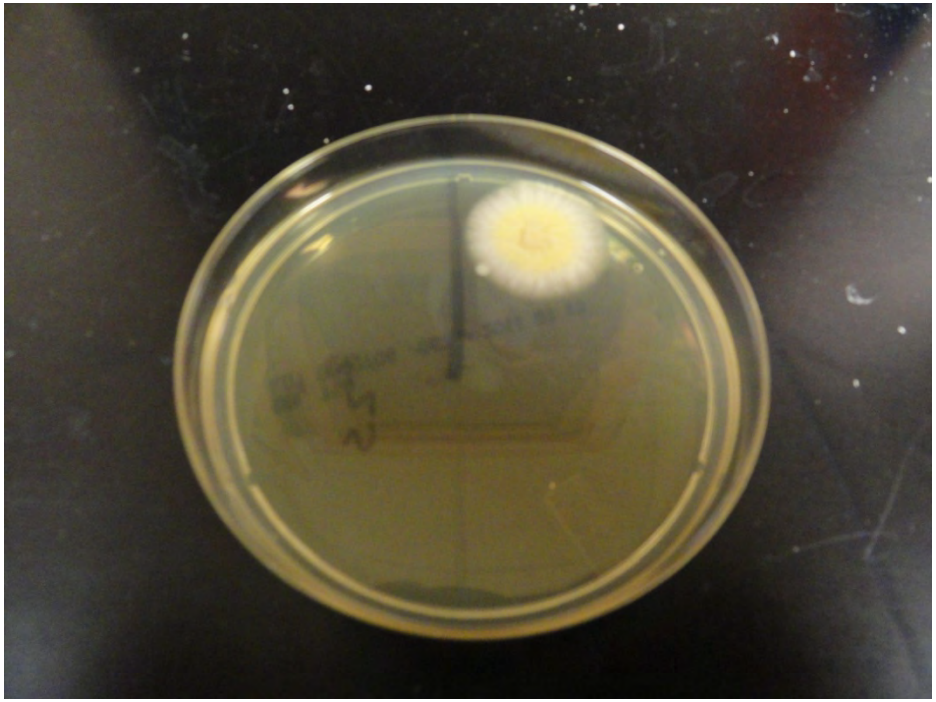
- **Slit Slit-To-Agar (STA)**



R2S

Active Viable Air Monitoring Slit to Agar Sampler

- **Slit Slit-To-Agar (STA)**



Results on TSA

Active Viable Air Monitoring Slit to Agar Sampler

- **Advantages**
  - CFU placement on the plate is correlated to the time sampled .
  - Measures volumes of up to 60 ft^3 .
  - Automatic timer with self contained vacuum source.
  - Can use remote probes .
  - Easy to set up and use .
  - Can be used for compressed gases.
- **Disadvantages**
  - The equipment is large and cumbersome.
  - Sample heads are sterilizable and body is surface sanitized.
  - Requires a power source
  - Exhaust air can disrupt critical air flow
  - Some systems use 150 mm agar plates
  - Remote Start/Stop not available

Active Viable Air Monitoring Slit to Agar Sampler

- **Slit Slit-To-Agar Manufacturers**
  - Mattson Garvin
  - New Brunswick
  - EM Technologies, R2S

Active Viable Air Monitoring Sieve Impaction Samplers

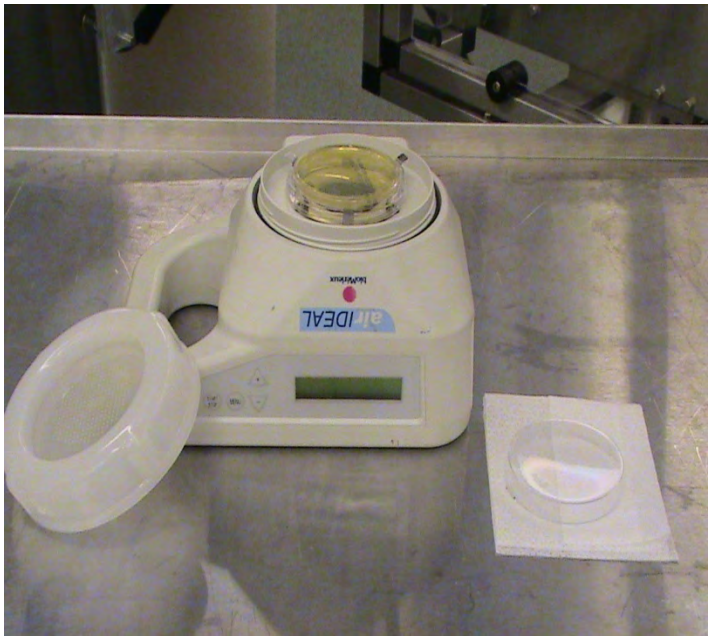
- **Portable Sieve Impaction Samplers**
  - The air is drawn through small holes in the sampling head using an impeller system
  - The organisms are impacted onto the agar surface and the air is exhausted
  - Uses RODAC or 100 mm sample plates
  - Most have a self-contained power supply
  - Organisms are relatively evenly distributed on the agar surface

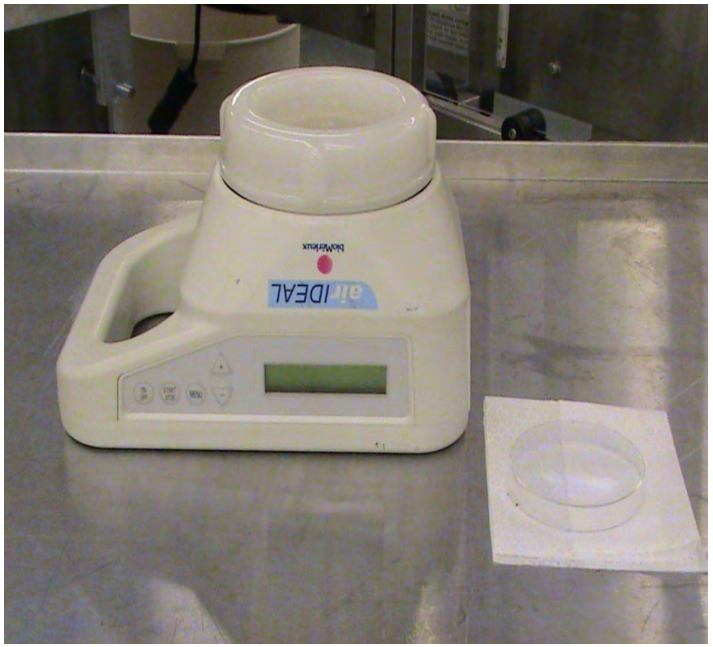
Active Viable Air Monitoring Sieve Impaction Samplers

- The size and number of holes are dependent on the manufacturer
- Some have delay start systems
- Many have down load capabilities
- Results are defined in terms of cubic feet, cubic meters or liters
- Internal and external areas can be sanitized with a sporicidal agent

Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Samplers**





Air Ideal

Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Air Ideal**

Results in TSA

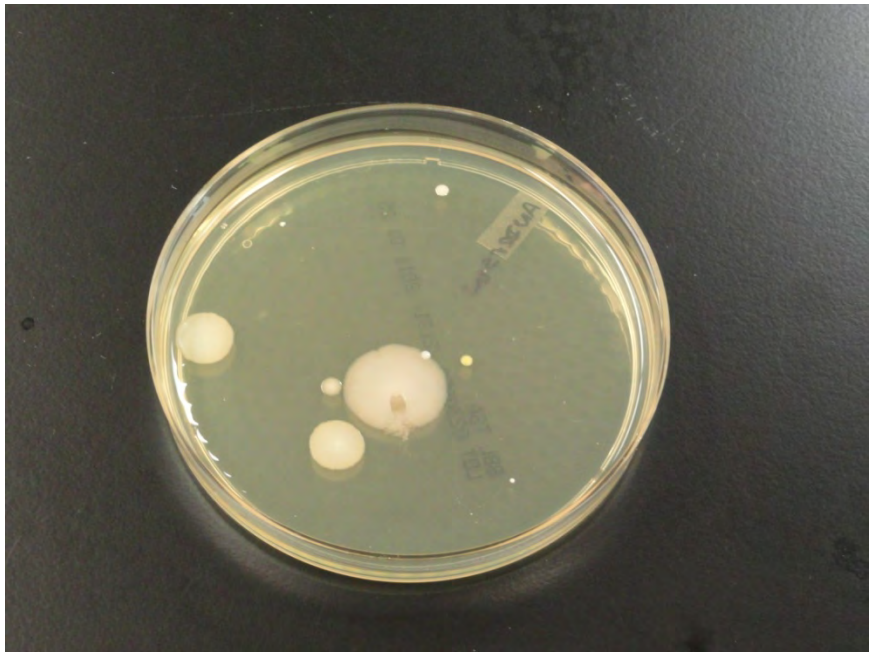
Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Samplers**

Anderson

Active Viable Air Monitoring Sieve Impaction Samplers

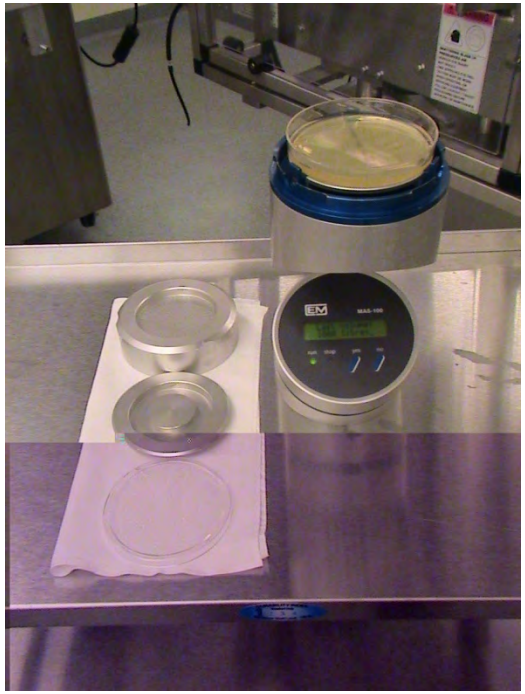
- **Portable Sieve Impaction Sampler Anderson**



Results on TSA

Active Viable Air Monitoring Sieve Impaction Samplers

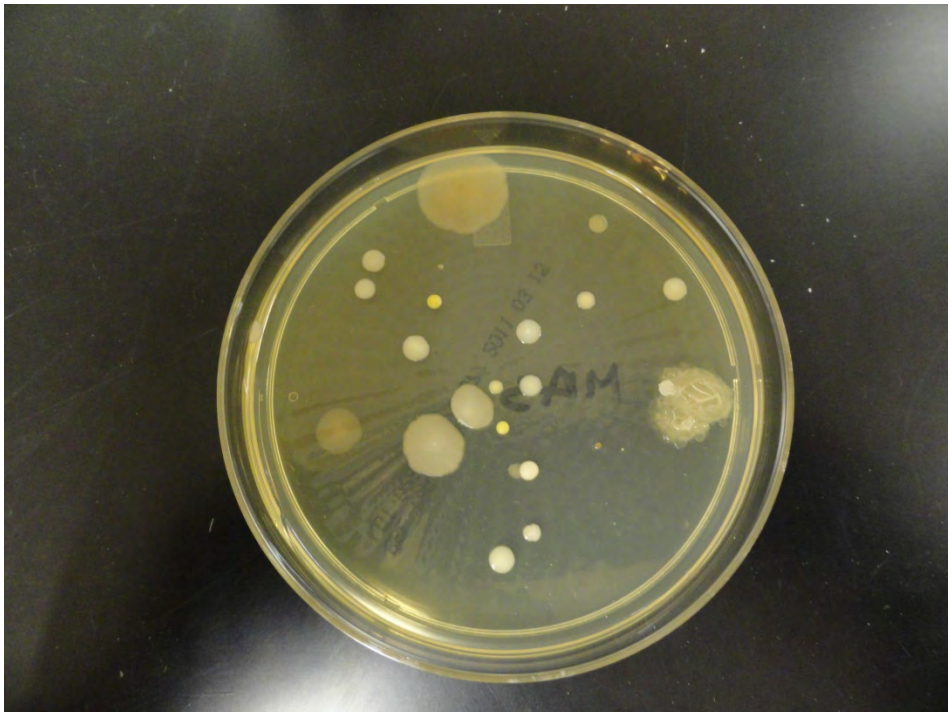
- **Portable Sieve Impaction Samplers**



MAS

Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Samplers MAS**



Results on TSA

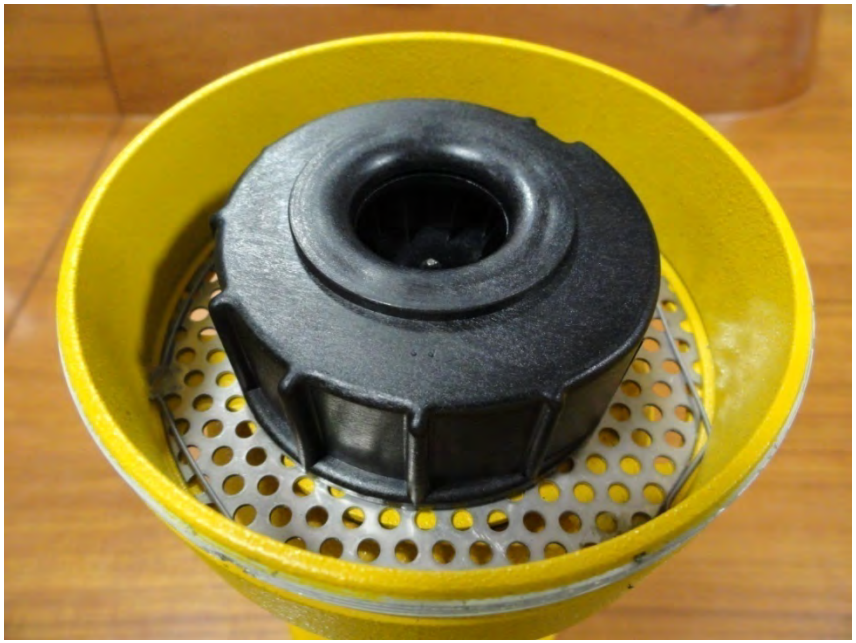
Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Samplers**

SAS

Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Samplers**



SAS

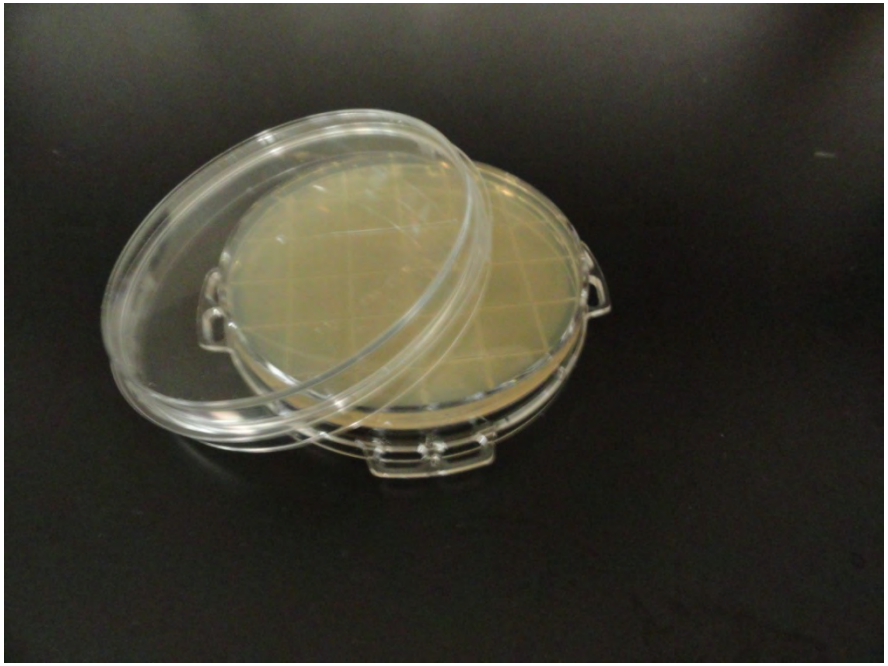
Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Sampler SAS**

Results on TSA

Active Viable Air Monitoring Sieve Impaction Samplers

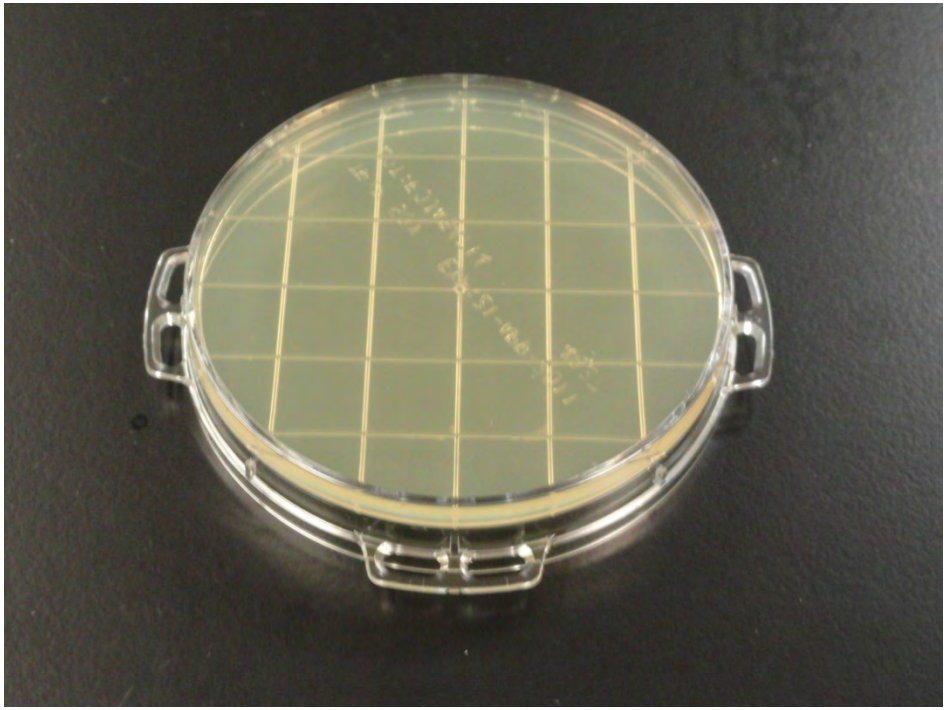
- **Portable Sieve Impaction Samplers**



M-Air-T

Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Sampler M-Air-T**



Results on Millipore TSA Plate

Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Sampler AES**

Active Viable Air Monitoring Fixed Sieve Samplers

- **Portable Sieve Impaction Sampler PMS**

Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Samplers**

Portable SMA

Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Samplers**

Portable SMA

Active Viable Air Monitoring Sieve Impaction Samplers

- **Portable Sieve Impaction Sampler SMA**

Results on TSA

Active Viable Air Monitoring Portable Sieve Samplers

- **Advantages**
  - Light weight and easy to use.
  - Fairly small footprint
  - No power source or vacuum source required
  - Can measure large volumes of air.
  - Many placement configurations
- **Disadvantages**
  - Test body is surface sanitizable only.
  - No time/location relationship.
  - Exhaust may interfere with processing.
  - Part 11 issues with down loading capabilities

Active Viable Air Monitoring Portable Sieve Sampler

- **Portable Sieve Manufacturers**
  - EM Sciences: Microbial Air Sampler, MAS
  - Bio-Merieux: Nu-Air System
  - Bio-Science International: Surface Air Sampler, SAS
  - VelTek: Sterilizable Microbial Atrium, SMA
  - Millipore: Millipore Air Tester M-Air-T
  - Anderson Air Sampler

Active Viable Air Monitoring Fixed Sieve Samplers

- **Fixed Vacuum Sieve Impactors**
  - The air is drawn through holes in a sampling head and organisms are impacted onto the agar surfaces
  - Holes in sample head is either 3/8 or 1/4 inches in diameter
  - Uses 100 mm sample plates
  - Sampling head is all stainless steel and can be sterilized

Active Viable Air Monitoring Fixed Sieve Samplers

- Uses a remote vacuum source that samples 1-ft^3/minute at the point of use
- Results are defined as CFU/ft^3

Active Viable Air Monitoring Fixed Sieve Samplers

- **Fixed Vacuum Sieve Impaction Systems**

Fixed SMA 0.25 inch orifice

Active Viable Air Monitoring Fixed Sieve Samplers

- **Fixed Vacuum Sieve Impaction Systems**

Fixed SMA 0.5 inch orifice

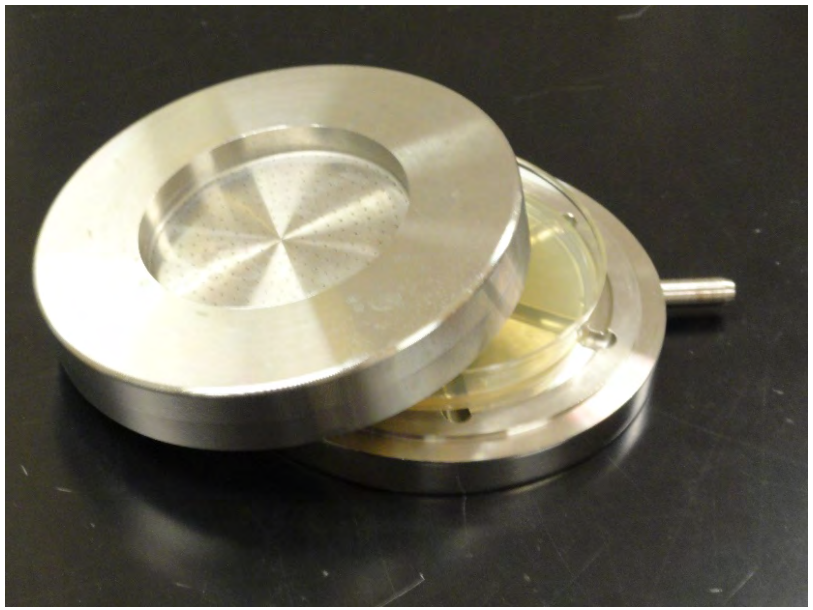
Active Viable Air Monitoring Fixed Sieve Samplers

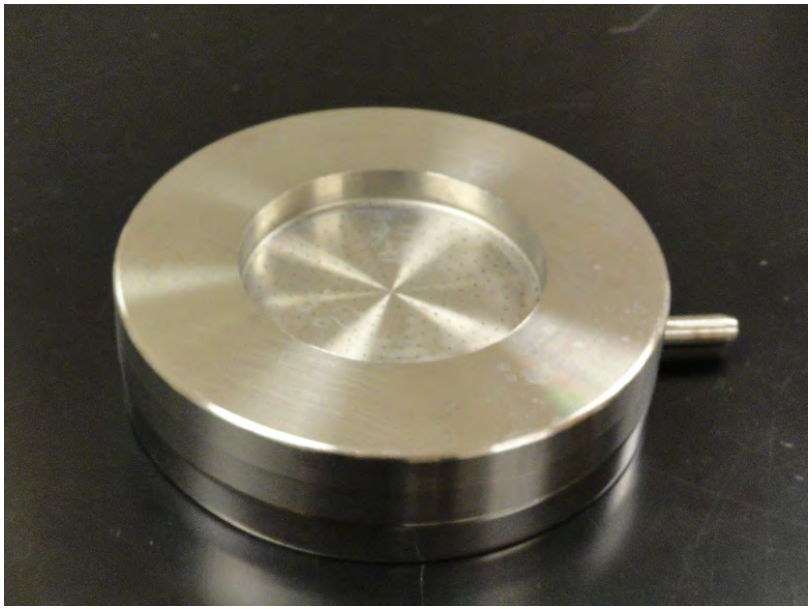
- **Fixed Vacuum Sieve Impaction System SMA**

Results on TSA

Active Viable Air Monitoring Fixed Sieve Samplers

- **Fixed Vacuum Sieve Impaction System SMA**





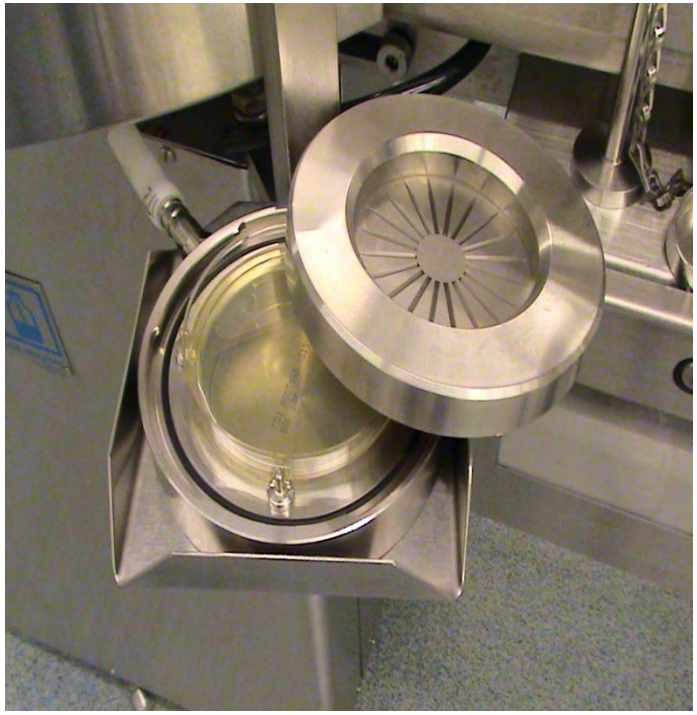
Active Viable Air Monitoring Fixed Sieve Samplers

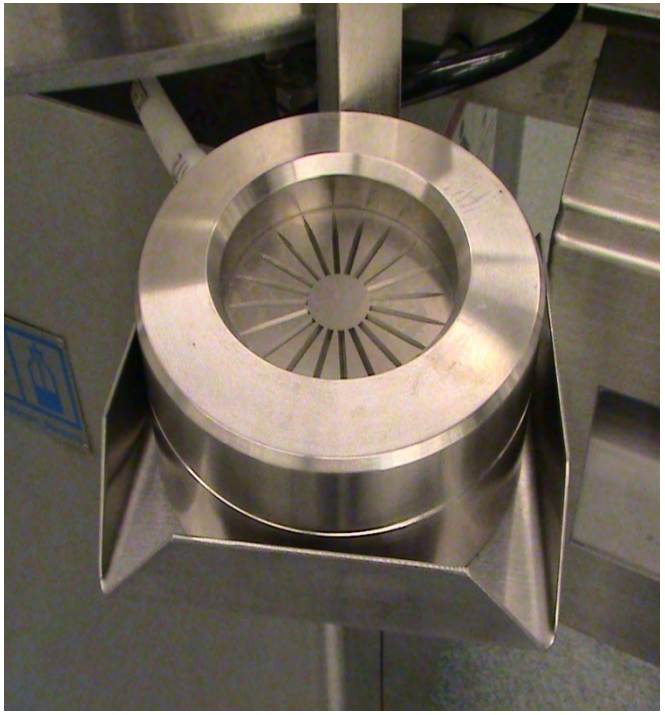
- **Fixed Vacuum Sieve Impaction Systems**

SMA Control Panel

Active Viable Air Monitoring Fixed Sieve Samplers

- **Fixed Vacuum Sieve Impaction systems**





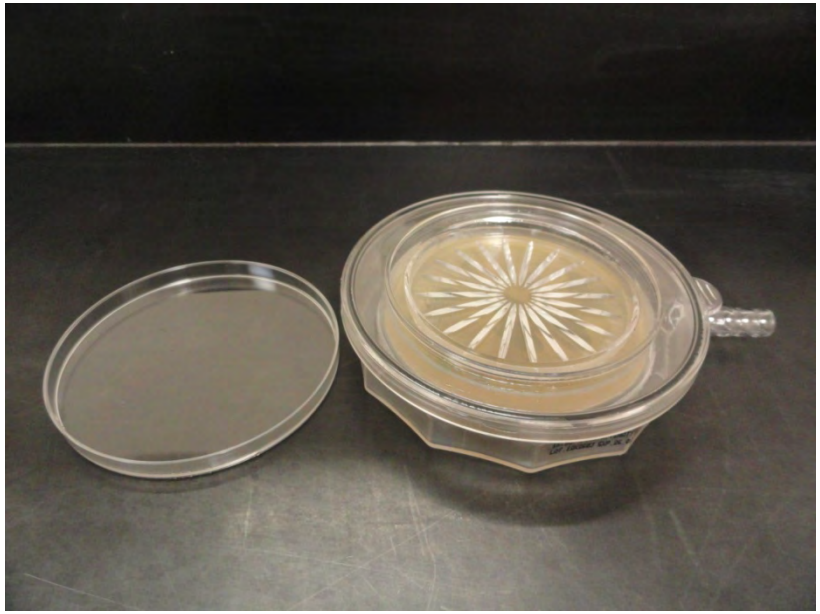
PMS

Active Viable Air Monitoring Fixed Sieve Samplers

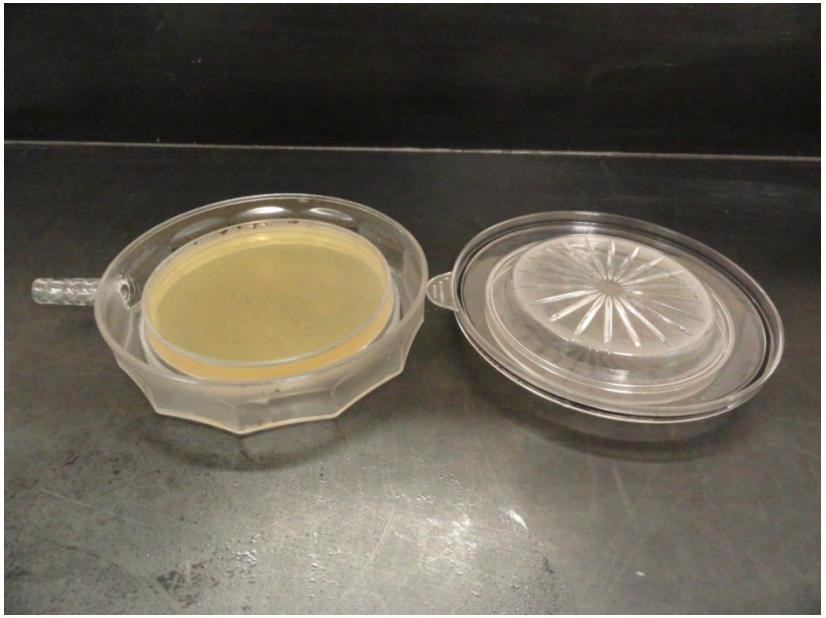
- **Disposable Sieve Impaction Systems PMS**

Active Viable Air Monitoring Fixed Sieve Samplers

- **Disposable Sieve Impaction Systems PMS**



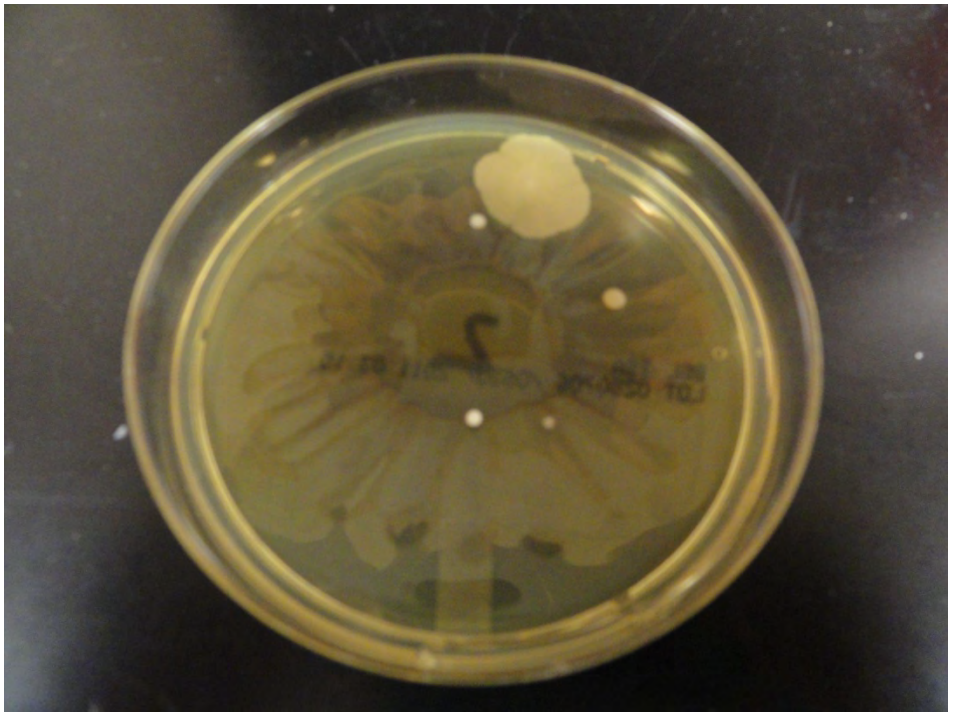
Open for Testing



Reading Plate

Active Viable Air Monitoring Fixed Sieve Samplers

- **Disposable Sieve Impaction Systems PMS**



Results on TSA

Active Viable Air Monitoring Fixed Sieve Samplers

- **Advantages**
  - Entire sampling head can be sterilized
  - Sample critical sites
  - Able to sample air volumes greater than 60 ft^3 if validated
  - Very small footprint
  - Easy to set up and use.
  - Can be placed anywhere with no exhaust issues

- **Disadvantages**
  - A fixed calibrated vacuum source is required at each site
  - Not recommended for areas with high microbial concentrations
  - System must be manually started and stopped
  - Vacuum tubing should be autoclaved and changed periodically

Active Viable Air Monitoring Fixed Sieve Samplers

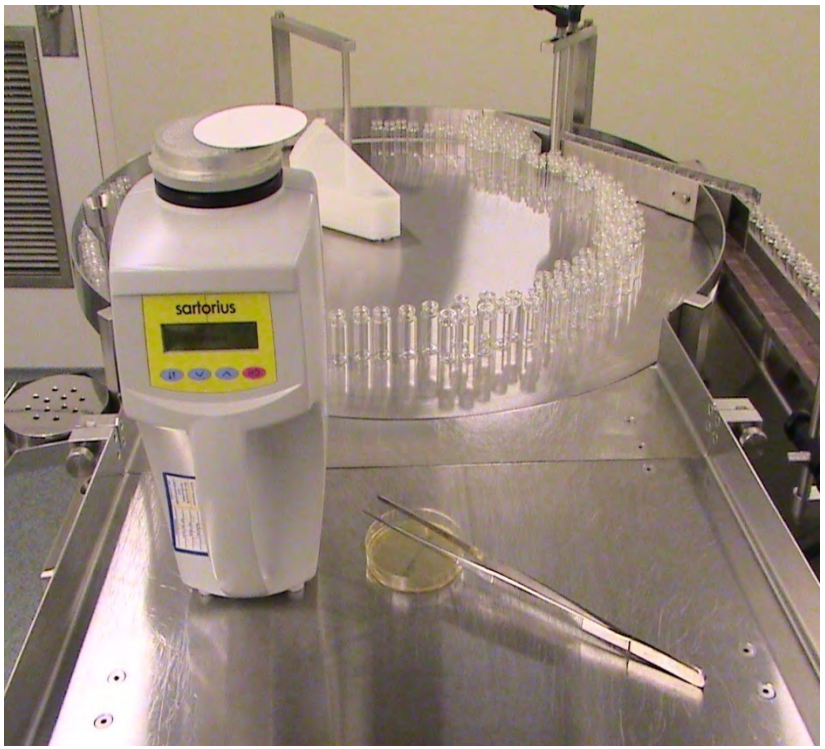
- Fixed Sieve Manufacturers
  - Veltek: Sterilizable Microbial Atrium, SMA
  - PMS: Radiating System

Active Viable Air Monitoring Membrane Filtration Testing

- **Membrane Filtration**
  - A vacuum source draws air through a filter where organisms are deposited
  - The filter is aseptically removed and placed onto a agar plate to culture the organisms
  - Can measure large volumes of air
  - Calibrated airflow required

Active Viable Air Monitoring Membrane Filtration Testing

- **Membrane Filtration**



Air Port MD-8

Active Viable Air Monitoring Membrane Filtration Testing

- **Advantages**
  - Electrical power source not required
  - Able to measure large volumes of air
  - Collection efficiency is relatively high
  - Numerous filter, media and pore sizes available.
- **Disadvantages**
  - No issues with exhaust air
  - After testing, samples must be aseptically placed on a agar plate.
  - Desiccation of organisms may occur
  - Multiple steps required which is cumbersome
  - Air may have effect on sensitive organisms

Active Viable Air Monitoring Membrane Filtration Testing

- **Filtration Testing Manufacturer**

  Sartorius: AirPort MD-8

Active Viable Air Monitoring Liquid Impingement Testing

- **Liquid Impingement**
  - A calibrated vacuum source is attached to a sterile collection system
  - The air is pulled into the sterile tub which is immersed in a sterile flask filled with liquid growth media, PBS or equivalent
    - If PBS is used, the liquid must be filtered or diluted and tested

Active Viable Air Monitoring Liquid Impingement Testing

- The sample bubbles into the media where the organisms are deposited
- Usually used to indicate positive or negative results
- Only semi quantifiable if diluting and plating for high concentrations
- The exhaust air is vented out of the flask away from the processing area

Active Viable Air Monitoring Liquid Impingement Testing

- **Advantages**
  - Electrical power source not required
  - Various media types available
  - Small footprint
  - Concentrated samples can be diluted
  - Can be used to sample over a long period
  - Economical
- **Disadvantages**
  - No issues with exhaust air
  - Liquid media can spill
  - Multiple steps required which can be cumbersome
  - Sample manipulations increase possibility of contamination

Active Viable Air Monitoring Liquid Impingement Testing

- **Liquid Impingement**

Active Viable Air Monitoring Liquid Impingement Testing

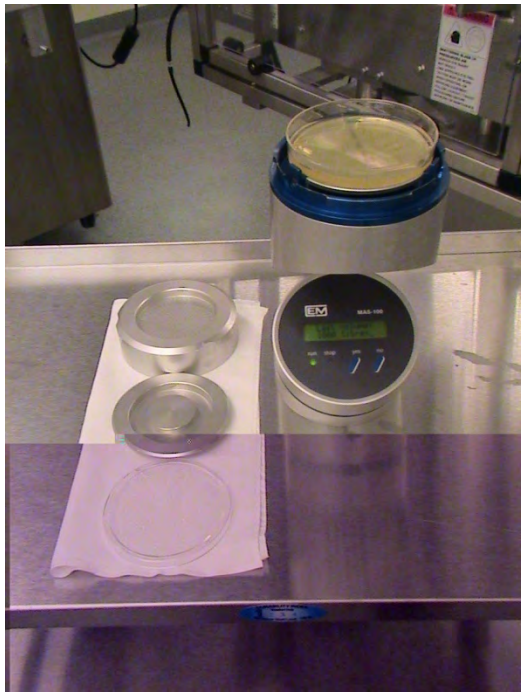
- **Liquid Impinging Manufacturer**
  - Use sterile media/tubing and define time sampled

Philosophy of Environmental Monitoring

- **Viable Air**
  - Viable frequency of sampling
    - Periodic: Once per a defined time period
    - Frequent: One sample every 60-minutes
    - Intermittent: Sampled on for a defined period and off for a defined period
    - Continuous: Sampled continuously during operations

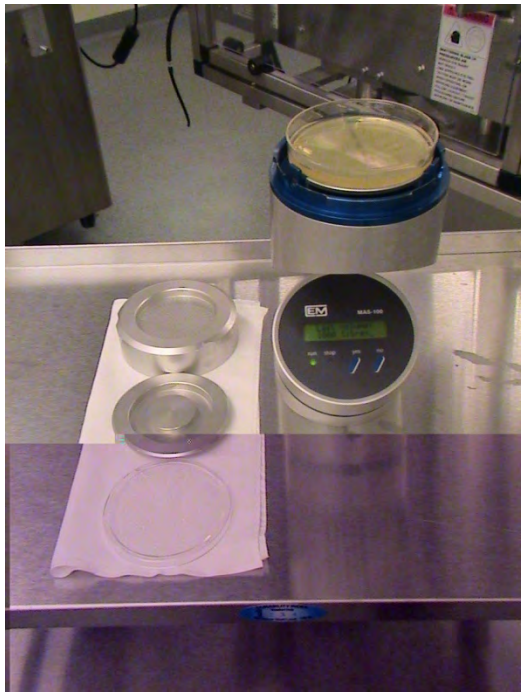
Philosophy of Environmental Monitoring

- **Periodic**
- **MAS 10 min every 240 min (4.2%)**



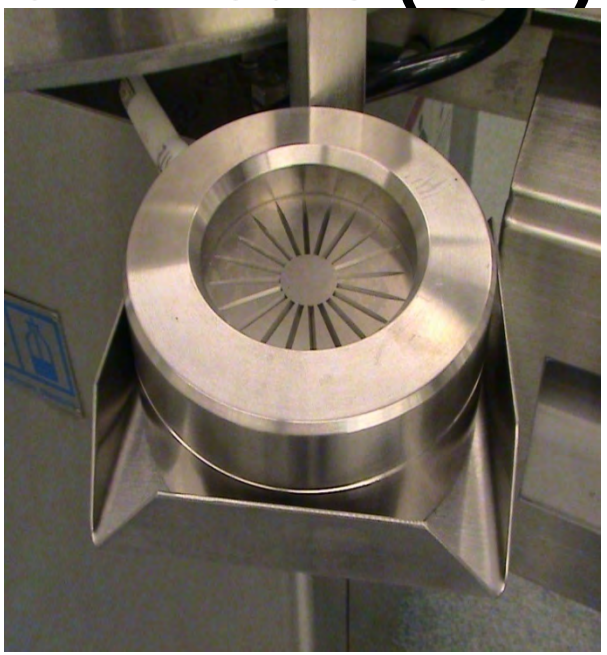
Philosophy of Environmental Monitoring

- **Frequent**
- **MAS, 10 min every 60 min (17%)**



Philosophy of Environmental Monitoring

- **PMS, 1-hour per plate or intermittently during processing**
- **15 min on 45 min off over 4 hours (25%)**



Philosophy of Environmental Monitoring

- **SMA continuous monitoring for up to 4-hours using a heavy fill plate 100%**

Philosophy of Environmental Monitoring

- **Viable Air**
  - Must validate the maximum run time per sampling equipment
  - Growth promotion is required based on sampling time used
  - Define ml of media, 24, 29 or 32
  - Assess cost of the plates

Passive Viable Air Monitoring Settling Plate/Liquid

- **Passive Monitoring**
  - Settling Plates
  - Fallout Liquid Agar

Passive Viable Air Monitoring Settling Plate/Liquid

- **Fall-out plates or liquid media**
  - This system is based on gravity
  - Utilizes a simple system of leaving exposed media plates or flasks directly exposed to the environmental conditions
  - The organisms settle out onto the surface or into the liquid media.
  - Usually used in conjunction with active air monitoring

Passive Viable Air Monitoring Settling Plate/Liquid

- In most cases the maximum exposure time is 4 hours unless otherwise validated
- Taken during filling operations
- Required by the European Union only

Passive Viable Air Monitoring Settling Plate/Liquid

- **Fall-out plates or liquid media**

Passive Viable Air Monitoring Settling Plate/Liquid

- **Fall-out plates or liquid media**

Results on TSA

Passive Viable Air Monitoring Settling Plate/Liquid

- **Advantages**
  - Ease of use.
  - Economical.
  - Small size allows for easy placement.
  - Can be useful in isolator systems.
  - No testing equipment required.
  - Continuous testing over a long period of time
  - No electrical or vacuum source required

- **Disadvantages**
  - Minimum/maximum exposure time must be validated.
  - Semi-qualitative.
  - Results not correlated with air volume
  - Liquid testing can be messy
  - Many variables are associated with recovery rates such as, temp, humidity, air direction and velocity

Passive Viable Air Monitoring Settling Plate/Liquid

- **Manufacturer Settling Plate/Liquid**
  - Use media plate or media in a container with a defined opening
  - Usually made by individual companies

Airborne Particulate Monitoring Systems

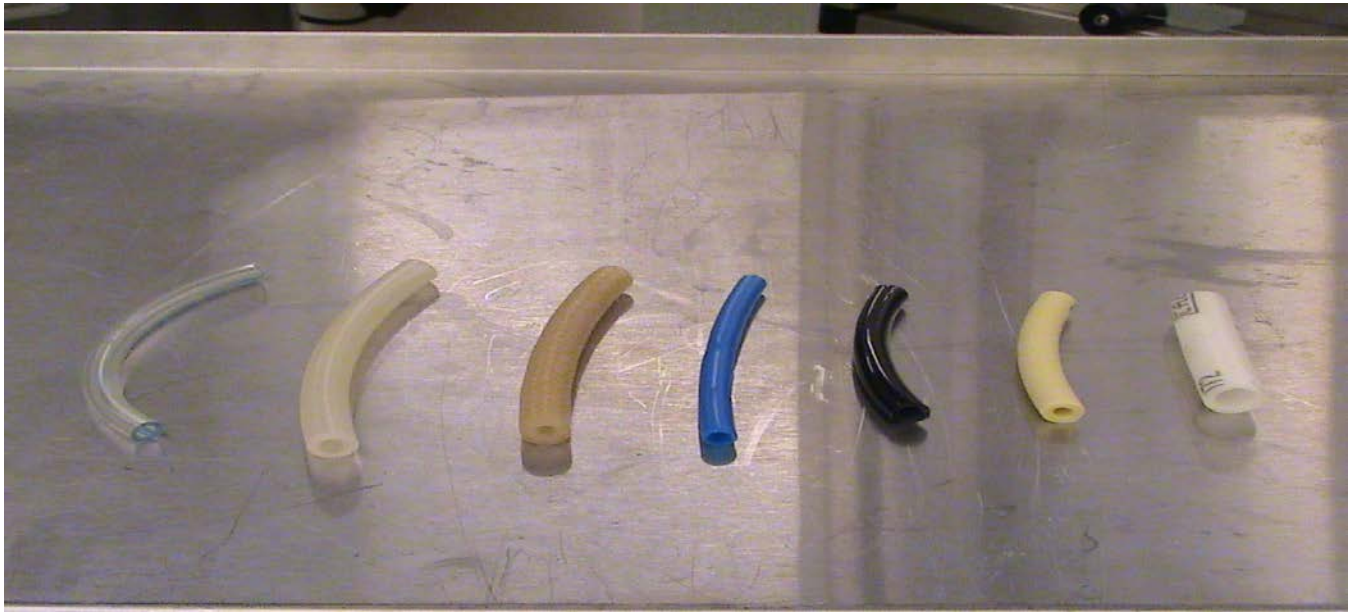
Total Particulate Monitoring

Airborne Particulate Monitoring Systems

- **Total Particulate Monitoring**
  - The recommended length of tubing from the sampling head to the detector should be less than 10 feet
  - Use Bevaline-Hytrel tubing, which has a Teflon coated interior
  - Most test units sample 1 ft^3/min
  - Sample should be individual 1-minute samples

Airborne Particulate Monitoring Systems

- **Total Particulate Monitoring**
  - Does tubing matter?



Airborne Particulate Monitoring Systems

- **Total Particulate Monitoring**
  - Use Bevaline-Hytrel tubing, which has a Teflon coated interior
  - What is the maximum length of tubing?
  - Does the condition and how it is placed on the sampling area matter?

Airborne Particulate Monitoring Systems

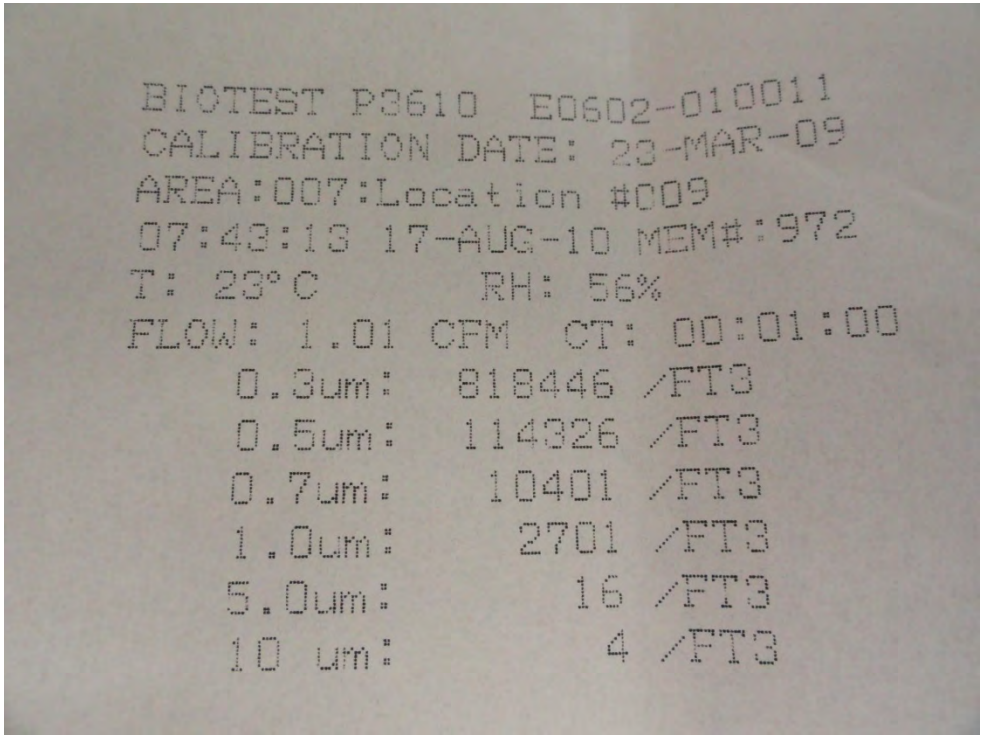
- **Total Particulate Monitoring**
  - Sample critical locations at the working height
  - Do not average individual counts
  - At a minimum, samples must be representative of the operation
  - Recommend continuous sampling in the critical areas.

Airborne Particulate Monitoring Systems

- **Portable Particulate Monitoring Systems**
  - Lightweight and easy to use
  - Tubing must not have any sharp bends
  - Ability to place probe in critical areas and keep detector in a less critical area
  - Exhaust air flow can disrupt airflow
  - Provides paper printouts as well as down load capabilities

Airborne Particulate Monitoring System

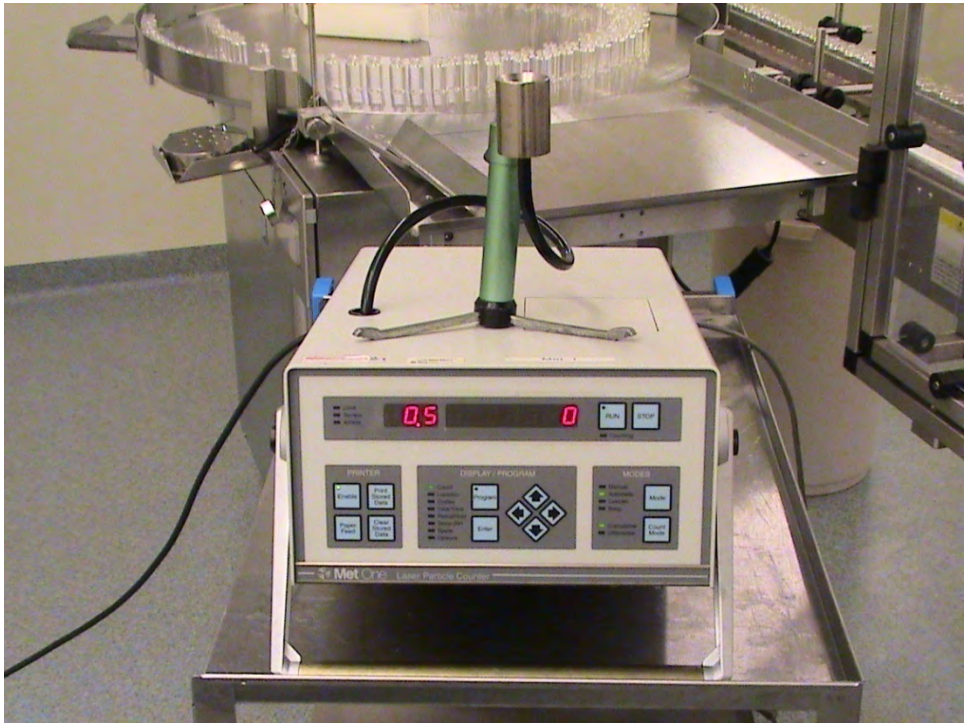
- **Particulate Monitoring Systems**



Bio-Test

Airborne Particulate Monitoring System

- **Particulate Monitoring Systems**



Clime
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Airborne Particulate Monitoring System

- **Particulate Monitoring Systems**

Bio-Test

Airborne Particulate Monitoring System

- **Particulate Monitoring Systems**

PMS

Airborne Particulate Monitoring System

- **Particulate Monitoring Systems**

PMS

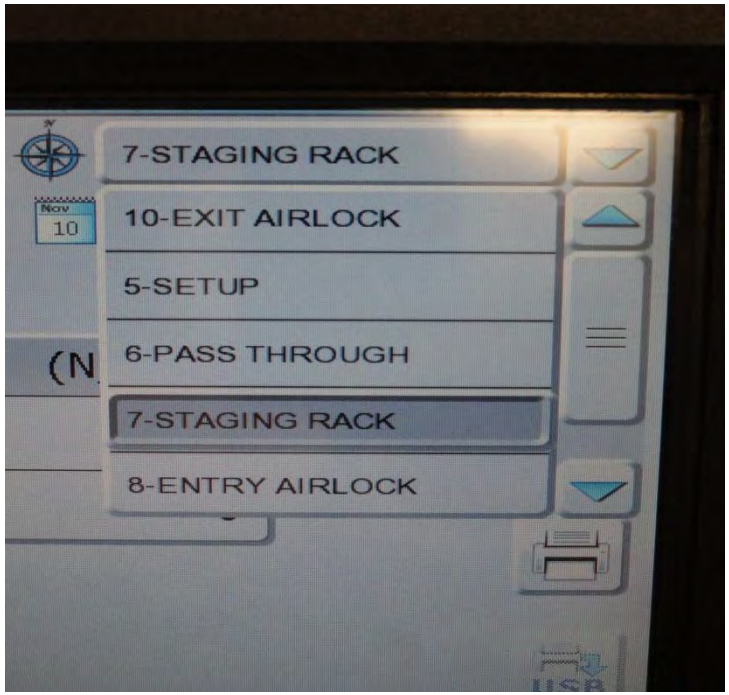
Airborne Particulate Monitoring System

- **Particulate Monitoring Systems**

PMS

Airborne Particulate Monitoring System

- **Particulate Monitoring Systems**



PMS

Airborne Particulate Monitoring System

- **Particulate Monitoring Systems**

PMS

Airborne Particulate Monitoring System

- **Fixed Particulate Monitoring Systems**
  - Sample heads in a fixed position
  - Sample head located in close proximity to detector
  - Cover sampling heads during sanitization of the facility
  - Usually tied into the Building Management Systems for alarms

Airborne Particulate Monitoring System

- **Fixed Particulate Monitoring Systems**
  - Provides immediate trending capabilities
  - Specific procedures must be defined for all excursions
  - Extremely easy to use
  - Need to determine frequency of sampling

Airborne Particulate Monitoring System

- **Fixed Particulate Monitoring Systems**

PMS

Airborne Particulate Monitoring System

- **Particulate Monitoring Systems**
  - Biotest
  - Climet
  - Met-One
  - Particulate Monitoring System

Airborne Particulate Monitoring System

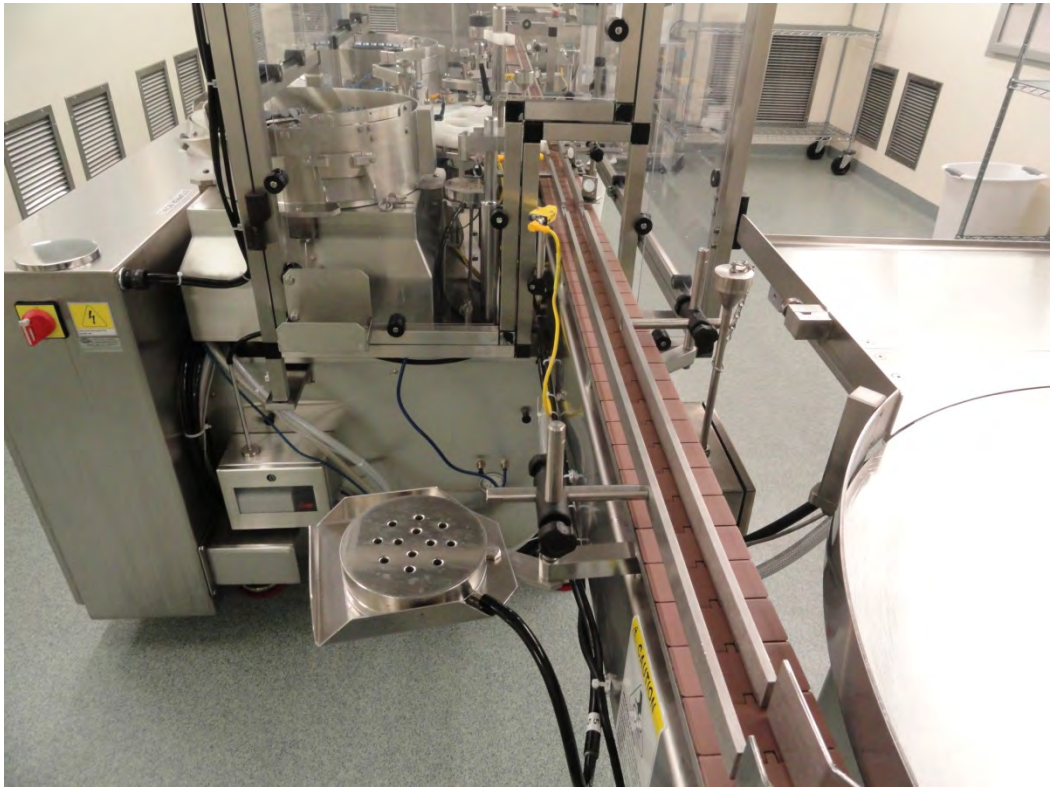
- **Placement of Viable Air and Particle Sampling Heads**

Airborne Particulate Monitoring System

- **Placement of Viable Air and Particle Sampling Heads**
- **Regulatory expectations have no scientific data to support their requirements**
  - Initially, the constraint was not more than12 inches from the top of the vial to the sampling head
  - Now, some inspector expect not more than a 12-inch radius from the vial, both vertical and horizontal

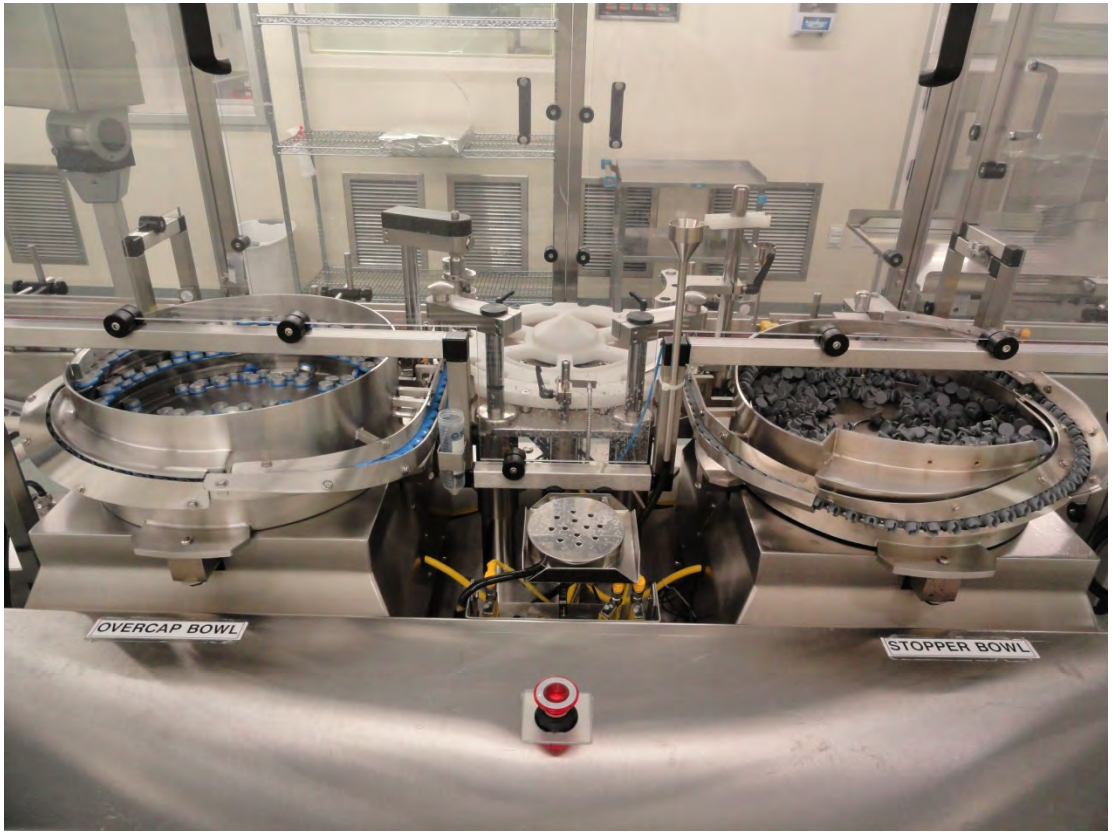
Airborne Particulate Monitoring System

- **Placement of Sampling Heads**



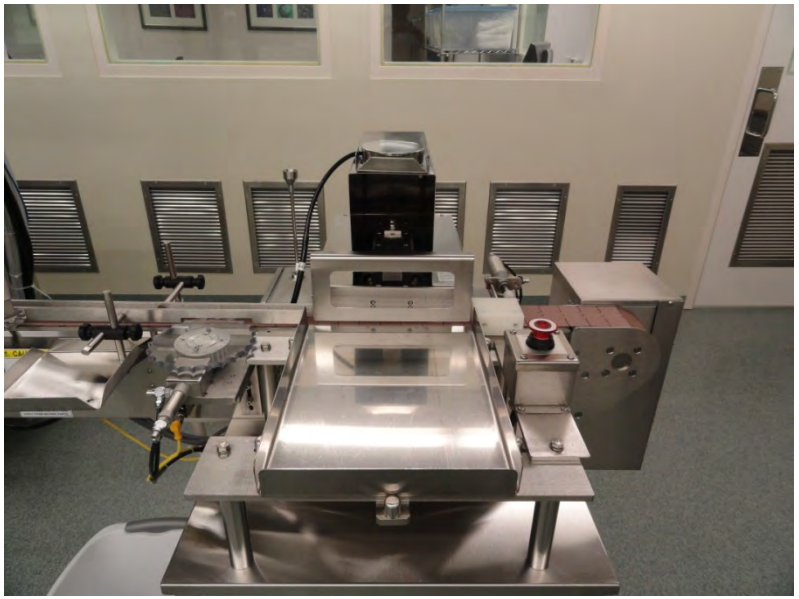
Airborne Particulate Monitoring System

- **Placement of Sampling Heads**



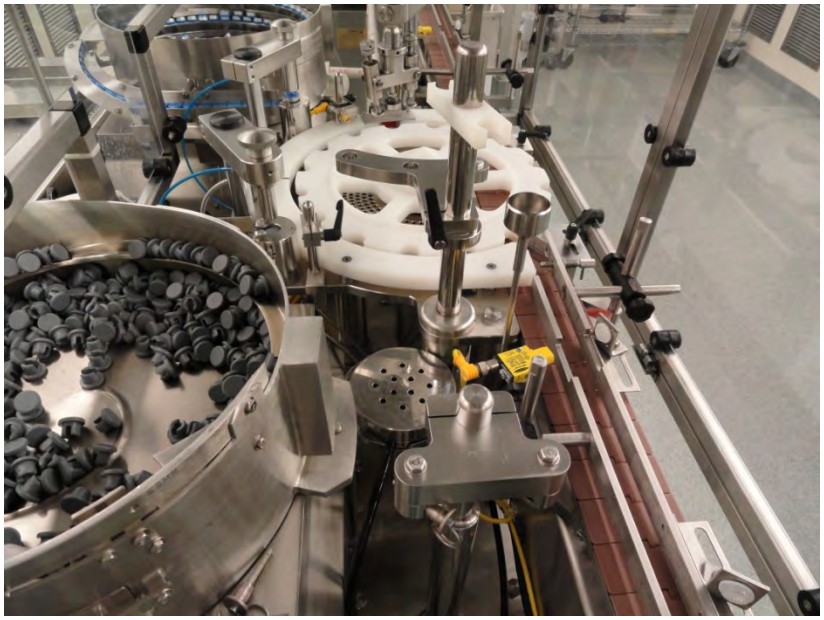
Airborne Particulate Monitoring System

- **Placement of Sampling Heads**



Airborne Particulate Monitoring System

- **Placement of Sampling Heads**



Airborne Particulate Monitoring System

- **Real Time Viable and Particle Testing by PMS**

PARTICLE MEASURING SYSTEMS

Airborne Particulate Monitoring System

BioVigilant©

Environmental Monitoring

- **Takeaway Message**
  - Ensure proper viable air sampler is being used based on exhaust air
  - Confirm all sample locations are justified based on the validation data
  - Routing sampling is not performed in static conditions
  - Ensure all testing methods are optimized