Verification, Validation and Documentation

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Verification and Validation

WATER SAFETY (RISK) MANAGEMENT STEPS

ROLES & RESPONSIBILITIES

WRITING THE SUMMARY

DESCRIBE THE BUILDING

IDENTIFY RISK

MITIGATE RISK

CORRECTIVE ACTIONS

DOCUMENTATION

RESOURCES & TOOLS

WSMP – verification & validation

Verification and Validation are your documentation!

Verification: Confirming activities of the WSM Plan are being done

- Checking temps
- Checking disinfectant
- Cleaning is done
- Everything is documented

Validation: Confirm the WSM Plan is *actually working*

- Testing for pathogen at predetermined sites

Source: ASHRAE 188:2018

WSM Plan – Verification
Doing what you said you'd do

Confirm that the control measures of the WSM plan are being performed and appropriately responded to.

The WSM Team assessed risk, identified control measures and put sampling and monitoring protocols in place along with corrective actions.

Now, what does the team do to insure those activities are taking place?

WSM Plan – verification example 1

Control measure: Chlorine level checks in Hydrotherapy spa

- The WSM plan states:
  - ✓ Chlorine level in this spa is to be 0.5 - 0.7 ppm
  - ✓ Spa is to be tested daily and results recorded in a log book
  - ✓ If it is below 0.5 ppm,
    - Request “R” (spa operator) adjust to the range
    - Notify WSM “A” contact who will cascade to the right “R’s” for necessary corrections, including re-training and potential infection risk

The “R” individual tasked with performing routine verification will check that these activities were performed and documented. Rather like an internal audit. They will check log book entries, values and note actions taken and if any Plan corrections were needed and done.

WSM Plan – verification example 2

Control measure: Boiler #1 to maintain at or above 140 ºF

- The WSM plan states:
  - ✓ Boiler #1 to maintain at or above 140 ºF
  - ✓ Temperature to be tested daily and results recorded in a log book
  - ✓ If temperature is below 140 ºF:
    - Request WSM “R” team member (boiler operator) adjust the temperature
    - Notify WSM “A” contact who will cascade to the right “R’s” for necessary corrections, including re-training and potential infection risk

The “R” individual tasked with performing routine verification will check that these activities were performed and documented. Rather like an internal audit. They will check log book entries, values and note actions taken and if any Plan corrections were needed and done.

WSM Plan – verification example 3

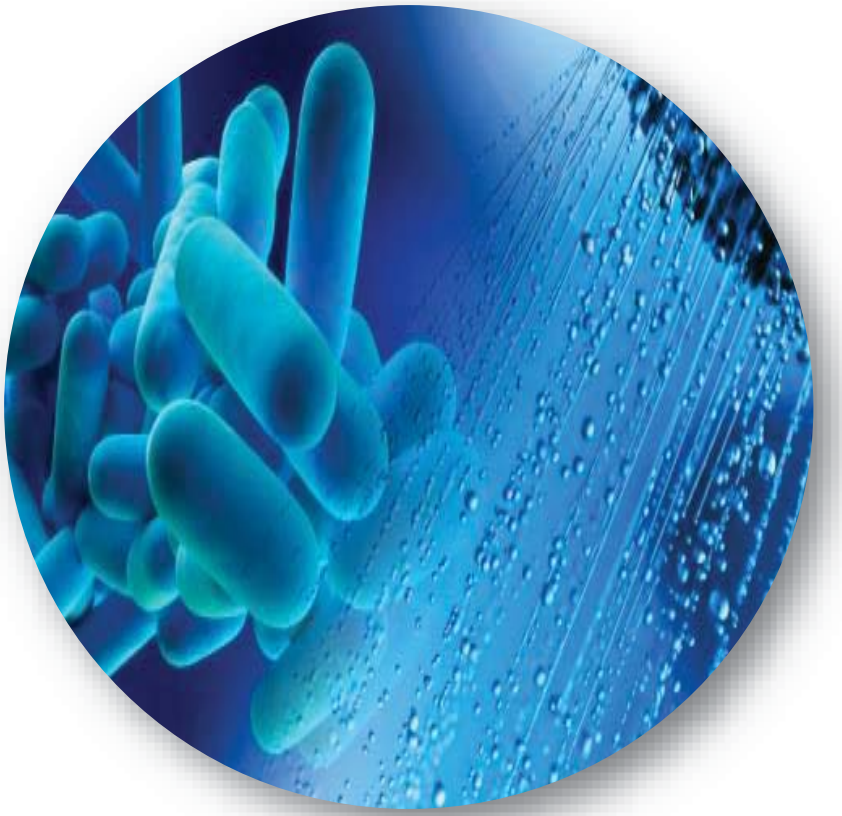
- Control measure: disinfectant residual checks
- The WSM plan states:
  - ✓ Preselected taps and showers must be at 0.2 – 0.5 ppm chlorine
  - ✓ Sites are tested weekly, results recorded in a log book
  - ✓ If it is outside 0.2 – 0.5 ppm :
    - Request “R” (water treatment) adjust to the range
    - Notify WSM “A” contact who will cascade to the right “R’s” for necessary corrections, including re-training and potential infection risk

The “R” individual tasked with performing routine verification will check that these activities were performed and documented. Rather like an internal audit. They will check log book entries, values and note actions taken and if any Plan corrections were needed and done.

Laboratory Validation Methods

WSM Plan – Validation

- Validation testing to determine if program is effectively preventing fouling, controlling corrosion, *Legionella* and other waterborne pathogens, and *biofilm growth* in the system
- Accomplished through microbiological testing for *Legionella* and other WBD pathogens
- WHO and other global organizations recognize *L. pneumophila* testing as the most protective of human health
- Routine validation testing for *L. pneumophila* is a cost-effective way to determine plan effectiveness



Who should do testing and analysis? ASHRAE 188 Annex C guidance if *Legionella* testing is utilized

- When testing is utilized, the laboratory should demonstrate proficiency in subject method.

- Labs performing routine microbiological testing of environmental water samples should be accredited by a regional, national, or international accrediting body according to a nationally or internally recognized standard, for example ISO/IEC 17025:2017, General Requirements for the Competence of Testing and Calibration laboratories, or similar.

- *Legionella* testing should be included in the laboratory's scope of accreditation. (FoT – Field of Testing)

*Per ASHRAE 188:2018, Appendix C and CDC ELITE website FAQs https://wwwn.cdc.gov/elite/Public/FAQ.aspx

Reliable data translates to cost effective actions

Accredited laboratories are more likely to produce reliable validation data; the laboratory should provide your WSM team with:

- A copy of their accreditation certificate and Scope of Accreditation
- Chain of Custody and Sampling Protocols, then train all sampling personnel to them
- Documentation of successful Proficiency Test samples
- A blinded Data Report, all reports should include Quality Control (QC) and Quality Assurance (QA) requirements

Additionally, an accredited laboratory will:

- Be able to identify the pathogen target, *L. pneumophila*; to avoid WSM Plan actions, and cost, for detecting non-pathogenic bacteria
- Develop a Quality Assurance Project Plans (QAPP) that covers customer testing, documentation and reporting needs

WSM Plan Validation: Pathogen Testing

Globally, ***Legionella pneumophila*** is accepted as the pathogen that causes Legionnaires' Disease, and the target to monitor to best manage risk. *World Health Organization*

You will get asked:

"What do you do to insure the WSM plan is working"

"We test for the pathogen"

*World Health Organization, Fact Sheet, Nov 2017
http://ec.europa.eu/environment/water/water-drink/pdf/WHO_parameter_report.pdf

Analytical Methods for Validation Testing

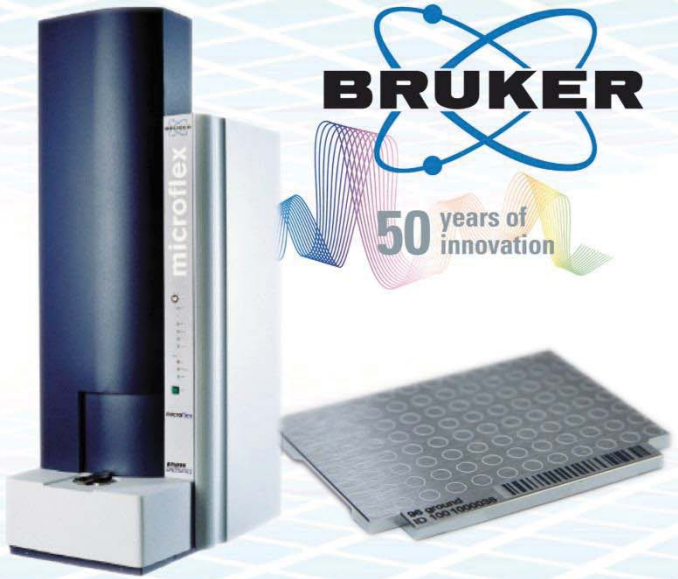
Concentrating potable water samples for CDC/ISO 11731 spread-plate culture

Bruker

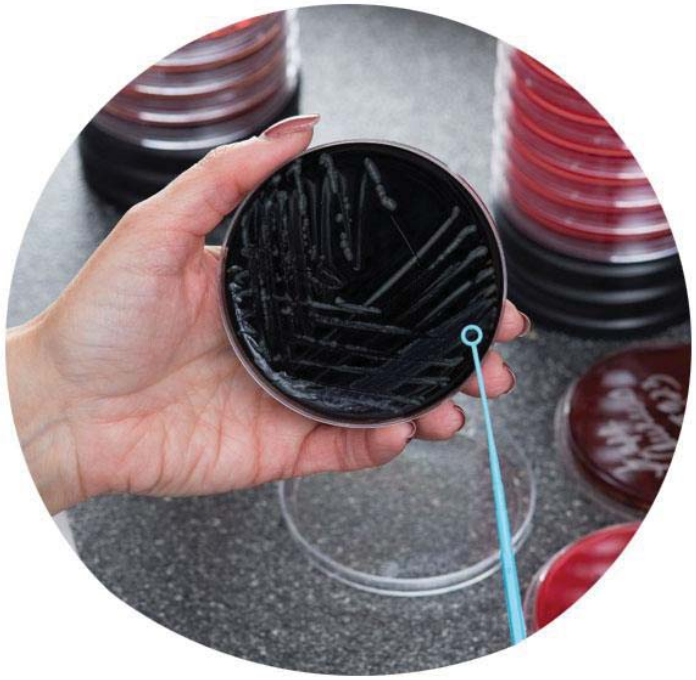
Legionella Speciation

MALDI Biotyper systems provide high-speed, high-confidence identification and taxonomical classification of clinical and environmental bacteria, yeasts, filamentous molds and mycobacterium. Classification and identification are based on proteomic fingerprinting using high-throughput MALDI-TOF (matrix-associated laser desorption/ionization) mass spectrometry.

Click for information

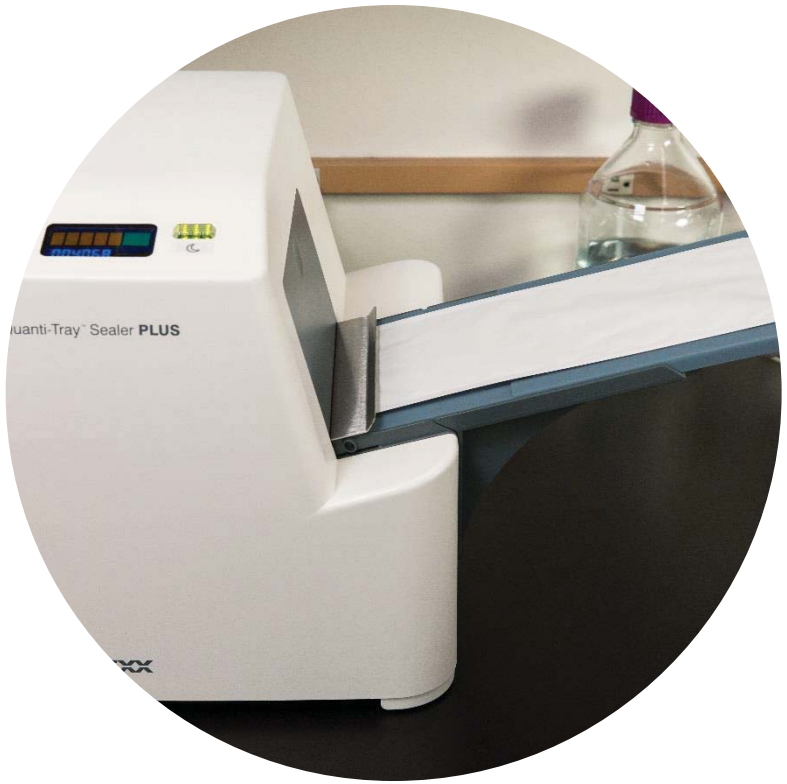


CDC & ISO 11731 Spread-Plate Culture



- 250 ml or 1000 ml sample
- Detects and quantifies LP and *Legionella* species
- Serogrouping 1 and 2 – 15 of LP and speciation of *Legionella* species by MALDI-TOF mass spec of *Legionella* directly from plate
- Results in 7- 12 days depending upon method

Legiolert liquid culture method



Detection of *L. pneumophila* by Legiolert

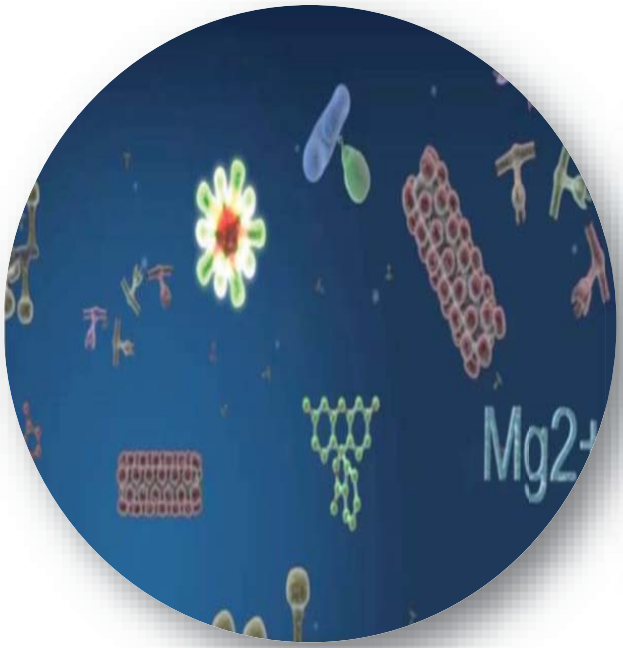
- Confirmed results without additional tests
- A positive result can be confirmed without additional incubation
- Detects and quantifies all serogroups of *Legionella pneumophila (Sg1 – 15)*
- 99% reproducibility and repeatability
- Smaller sample size of 100 mL
- Quicker TAT, results in 7 days

MPN and CFU Discussion

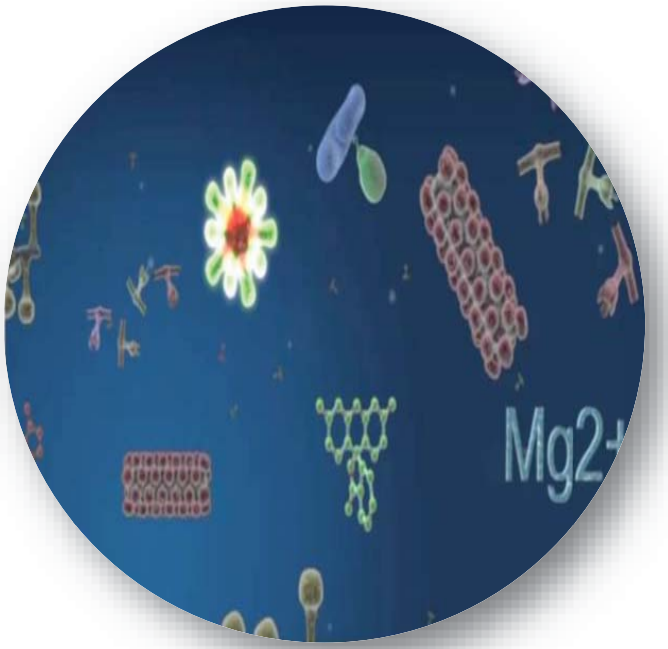
Growth medium		Reporting unit
Solid (e.g., agar)		**CFU** (colony forming units)
Liquid (e.g., Colilert®, multiple-tube fermentation)		**MPN** (most probable number)

- Both units are used to report the estimated number of bacteria in a sample.
- Utilities, facilities, public health agencies regularly rely on MPN methods for accurate results.
- Regulatory bodies, like U.S. EPA, allow both CFU and MPN reporting and use the units interchangeably.

qPCR for *L. pneumophila* and L. species

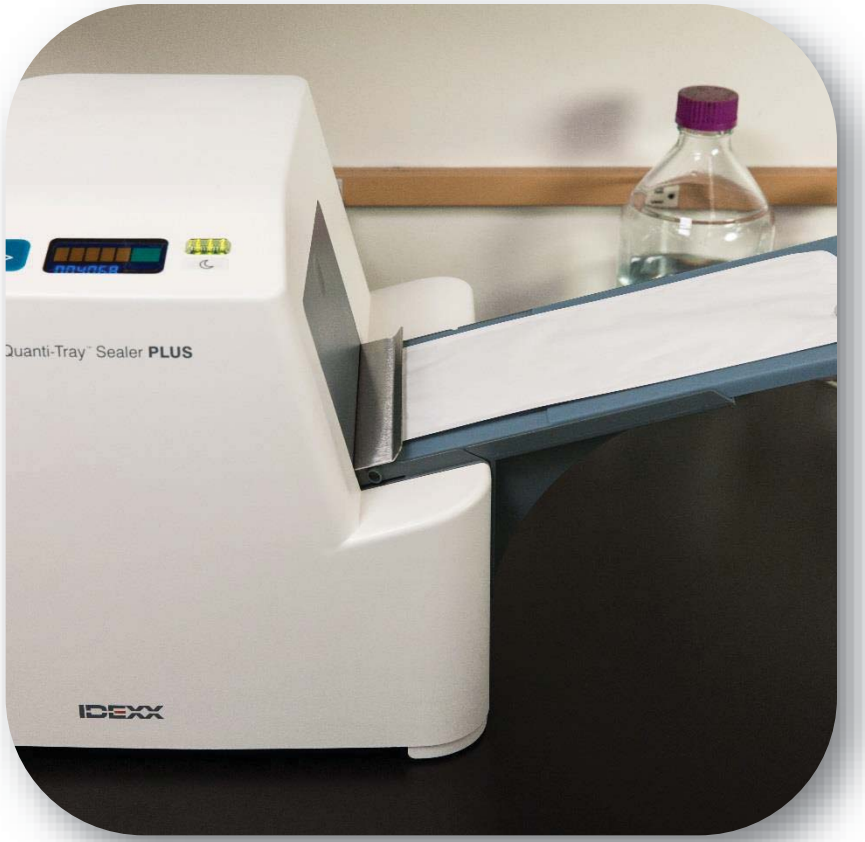


qPCR for *L. pneumophila* and L. species



- Outbreak investigations
- Same day results
- No confirmation required
- Smaller sample size – 120 mL
- Potable and non-potable
- Reported in Genomic Units GU

Pseudalert method



Detection of *P. aeruginosa* by Pseudalert

- 24-hour detection of *Pseudomonas aeruginosa*
- Definitive results with no confirmation necessary
- Presence/Absence or quantification

Spread-plate culture vs Legiolert

Spread-Plate Culture

- 250 ml or 1000 ml sample
- Detects/quantifies LP and L. species
- Serogrouping and speciation direct from plate
- 7-12 day TAT
- Higher variability in processing
- Media performance and Interference from background bacteria, yeasts and filamentous molds
- Possibility of mixed Legionella species

Legiolert Culture

- 120 ml sample
- Detects and quantifies LP missed by spread-plate cultures
- 7-day TAT
- Serogrouping directly from Quanti-Tray
- Low variability in processing
- 99% Reproducibility
- High specificity for all LP
- Reduce the need to re-test because of overgrowth (vs. TNTC plates)

Legionella Testing Methods

	CDC Culture Method Test Code 1015	Legiolert Method Test Code 1015.4	ISO Culture Method Test Code 1015.6	qPCR Method Test Code 2015
120 mL Sample Size		●	●	
250 mL Sample Size	●	●	●	●
1 Liter Sample Size	●			●
Turnaround Time: Same Day				
Turnaround Time: 7 Days		●		●
Turnaround Time: 7-10 Days	●			
Turnaround Time: 10-12 Days			●	

CDC Culture Method Description: The CDC culture method, is used for processing both potable and non-potable samples. Potable waters are concentrated and non-potable waters such as cooling towers are acid treated to kill background bacteria and select for *Legionella*. Detects *L. pneumophila* Serogroup 1, *L. pneumophila* Serogroup 2-15 and *Legionella* species in 7-10 days. Please use 1 Liter or 250 mL sterile sample bottles with preservative. Include 3-5 mL water sample with swabs from the same location.

Legiolert Method Description: Legiolert is a culture method is used for processing both potable and non-potable samples. It uses bacterial enzyme technology by IDEXX to detects *Legionella pneumophila* in water, with results in 7 days. The detection limit for potable water is >10 MPN /100 mL and non-potable water is >1000 MPN /100 mL.

ISO Culture Method Description: ISO 11731:1998 method is for samples taken in the state of New York to comply with the NY proposed permanent regulation, Part 4 of Title 10 NYCRR, protection against *Legionella*. Detects *L. pneumophila* Serogroup1, *L. pneumophila* Serogroup 2-15 and *Legionella* species. Please use 1 Liter or 250ml sample bottles with preservatives. Samples can be accepted in the NJ lab Monday - Saturday until 1pm and also at our service center in New York City at 1460 Broadway from Monday to Friday.

qPCR Method Description: Real time qPCR is a rapid molecular method that can be used to detect and quantitate *Legionella pneumophila* and *Legionella* species not *pneumophila* in potable and non-potable water. Rapid detection down to genomic units which cannot be equated to cfu/mL. All water sources, biofilm and aerosol samples can be analyzed using qPCR.

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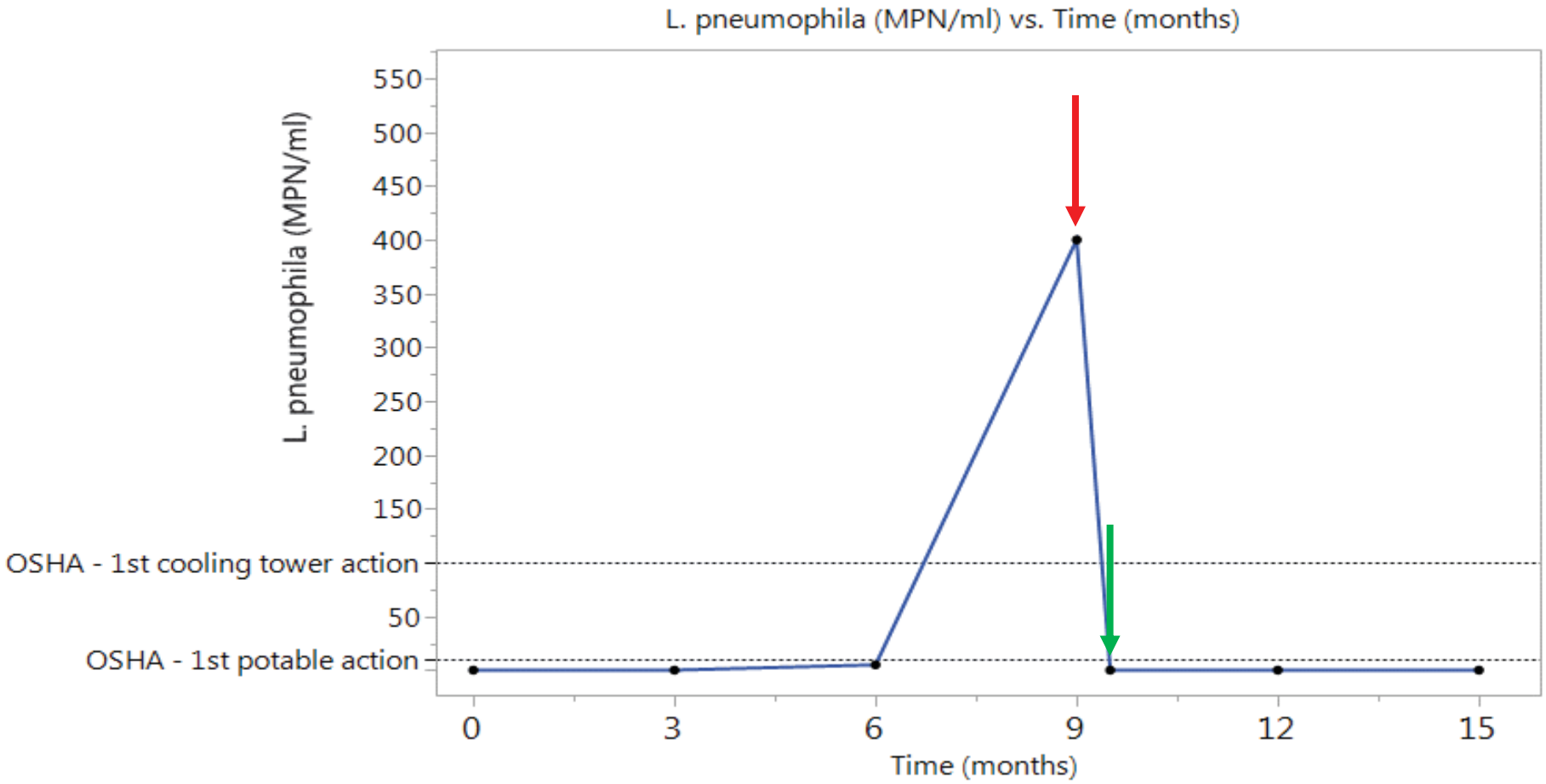
WSM Plan validation – Interpreting routine test results for *L. pneumophila*

1. How much is there/ what is the concentration?
2. Is this a **change** from an accepted baseline?
   - Results from test to test must be reliable to know this



Example Report

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Certificate of Analysis
AIHA-LAP EMLAP# 218951

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Aerobiology Laboratory - CA
15061 Springdale St
Huntington Beach, California 92649
Attn: Megan McElheny
Project: **Legiolert Test Report**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 05/16/2018
Date Received: 05/16/2018
Date Analyzed: 05/23/2018
Date Reported: 05/23/2018
Project ID: 18015901

Client Sample #: 1
Lab Sample #: 18015901-001
Sample Location: Positive Potable
Test: 1015.4, Water, Legionella pnemophila Detection, Legiolert (Quanti-Tray)
Results: **977 MPN/100mL**
Liquid Volume: **100 (mL)**
MRL: **10 CFU/100mL**

Client Sample #: 2
Lab Sample #: 18015901-002
Sample Location: Positive Non-potable
Test: 1015.4, Water, Legionella pnemophila Detection, Legiolert (Quanti-Tray)
Results: **93900 MPN/100mL**
Liquid Volume: **100 (mL)**
MRL: **1000 CFU/100mL**

Client Sample #: 3
Lab Sample #: 18015901-003
Sample Location: Negative Potable
Test: 1015.4, Water, Legionella pnemophila Detection, Legiolert (Quanti-Tray)
Results: **<10 MPN/100mL**
Liquid Volume: **100 (mL)**
MRL: **10 CFU/100mL**

Client Sample #: 4
Lab Sample #: 18015901-004
Sample Location: Negative Non-potable
Test: 1015.4, Water, Legionella pnemophila Detection, Legiolert (Quanti-Tray)
Results: **<1000 MPN/100mL**
Liquid Volume: **100 (mL)**
MRL: **1000 CFU/100mL**

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15061 Springdale St
Huntington Beach, California 92649
Attn: Megan McElheny
Project: **Legiolert Test Report**
Condition of Sample(s) Upon Receipt: Acceptable

Date Collected: 05/16/2018
Date Received: 05/16/2018
Date Analyzed: 05/23/2018
Date Reported: 05/23/2018
Project ID: 18015901

Footnotes and Additional Report Information

Debris Rating Table

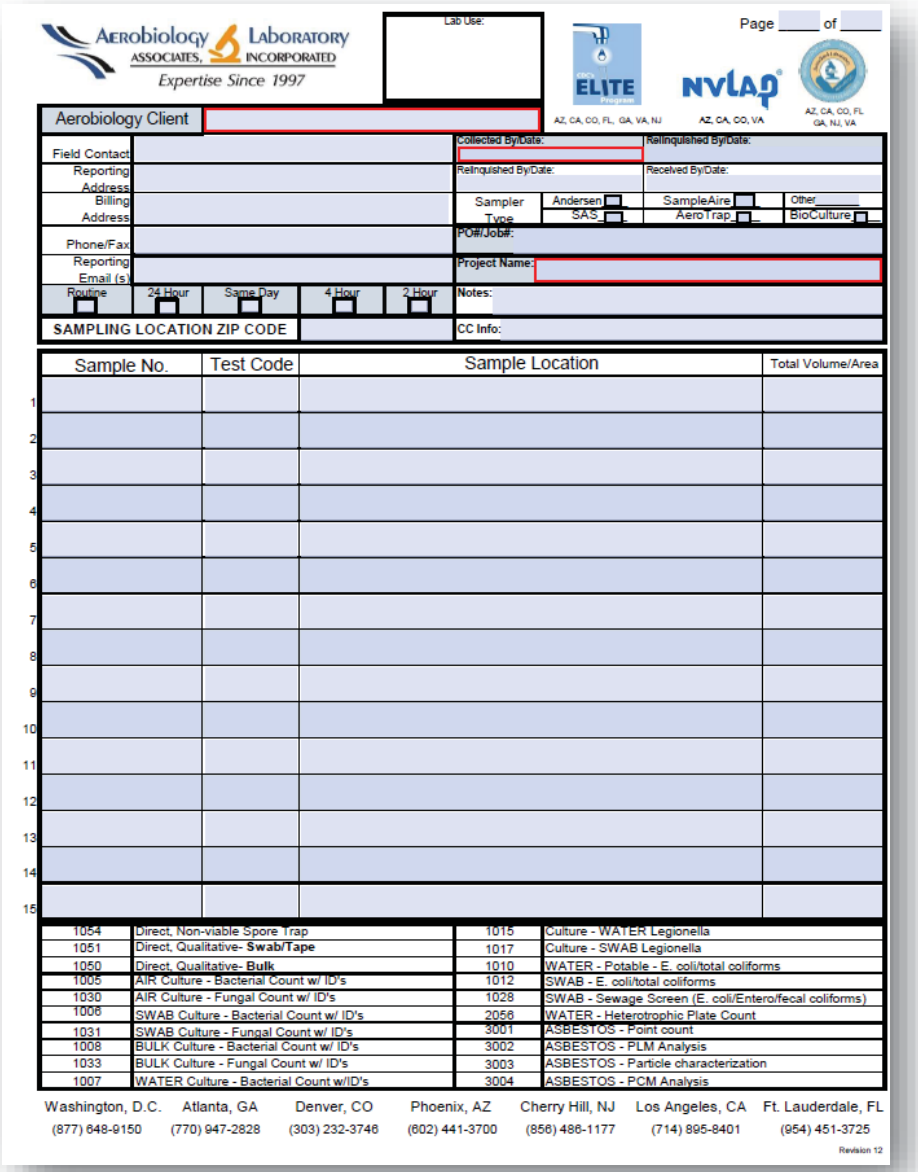
1	Minimal (<5%) particular present	Reported values are minimally affected by particulate load.
2	5% to 25% of the trace occluded with particulate	Negative bias is expected. The degree of bias increases directly with the percent of the trace that is occluded.
3	26% to 75% of the trace occluded with particulate	Negative bias is expected. The degree of bias increases directly with the percent of the trace that is occluded.
4	75% to 90% of the trace occluded with particulate	Negative bias is expected. The degree of bias increases directly with the percent of the trace that is occluded.
5	Greater than 90% of the trace occluded with particulate	Quantification not possible due to large negative bias. A new sample should be collected at a shorter time interval or other measures taken to reduce particulate load.

1. Penicillium/Aspergillus group spores are characterized by their small size, round to ovoid shape, being unicellular, and usually colorless to lightly pigmented. There are numerous genera of fungi whose spore morphology is similar to that of the Penicillium/Aspergillus type. Two common examples would be Paecilomyces and Acremonium. Although the majority of spores placed in this group are Penicillium, Aspergillus, or a combination of both. Keep in mind that these are not the only two possibilities.
2. Ascospores are sexually produced fungal spores formed within an ascus. An ascus is a sac-like structure designed to discharge the ascospores into the environment, e.g. Ascobolus.
3. Basidiospores are typically blown indoors from outdoors and rarely have an indoor source. However, in certain situations a high basidiospore count indoors may be indicative of a wood decay problem or wet soil.
4. The colorless group contains colorless spores which were unidentifiable to a specific genus. Examples of this group include Acremonium, Aphanocladium, Beauveria, Chrysosporium, Engyodontium microconidia, yeast, some arthrospores, as well as many others.
5. Hyphae are the vegetative mode of fungi. Hyphal elements are fragments of individual Hyphae. They can break apart and become airborne much like spores and are potentially allergenic. A mass of hyphal elements is termed the mycelium. Hyphae in high concentration may be indicative of colonization.
6. Dash (-) in this report, under raw count column means 'not detected (ND)'; otherwise 'not applicable' (NA).
7. The positive-hole correction factor is a statistical tool which calculates a probable count from the raw count, taking into consideration that multiple particles can impact on the same hole; for this reason the sum of the calculated counts may be less than the positive hole corrected total.
8. Due to rounding totals may not equal 100%.
9. Analytical Sensitivity for each spores is different for Non-viable sample when the spores are read at different percentage. Analytical Sensitivity is calculated as spr/m^3 divided by raw count. spr/m^3 = raw counts x (100/ % read) x (1000/Sample volume). If Analytical Sensitivity is 13 spr/m^3 at 100% read, Analytical Sensitivity at 50% read would be 27 spr/m^3, which is 2 times higher. Analytical Sensitivity provided on the report is based on an assumed 100% of the trace being analyzed.
10. Minimum Reporting Limits (MRL) for BULKS, DUSTS, SWABS, and WATER samples are a calculation based on the sample size and the dilution plate on which the organism was counted. Results are a compilation of counts taken from multiple dilutions and multiple medias. This means that every genus of fungi or bacteria recovered can be counted on the plate on which it is best represented.
11. If the final quantitative result is corrected for contamination based on the blank, the blank correction is stated in the sample comments section of the report.
12. Analysis conducted on non-viable spore traps is completed using Indoor Environmental Standards Organization (IESO) Standard 2210.
13. The results in this report are related to this project and these samples only.
14. For samples with an air volume of < 100L, the number of significant figures in the result should be considered (2) two. For samples with air volumes between 100-999L, the number of significant figures in the result should considered (3) three. For example, a sample with a result of 55,443 spr/m^3 from a 75L sample using significant figures should be considered 55,000. The same result of 55,443 from a 150L sample using significant figures should be considered 55,400 spr/m^3.
15. If the In/Out ratio is greater than 100 times it is indicated >100/1, rather than showing the real value.

Terminology Used in Direct Exam Reporting

Conidiophores are a type of modified hyphae from which spores are born. When seen on a surface sample in moderate to numerous concentrations they may be indicative of fungal growth.

Chain of Custody Example



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Lab Use:

Page ____ of ____

ELITE AZ, CA, CO, FL, GA, VA, NJ
NVLAP AZ, CA, CO, VA
AZ, CA, CO, FL GA, NJ, VA

Aerobiology Client

Field Contact		Collected By/Date:	Relinquished By/Date:
Reporting Address		Relinquished By/Date:	Received By/Date:
Billing Address		Sampler Type: Andersen ☐ SAS ☐	SampleAire ☐ AeroTrap ☐ Other ☐ BioCulture ☐
Phone/Fax		PO#/Job#:	
Reporting Email (s)		Project Name:	
Routine ☐ 24 Hour ☐ Same Day ☐ 4 Hour ☐ 2 Hour ☐		Notes:	
SAMPLING LOCATION ZIP CODE		CC Info:	

	Sample No.	Test Code	Sample Location	Total Volume/Area
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				

1054	Direct, Non-viable Spore Trap	1015	Culture - WATER Legionella
1051	Direct, Qualitative- **Swab/Tape**	1017	Culture - SWAB Legionella
1050	Direct, Qualitative- **Bulk**	1010	WATER - Potable - E. coli/total coliforms
1005	AIR Culture - Bacterial Count w/ ID's	1012	SWAB - E. coli/total coliforms
1030	AIR Culture - Fungal Count w/ ID's	1028	SWAB - Sewage Screen (E. coli/Entero/fecal coliforms)
1006	SWAB Culture - Bacterial Count w/ ID's	2056	WATER - Heterotrophic Plate Count
1031	SWAB Culture - Fungal Count w/ ID's	3001	ASBESTOS - Point count
1008	BULK Culture - Bacterial Count w/ ID's	3002	ASBESTOS - PLM Analysis
1033	BULK Culture - Fungal Count w/ ID's	3003	ASBESTOS - Particle characterization
1007	WATER Culture - Bacterial Count w/ID's	3004	ASBESTOS - PCM Analysis

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Revision 12

Routine Legionella validation testing provides concrete evidence of WSM Plan effectiveness

An ounce of prevention is worth a pound of cure…

Reasons building owners and managers are increasingly asking about routine Legionella testing:

- ✓ To reduce the risk of a deadly outbreak “on their watch”
- ✓ To reduce their liability
- ✓ To reduce the risk to their reputation
- ✓ To reduce their insurance costs or exposure

Verification and validation

Summary:

- Verification Confirms the WSM plan is being implemented
- Validation Confirms the WSM plan is effective
- Can uncover if there are any issues needing attention from the team
- Validation testing for the pathogen reduces risk and cost
- Insure all verification and validation results are documented