



CENTER FOR
ENVIRONMENTAL
TRAINING

Environmental Monitoring: Applications for Infection Control

Participants will be in listen only mode.

9 a.m. (PST)

Presented by:

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Download the PDF:

<http://www.emlab.com/m/media/infection-control-webinar.pdf>



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Outline

- Infections
- Infection Control Risk Assessment (ICRA)
- USP <797>
- *Legionella* Risk Management
- Environmental Monitoring
- Additional Methods (PCR, Endotoxin)

Infections

- **Infection** is the invasion of a host organism's bodily tissue by disease causing organisms their multiplication, and the reaction of host tissues to these organisms and the toxins they produce.
- Infectious **pathogens** include viruses, bacteria, fungi, protozoa, multicellular parasites, and prions.
 - **Primary pathogens** cause disease as a result of their presence or activity within the normal, healthy host.
 - **Opportunistic pathogens** cause an infectious disease in a host with depressed resistance.

Opportunistic Pathogens

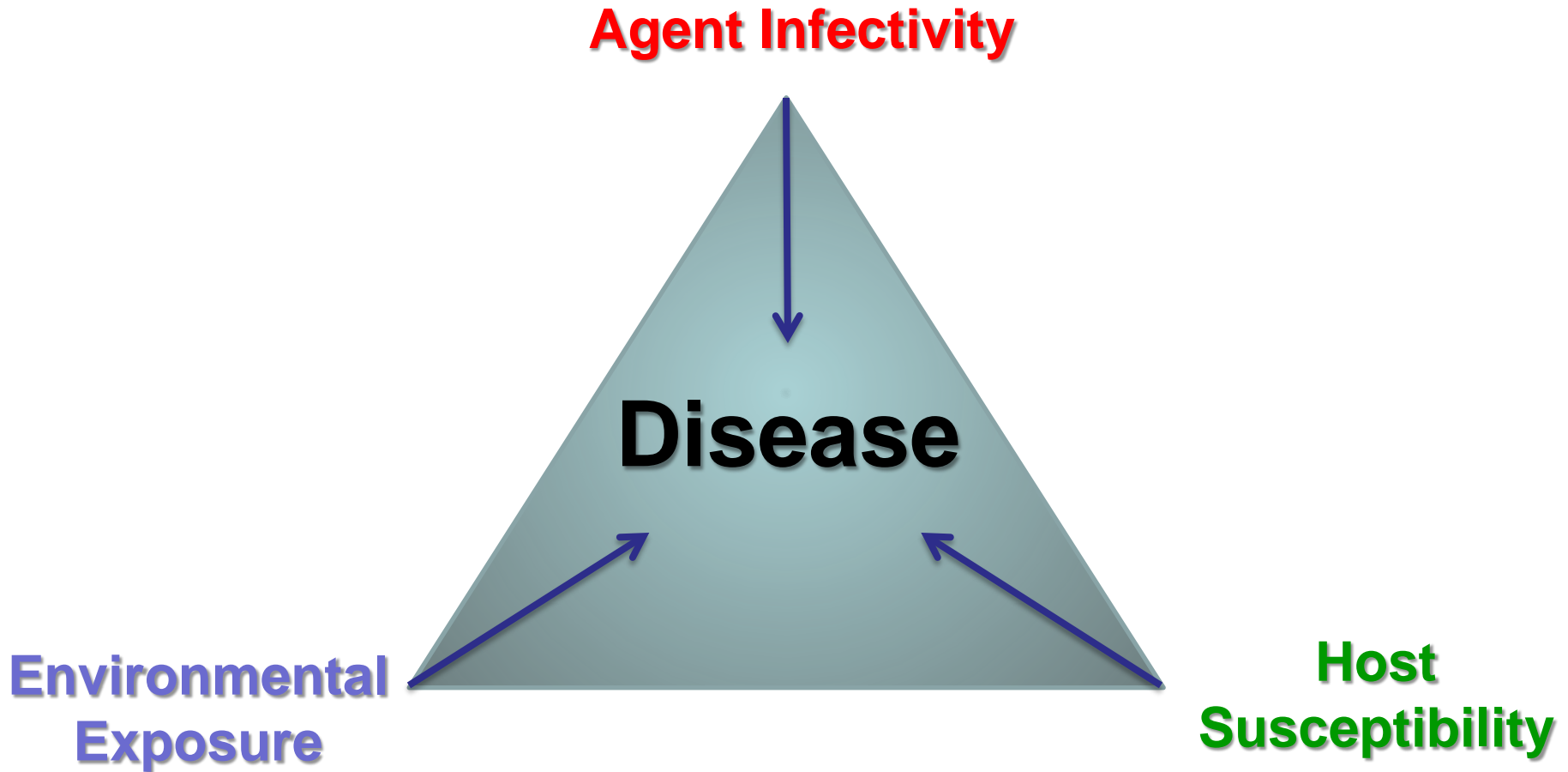
- **Risk factors**

- Immune-suppressed patients (e.g. chemotherapy, organ transplant, HIV)
- Disruption or natural barriers (e.g. wound infections, catheters, dialysis, surgery)
- High concentration of opportunistic pathogens in the environment (e.g. *Legionella* bacteria in cooling towers)
- Other risk groups (e.g. elderly, smokers, CPOD patients)

Examples of Opportunistic Pathogens

- **Organisms (examples)**
 - *Staphylococcus aureus* and MRSA
 - *Legionella* bacteria
 - Mycobacteria
 - Candida (yeast)
 - *Aspergillus*

Infectious Diseases



Routes of Transmission

One-to-one contact	Direct	Direct physical contact (body surface to body surface) between infected or colonized individual and susceptible host.
	Indirect	Infectious agent deposited onto an object or surface (fomite) and survives long enough to transfer to another person .
	Droplet	Contact, but transmission is through the air. Droplets are typically $>5 \mu\text{m}$.
Non-contact	Airborne	Transmission via aerosols (airborne particles $<5 \mu\text{m}$) that contain organisms in droplet nuclei or in dusts.
	Vehicle	For example food-borne outbreaks. Single contaminated source.
	Vector borne	Transmission by insect or animal vectors (e.g. Malaria).

Infection Control in Hospitals

HAI Estimates Occurring in US Acute Care Hospitals, 2011

Major Site of Infection	Estimated No.
Pneumonia	157,500
Gastrointestinal Illness	123,100
Urinary Tract Infections	93,300
Primary Bloodstream Infections	71,900
Surgical site infections from any inpatient surgery	157,500
Other types of infections	118,500
Estimated total number of infections in hospitals	721,800

<http://www.cdc.gov/hai/surveillance/index.html>

Guidelines for Infection Control

CDC: Guidelines for Environmental Infection Control in Health-Care Facilities (2003 last updated in 2017)

Part I: Background Information: Environmental Infection Control in Health-Care Facilities

- Construction, demolition, renovation, and repairs of health-care facilities.
- Infection-control risk assessment (ICRA)
- Catastrophic events (e.g., flooding, sewage spills, loss of electricity and ventilation, and disruption of the water supply) etc.

Part II: Recommendations for Environmental Infection Control in Health-Care Facilities

- Measures for preventing infections associated with air, water, and other elements of the environment .

<https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines.pdf>

CDC/HICPAC on Environmental Monitoring

For hospital construction, renovation, remediation, repair, and demolition projects.

- Establish and maintain surveillance for airborne environmental disease (e.g., aspergillosis) as appropriate during construction, renovation, repair, and demolition activities.
- No recommendation is offered regarding routine microbiologic air sampling before, during, or after construction...**Unresolved issue.**
- Before the project gets under way, perform an Infection Control Risk Assessment (ICRA) to define the scope of the activity and the need for barrier measures.

Unresolved issue. *No recommendation is offered. No consensus or insufficient evidence exists regarding efficacy.*

http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5210a1.htm?s_cid=w_c_CustomRssWidget_frm_001

Hospital Construction and Renovation

Example for Infection Control Risk Assessment

- **Infection control risk assessment (CCDR, Vol.2752, July 2001. ISSN 1188-4169)**
- **Matrix**
 - Step 1: Determine type of construction activity
 - Step 2: Identify patient risk groups
 - Step 3: Match patient risk group with planned construction project type to determine level of infection control activities

http://publications.gc.ca/collections/collection_2016/aspc-phac/HP3-1-27-S2-eng.pdf

Infection Control Risk Assessment

<p>TYPE A</p>	<p>Inspection and Non-Invasive Activities. Includes, but is not limited to:</p> <ul style="list-style-type: none"> •removal of ceiling tiles for visual inspection only, e.g., limited to 1 tile per 50 square feet •painting (but not sanding) •wallcovering, electrical trim work, minor plumbing, and activities which do not generate dust or require cutting of walls or access to ceilings other than for visual inspection.
<p>TYPE B</p>	<p>Small scale, short duration activities which create minimal dust Includes, but is not limited to:</p> <ul style="list-style-type: none"> •installation of telephone and computer cabling •access to chase spaces •cutting of walls or ceiling where dust migration can be controlled.
<p>TYPE C</p>	<p>Work that generates a moderate to high level of dust or requires demolition or removal of any fixed building components or assemblies Includes, but is not limited to:</p> <ul style="list-style-type: none"> •sanding of walls for painting or wallcovering •removal of floor coverings, ceiling tiles and casework •new wall construction •minor duct work or electrical work above ceilings •major cabling activities •any activity which cannot be completed within a single workshift.
<p>TYPE D</p>	<p>Major demolition and construction projects Includes, but is not limited to:</p> <ul style="list-style-type: none"> •activities which require consecutive work shifts •requires heavy demolition or removal of a complete cabling system •new construction.

Infection Control Risk Assessment (cont'd)

Low Risk	Medium Risk	High Risk	Highest Risk
<ul style="list-style-type: none"> Office areas 	<ul style="list-style-type: none"> Cardiology Echocardiography Endoscopy Nuclear Medicine Physical Therapy Radiology/MRI Respiratory Therapy 	<ul style="list-style-type: none"> CCU Emergency Room Labor & Delivery Laboratories (specimen) Medical Units Newborn Nursery Outpatient Surgery Pediatrics Pharmacy Post Anesthesia Care Unit Surgical Units 	<ul style="list-style-type: none"> Any area caring for immuno-compromised patients Burn Unit Cardiac Cath Lab Central Sterile Supply Intensive Care Units Negative pressure isolation rooms Oncology Operating rooms including C-section rooms

Infection Control Risk Assessment (cont'd)

Risk Matrix

	Construction Project Type			
Patient Risk Group	TYPE A	TYPE B	TYPE C	TYPE D
Low	I	II	II	III/IV
Medium	I	II	III	IV
High	I	II	III/IV	IV
Highest	II	III/IV	III/IV	IV

Infection control risk assessment (CCDR, Vol.2752, July 2001. ISSN 1188-4169)

Infection Control Risk Assessment (cont'd)

Part D: Specifications for Infection Prevention and Control Measures

Class I	<p>Engineer/Maintenance Staff & Contractors</p> <p><i>a) Construction/Renovation Activities</i></p> <p>Dust Control*</p> <ul style="list-style-type: none"> • Immediately replace tiles displaced for visual inspection • Vacuum work area.
Date:	
Initials:	<p><i>b) Plumbing Activities</i></p> <ul style="list-style-type: none"> • Schedule water interruptions during low activity (e.g. evenings if at all possible) • Flush water lines prior to reuse • Observe for discoloured water • Ensure water temperature meets the standards set by the health care facility • Ensure gaskets and items made of materials that support the growth of <i>Legionella</i> are not being used • Ensure faucet aerators are not installed or used • Maintain as dry an environment as possible and report any water leaks that occur to walls and substructures <p>Environmental Services</p> <p><i>a) Plumbing Activities</i></p> <ul style="list-style-type: none"> • Report discoloured water and water leaks to maintenance and ICP <p>Medical/Nursing Staff</p> <p><i>a) Construction/Renovation Activities</i></p> <p>Risk Reduction</p> <ul style="list-style-type: none"> • Minimize patients' exposure to construction/renovation area <p><i>b) Plumbing Activities</i></p> <ul style="list-style-type: none"> • Report discoloured water and water leaks to maintenance and ICP

* Note. Class II specifications must be followed if dust should be created during the Type A construction activity.

Infection Control Risk Assessment (cont'd)

Class IV	The following specifications are to be considered in addition to those in Class I, II and III
Date:	<p>Engineer/Maintenance Staff & Contractors</p> <p>a) <i>Construction/Renovation Activities</i></p> <p>1) Dust Control</p> <ul style="list-style-type: none"> • Before starting the construction project erect an impermeable dust barrier that also has an anteroom • Place a walk-off mat outside the anteroom in patient care areas and inside the anteroom to trap dust from the workers' shoes, equipment and debris that leaves the construction zone • Ensure that construction workers leave the construction zone through the anteroom so they can be vacuumed with a HEPA filtered vacuum cleaner before leaving the work site; or that they wear cloth or paper coveralls that are removed each time they leave the work site • Direct all personnel entering the construction zone to wear shoe covers • Ensure that construction workers change the shoe covers each time they leave the work site • Repair holes in walls within 8 hours or seal them temporarily <p>2) Ventilation</p> <ul style="list-style-type: none"> • Ensure negative pressure is maintained within the anteroom and construction zone • Ensure ventilation systems are working properly in adjacent areas • Review ventilation system requirements in the construction area with ICP to ensure system is appropriate and is functioning properly <p>3) Evaluation</p> <ul style="list-style-type: none"> • Review infection control measures with other members of the planning team or delegate to evaluate their effectiveness and identify problems at the end of the construction project <p>b) <i>Plumbing Activities</i></p> <ul style="list-style-type: none"> • If there are concerns about <i>Legionella</i>, consider hyperchlorinating stagnant potable water or superheating and flushing all distal sites before restoring or repressurizing the water system <p>Environmental Services</p> <p>a) <i>Construction/Renovation Activities</i></p> <p>Evaluation</p> <ul style="list-style-type: none"> • Review infection prevention and control measures with other members of the planning team or delegate to evaluate their effectiveness and identify problems at the end of the construction project <p>Infection Prevention and Control Personnel</p>
Initials:	

Infection control risk assessment (CCDR, Vol.2752, July 2001. ISSN 1188-4169)

Infection Control Risk Assessment (cont'd)

Environmental Monitoring

Surveillance activities should augment preventive strategies during construction projects. By determining baseline levels of health-care acquired airborne and waterborne infections, infection-control staff can monitor changes in infection rates and patterns during and immediately after construction, renovations, or repairs.

<https://www.cdc.gov/infectioncontrol/pdf/guidelines/environmental-guidelines.pdf>

Environmental Monitoring

Environmental testing strategies and methods:

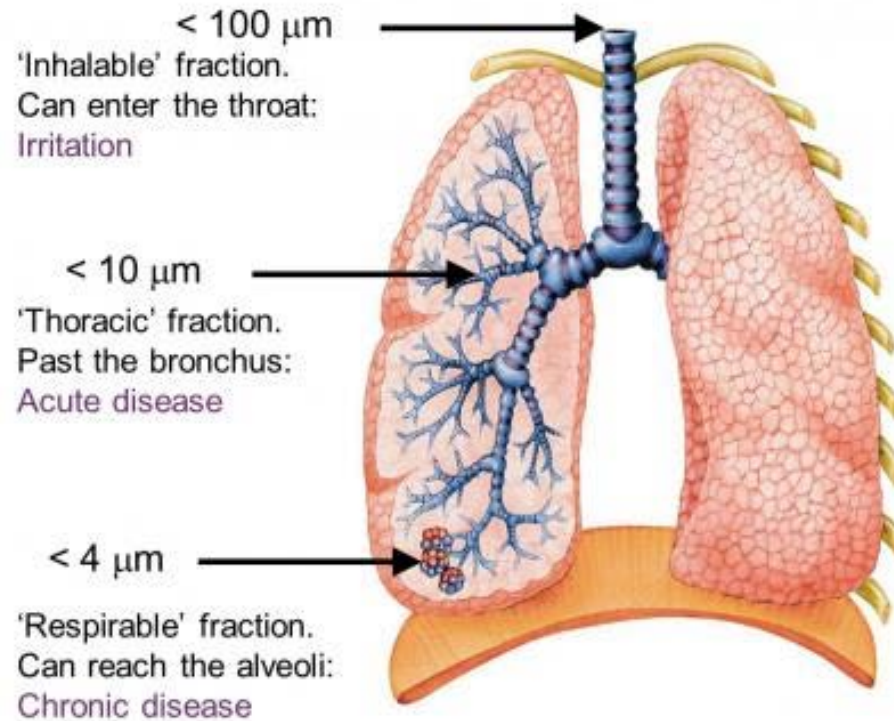
- ISO 14644 (total particle counts)
- Air and surface testing (e.g. USP797)
- Water testing (e.g. *Legionella*)
- Polymerase Chain Reaction (PCR)
- Endotoxin testing

ISO 14644 and FED-STD-209E

Number of Particles per Cubic Meter by Micrometer Size

ISO Class	0.1 μm	0.2 μm	0.3 μm	0.5 μm	1 μm	5 μm	FED STD 209 Class
ISO 1	10	2					
ISO 2	100	24	10	4			
ISO 3	1,000	237	102	35	8		1
ISO 4	10,000	2,370	1,020	352	83		10
ISO 5	100,000	23,700	10,200	3,520	832	29	100
ISO 6	1,000,000	237,000	102,000	35,200	8,320	293	1000
ISO 7				352,000	83,200	2,930	10000
ISO 8				3,520,000	832,000	29,300	100000
ISO 9				35,200,000	8,320,000	293,000	

Particle Size



https://volcanoes.usgs.gov/volcanic_ash/respiratory_effects.html

ISO 14644

- **ISO 14644**
 - Counting particle via handheld particle counter



USP <797>

- A chapter of the United States Pharmacopeia – National Formulary (USP-NF)
- Establishes best practices and regulations for the production of compounded sterile preparations



Where Does USP <797> Apply?

- Any facility producing CSPs and any personnel who perform compounding are subject to regulation by USP <797>.
- The **Act of Compounding** determines regulation, not the nature of the facility.
- Requirements of USP <797> depend on the nature of the compounding being performed.

Action Levels

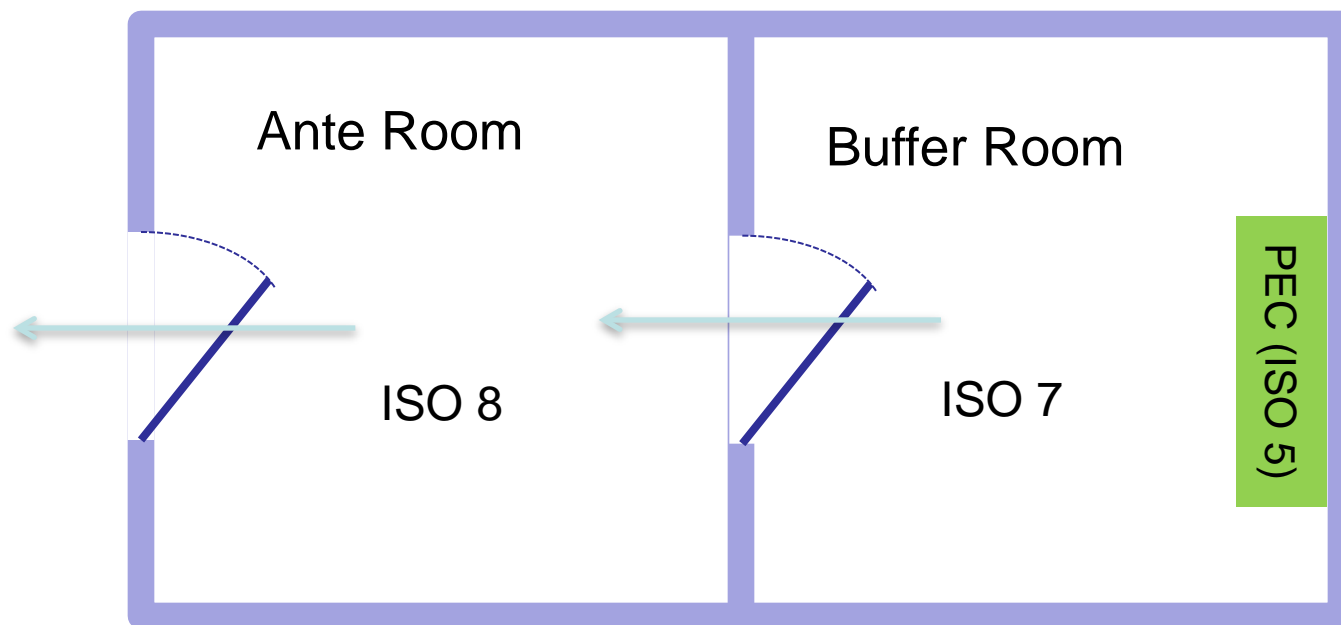
ISO Class	$\geq 0.5 \mu\text{m}$ Nonviable particles/m ³	Viable Airborne (cfu*/m ³)	Viable Surface** (cfu/contact plate)
5	3,520	>1	>3
7	352,000	>10	>5
8	3,520,000	>100	>100

- Recommended action levels are on the chart, also need to look for excursions from baseline.
- Documentation is the key to determining baseline levels.

*CFU – Colony Forming Units

** Contact plate areas vary from 24 to 30 cm². When swabbing is used in sampling, the area covered should be at least 24 cm² but no larger than 30 cm².

Cleanroom Design



Environmental Sampling – Types

- **Non-viable (ISO 14644)**
- **Viable testing**
 - Environmental Monitoring
 - ✓ Air
 - ✓ Surface
 - Personnel Qualification
 - ✓ Gloved finger tip
 - ✓ Media fill test

Viable Testing: Air Sampling

- ✓ Air sampling in all classified areas
- ✓ Volumetric sampling at 400 – 1000 liters
- ✓ During typical operating conditions at least monthly semi annually
- ✓ Use general microbiological growth medium (e.g. TSA or Soybean Casein Digest Medium)
- ✓ Proposed changes (new revision):
 - Frequency of sampling (monthly)
 - Air volume (1000 liter for all)
 - Revised risk classifications
 - Etc.



Viable Testing: Air Sampling (cont'd)

- ✓ Decontaminate sampling equipment
- ✓ Examine media for contamination
- ✓ Start sampling
- ✓ Close the plate, label & transport to lab/incubator
- ✓ Incubate bacterial plates (e.g. TSA) for 2 – 3 days at 30°C - 35°C
- ✓ Incubate fungal plates (e.g. MEA) for 5 – 7 days at 20°C - 25°C
- ✓ Proposed change: Dual incubation on one medium

Viable Testing: Surface Sampling

- ✓ Testing for contamination of work surfaces
- ✓ Evaluate disinfection and cleaning procedures
- ✓ Must be performed in all ISO classified area
- ✓ Must be performed at the conclusion of compounding activities but before cleaning/disinfection
- ✓ Media must be supplemented with additives to neutralize effects of disinfectants (e.g. TSA with lecithin and polysorbate 80)
- ✓ Sampling must be conducted periodically
- ✓ Proposed change: Sampling at least monthly

Viable Testing: Surface Sampling (cont'd)

Contact Plates or Paddles (24 – 30 cm²)

- Easy to use
- Accurate
- Less handling



Swabs

- Can sample curved surfaces
- Convenient
- Less expensive



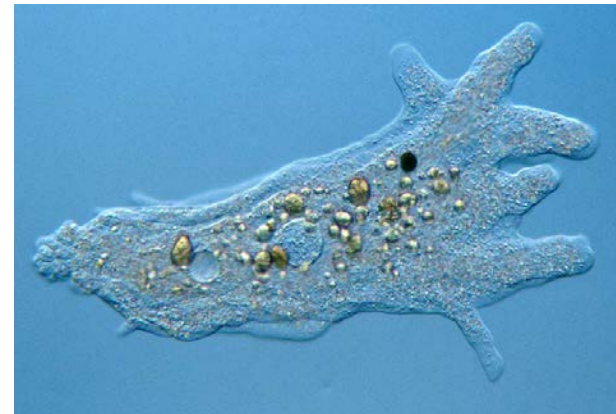
Sampling Plan

Where Should Samples Be Taken?

- One sample from each area, ISO 5, 7 and 8 at minimum. All separate areas must be tested.
- Use a map to identify and test critical areas.
- Sample during compounding operations or immediately afterwards.
- Document location, collection method, frequency of sampling, volume, and time of day relative to compounding activities.

Legionella – Basic Biology

- Gram negative rod-shaped bacterium
- Approx. 60 species and 70 serogroups have been described
- Widely distributed natural inhabitant of water.
- Survives and multiplies as intracellular parasite (e.g. in Amoebae)



Amoeba proteus.

Source: <http://www.microscopy-uk.org.uk>

Legionella – Temperature Requirements

- 35-46°C (95 - 115°F): Optimum temperature range for growth
- Below 20°C (<68°F): Predominantly dormant but viable
- Above 50°C (>122°F): 90% kill in 2 hrs
- Above 60°C (>140°F): 90% kill in 2 min
- Above 70°C (>158°F): 100% rapid kill



Optimal temperature range for growth of *Legionella* (20°C - 50°C)

Legionella – Basic Pathology

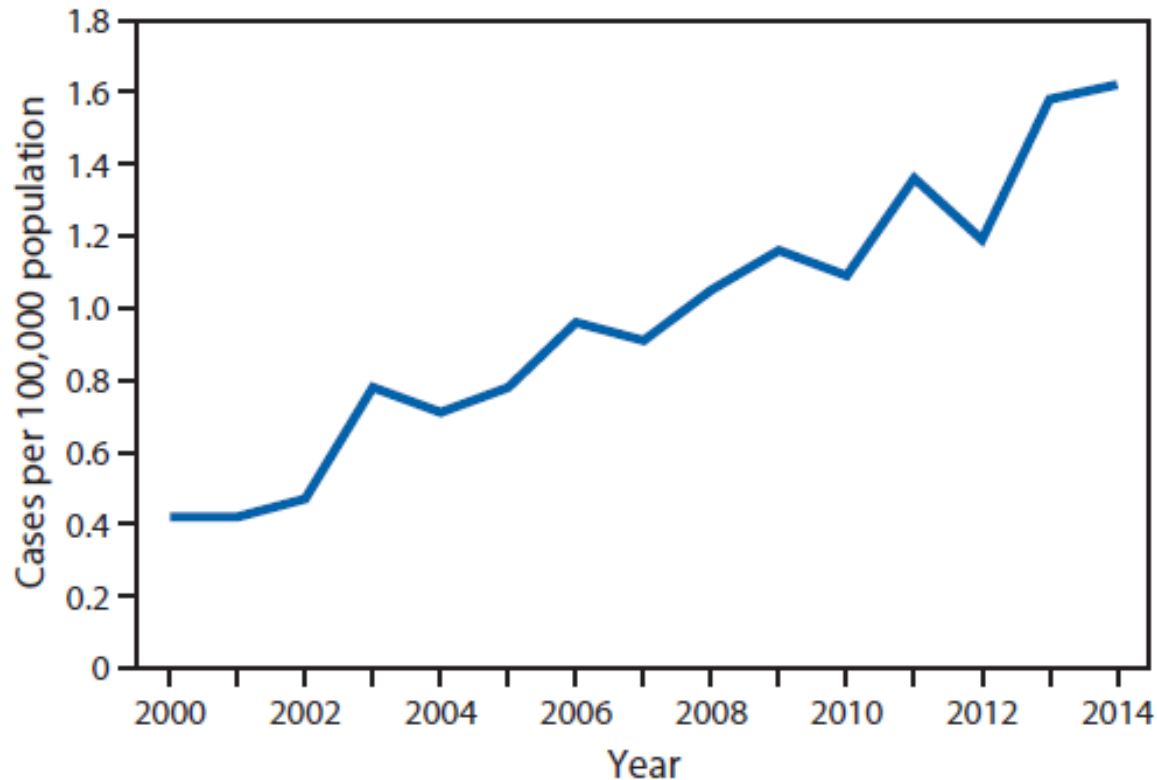
- **Legionella is the causative agent of Legionellosis**

Legionellosis takes two distinct forms:

- **Pontiac fever:** respiratory illness without pneumonia, symptoms resemble acute influenza
- **Legionnaires' disease:** symptoms include fever, chills, cough, muscle aches, headache, tiredness, loss of appetite, loss of coordination (ataxia), and occasionally diarrhea and vomiting.

Legionella – CDC review

Reported Cases of Legionellosis, US, 2000-2014



Source: <http://www.cdc.gov/mmwr>

Legionella – CDC review

JUNE 2016
Vital signs™

Legionnaires' Disease

Use water management programs in buildings to help prevent outbreaks

CDC investigated the first outbreak of Legionnaires' disease, a serious lung infection (pneumonia), in 1976. An increasing number of people in the US are getting this disease, which is caused by breathing in small water droplets contaminated with *Legionella* germs. About 5,000 people are diagnosed with Legionnaires' disease and there are at least 20 outbreaks reported each year. Most identified outbreaks are in buildings with large water systems, such as hotels, long-term care facilities, and hospitals. *Legionella* grows best in building water systems that are not well maintained. Building owners and managers should adopt newly published standards that promote *Legionella* water management programs, which are ways to reduce the risk of this germ in building water systems.

Building owners and managers can:

- Learn about and follow newly published standards for *Legionella* water management programs. <http://bit.ly/1P3wOP>
- Determine if the water systems in their buildings are at increased risk of growing and spreading *Legionella*.
- Develop and use a *Legionella* water management program as needed. www.cdc.gov/legionella/WMPoolkit
- Monitor and respond to changes in water quality.

Want to learn more? www.cdc.gov/vitalsigns/legionnaires

National Center for Immunization and Respiratory Diseases
National Center for Environmental Health

U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

4x
The number of people with Legionnaires' disease grew by nearly 4 times from 2000–2014.


1 in 10
Legionnaires' disease is deadly for about 10% of people who get it.

9 in 10
CDC investigations show almost all outbreaks were caused by problems preventable with more effective water management.

CDC reports:

- ✓ 4x increase of legionellosis between 2000 and 2014
- ✓ 10% fatality rate
- ✓ 9 in 10 cases were caused by problems preventable with more effective water management

Legionella – CDC review



A *Legionella* water management program consists of:

- 1 Establishing a water management program team.
- 2 Describing the building water systems using words and diagrams.
- 3 Identifying areas where *Legionella* could grow and spread.
- 4 Deciding where control measures should be applied and how to monitor them.
- 5 Establishing ways to intervene when control limits are not met.
- 6 Making sure the program is running as designed and is effective.
- 7 Documenting and communicating all the activities.

www.cdc.gov/legionella/WMPtoolkit

SOURCE: ASHRAE 188: Legionellosis: Risk Management for Building Water Systems
June 26, 2015.

Water management program

- 1) Establish management team
- 2) Describe building water system
- 3) Identify areas where *Legionella* could grow and spread
- 4) Decide where control measures are applied and how to monitor them
- 5) Establish ways to intervene when control limits are not met
- 6) Make sure the program is effective
- 7) Document and communicate all activities

ANSI/ASHRAE Standard 188

purpose

... to establish minimum Legionellosis risk management requirements for building water systems.

scope

... applies to human-occupied commercial, institutional, multiunit residential, and industrial buildings - excluding single-family homes

intended use

... building owners and managers as well as individuals involved in design, installation, commissioning etc. of centralized building water systems and components

ANSI/ASHRAE 188 – Relevance

Applicable to buildings with the following features:

- multiple housing units with one or more centralized potable water heater systems,
- more than 10 stories high
- healthcare facilities where patient stays exceed 24 hours,
- buildings containing one or more areas for the purpose of housing or treating occupants receiving treatment for burns, chemotherapy for cancer, or solid organ transplantation etc.
- buildings containing one or more areas for the purpose of housing or treating occupants that are immuno-compromised, at-risk, are taking drugs that weaken the immune system, have renal disease, have diabetes or have chronic lung disease etc.
- buildings identified by the owner or designee as being for the purpose of housing occupants over the age of 65 years.

...when any one of the risk factors applies

ANSI/ASHRAE 188 – Compliance

Are building owners required to comply with ASHRAE 188?

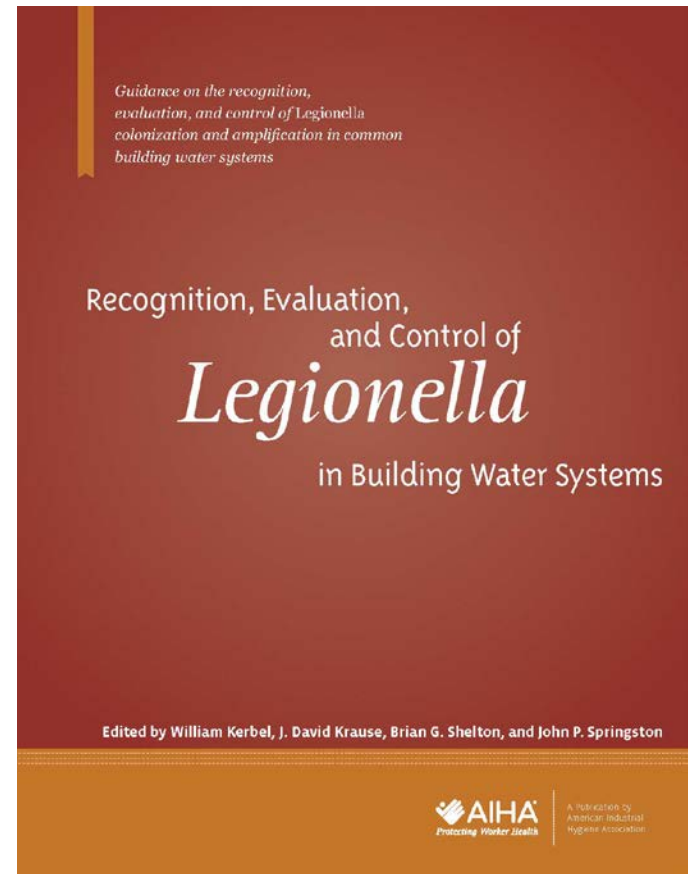
- ASHRAE Standard 188 is a set of standards, not legislation!
- It provides a robust and effective *Legionella* risk management system
- It provides protection against allegations of wrongdoing or negligence, should a *Legionella* outbreak occur.

AIHA *Legionella* Guidelines

American Industrial Hygiene Association (AIHA)

Published on August 10, 2015

“This is the first guideline that takes a new, preventive approach, based on proven industrial hygiene principles to controlling the spread of *Legionella*.”



New York Regulations

Secure | <https://regs.health.ny.gov/content/part-4-protection-against-legionella>

**New York Codes, Rules
and Regulations**

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Effective Date

07/06/2016

Part 4 - Protection Against Legionella

- [Subpart 4-1 - Cooling Towers](#)
- [Subpart 4-2 - Health Care Facilities](#)
- [Appendix 4-A - Interpretation of Legionella Culture Results from Cooling Towers](#)
- [Appendix 4-B - Interpretation of Routine Legionella Culture Results from Covered Facilities](#)

Sampling for *Legionella*

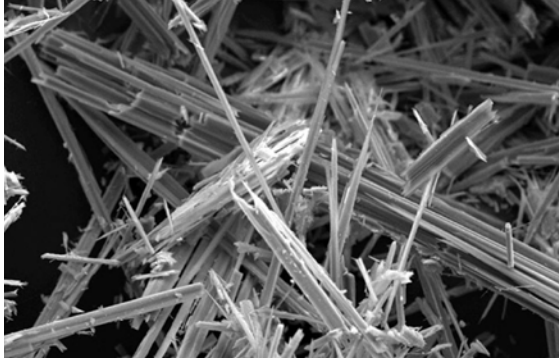
Sample types

- Water samples
- Swab samples
- Air samples

Sampling instructions:

www.osha.gov/dts/osta/otm/legionnaires/sampling.html

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Or email **mdeese@emlabpk.com**

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the Press:
8th edition!

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- Updated MoldRange™ data from over 350,000 spore trap samples
- Data interpretation guidelines

To order a complimentary Pocket Guide, please complete the survey after the webinar.

NOTE: Sent to United States and Canada only. Limit one per person per calendar year. See “Thank you” email (sent an hour after the webinar) for a link to the survey to order your Pocket Guide.

Sampling for *Legionella* (cont'd)

Respiratory Protection

- If significant potential exists for exposure to high concentrations of contaminated aerosols
- Respirators should be equipped with a HEPA or similar filter capable of effectively collecting particles of 1-micrometer



Sampling – Water Samples

- 250 ml or 1 L polypropylene bottles
- Collect 250 ml - 1 L water
- Add sodium thiosulfate
- Warm water systems
- Collect pre- and post-flush sample
- Cold water systems may also contain *Legionella* bacteria



Sampling – Surface Swabs

- Swabs can be used to collect surface samples
- Especially useful for investigating biofilms



Sampling – Air Samples

- Air sampling is typically not recommended.
- Impaction samplers often collect fast growing fungi and bacteria which overwhelm slow growing *Legionella*.
- Concentration of *Legionella* in water is generally higher than in air and easier to detect.



Source: CDC 2005: Procedures for the Recovery of *Legionella* from the Environment.

Shipping Samples

- Overnight
- Temperature stable coolers
- ISO recommended shipping temp: 6° C - 18° C
- Check for local regulations



Action Limits

- There are no mandated action limits or threshold levels beyond which remediation should take place except New York.
- Action limits should be based on the threat of infection from exposure
- Ideally, for clinics, hospitals and nursing homes the level of “acceptable” contamination should be below the limits of detection.

Action Limits – EWGLI

European Working Group on *Legionella* Infections...

Hot and cold water systems

Legionella bacteria per liter	Action required
More than 1000 up to 10,000	<ul style="list-style-type: none">• At 10 – 20% positive samples, re-sample, review control measures, conduct risk assessment.• If most samples are positive, in addition consider disinfection.
More than 10,000	<ul style="list-style-type: none">• Identify remedial actions, immediate review control measures, conduct risk assessment, identify remedial actions.

Action Limits – EWGLI (cont'd)

European Working Group on *Legionella* Infections...

Cooling towers

Legionella bacteria per liter	Action required
1000 or less	<ul style="list-style-type: none">• System under control
More than 1000 less than 10,000	<ul style="list-style-type: none">• Review program operation. Review of control measures and risk assessment should be carried out to identify any remedial actions.
More than 10,000	<ul style="list-style-type: none">• Conduct risk assessment and implement corrective action.

Action Limits – OSHA

- **OSHA technical manual...**

- Action 1: Prompt cleaning and/or treatment of the system.
- Action 2: Immediate cleaning and take prompt steps to prevent employee exposure.

Action	Cooling Tower	Domestic Water	Humidifier
1	100 CFU/ml	10 CFU/ml	1 CFU/ml
2	1,000 CFU/ml	100 CFU/ml	10 CFU/ml

NY Result Interpretation – Cooling Towers

- Appendix 4-A (NY Regulations) – Interpretation of *Legionella* Culture Results from Cooling Towers

Results (cfu per ml)	Approach
<20 (or no detection)	Maintain treatment program and <i>Legionella</i> monitoring
≥20	Review treatment program
<100 (but >20)	Institute immediate online disinfection Retest water in 3 -7 days Continue retest and treatments until 2 consecutive acceptable tests are obtained
<1000 (but >100)	Further investigate treatment program in addition
≥1000	Review treatment program Institute immediate online decontamination Continue retest and treatments until 2 consecutive acceptable tests are obtained

<https://regs.health.ny.gov/volume-title-10/1339572150/appendix-4-interpretation-legionella-culture-results-cooling-towers>

NY Result Interpretation - Health Care Facilities

- Appendix 4-B (NY Regulations) – Interpretation of Routine *Legionella* Culture Results from Covered Facilities

% positive <i>Legionella</i> test sites	Approach
< 30%	Maintain environmental assessment and <i>Legionella</i> monitoring in accordance with the sampling and management plan.
≥ 30%	Immediately institute short term control measures Re-sample no sooner than 7 days and no later than 4 weeks Implement long term control measures to ensure ≤30% positive sites If ≥30% positive sites, repeat short term control measures

<https://regs.health.ny.gov/volume-title-10/11428922/appendix-4-b-interpretation-routine-legionella-culture-results-covered>

Action Limits – Considerations

- The presence of any viable cells can lead to infection if inhaled
- Strive for levels below limits of detection for immune suppressed populations
- Always be aware of local regulations

Remediation

- ✓ **Heat:** 158°-176° F (70°-80° C): Disinfection range
- ✓ **Chlorination:** free Chlorine (Cl_2), Chlorine Dioxide (ClO_2), Monochloramine (NH_2Cl)
- ✓ **Copper/Silver Ionization**
- ✓ **Biocides**
- ✓ **UV light**
- ✓ **Ozone**



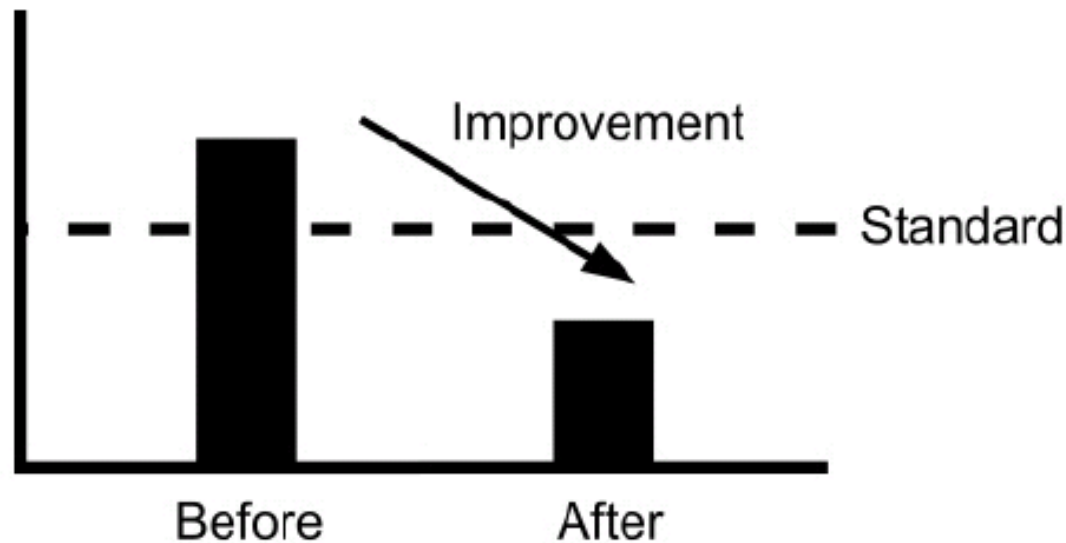
Source: <http://www.ozotech.com/>



Source: David Swiderski, Liquitech

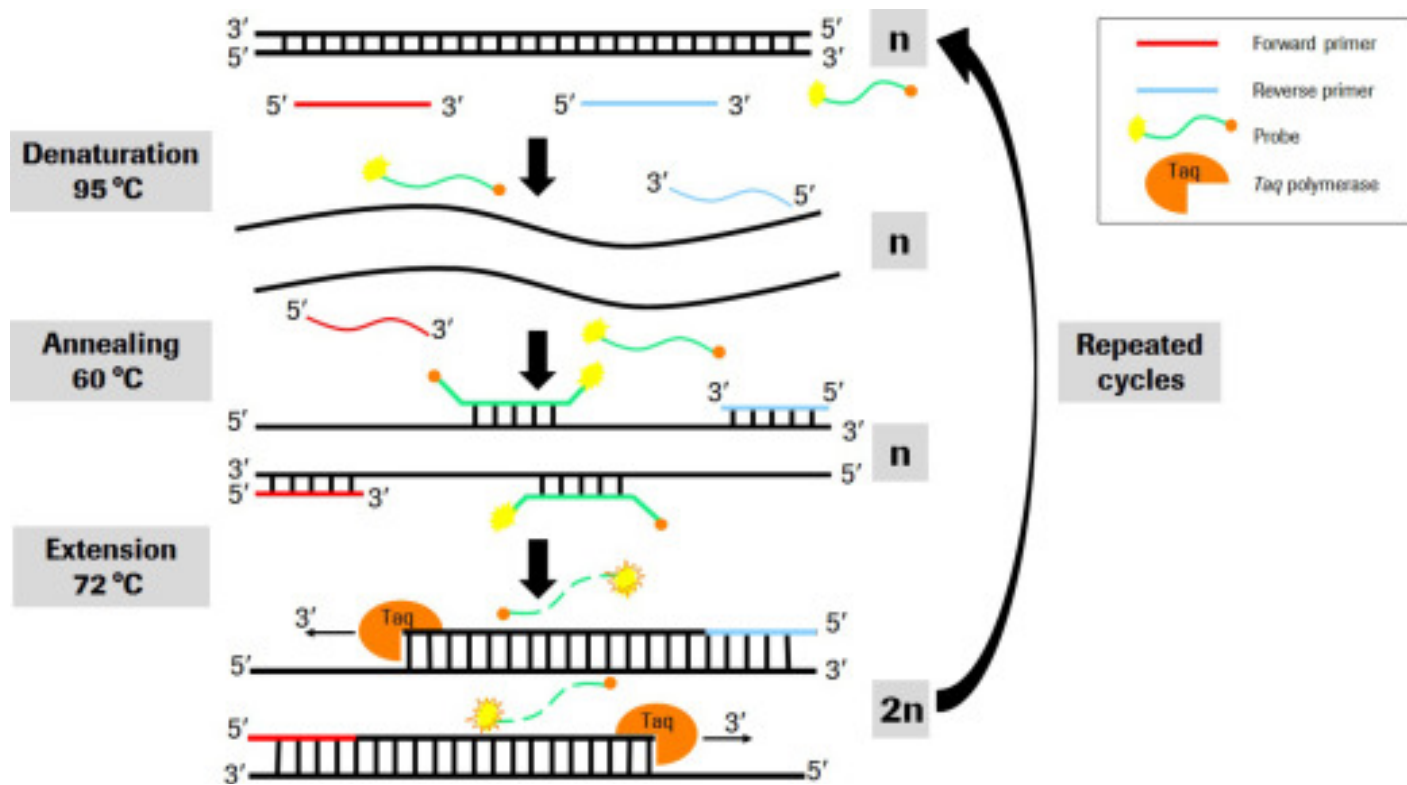
Confirmation of Disinfection

- Samples should be collected after treatment to demonstrate successful elimination of the *Legionella* contamination



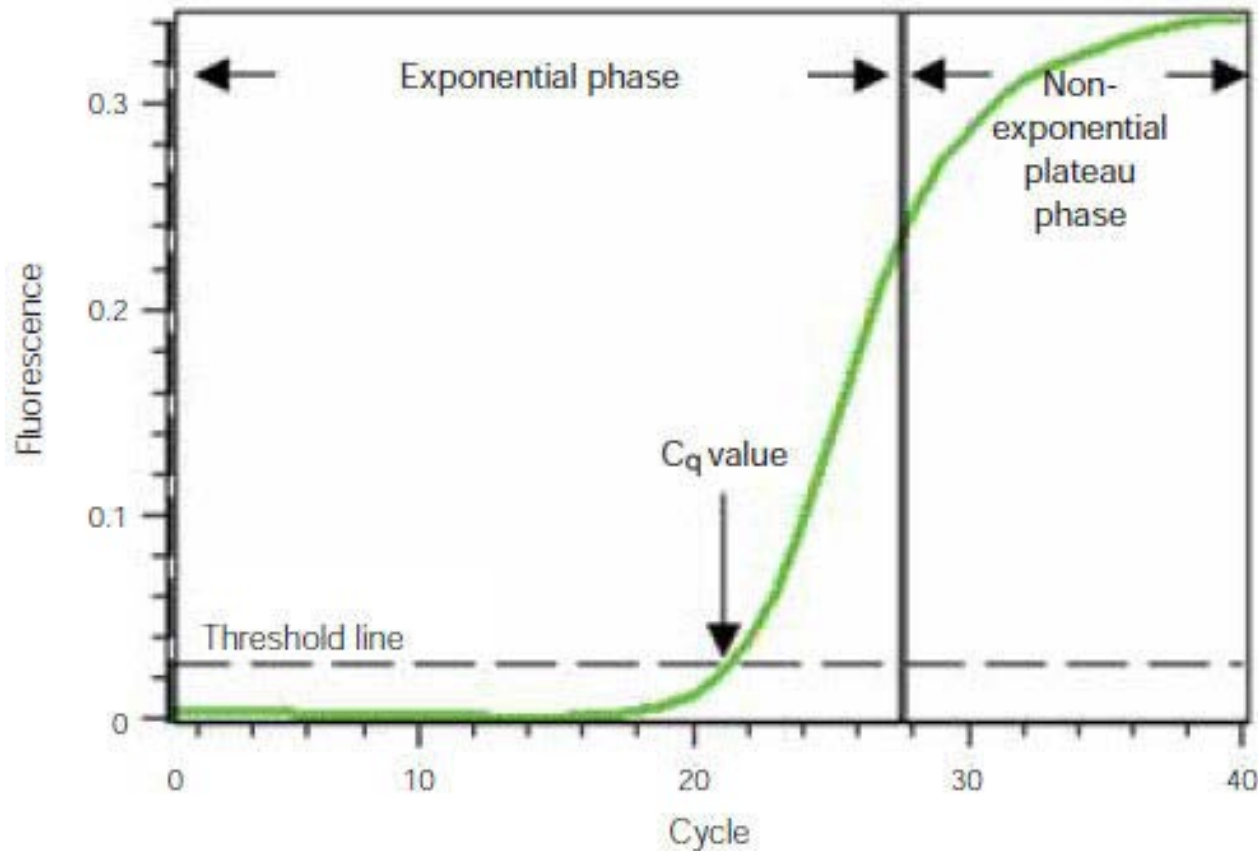
Polymerase Chain Reaction (PCR)

- Principle of the qPCR



PCR Testing

- qPCR detection and quantification






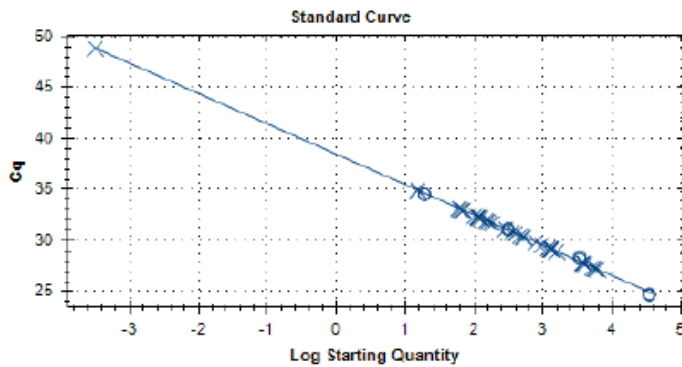
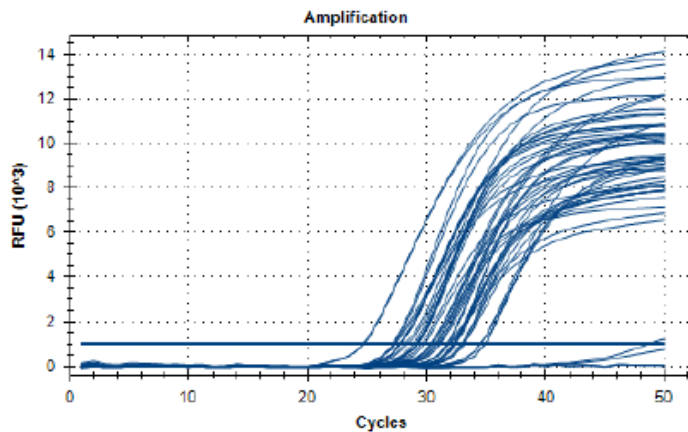
Legionella PCR

- Extract DNA from concentrated water sample
- Add chemicals and run qPCR
- Extraction + qPCR = 4 hours
- Quick turn-around-time
- Inhibitors can be an issue



BioRad iQ-Check

Symbol	Comment
Negative	Negative, the quantity is below the limit of detection of the method
	Inhibition, underestimated quantity
	Positive, higher than UQL
	Positive, lower than LOQ



- ✓ Kit provides validated standards
- ✓ Streamlined and easy to use
- ✓ Validated against ISO12869
- ✓ Provides a solid solution for quick TAT Legionella testing
- ✓ Specific for *L. pneumophila* and *L spp*

Validation

Published validation...

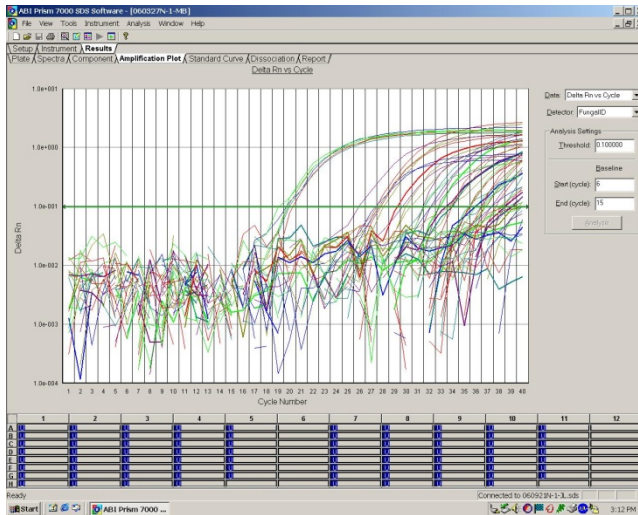
provides technical information on

- Detection and quantification limits
- Efficiency and robustness
- Selectivity (inclusivity and exclusivity)

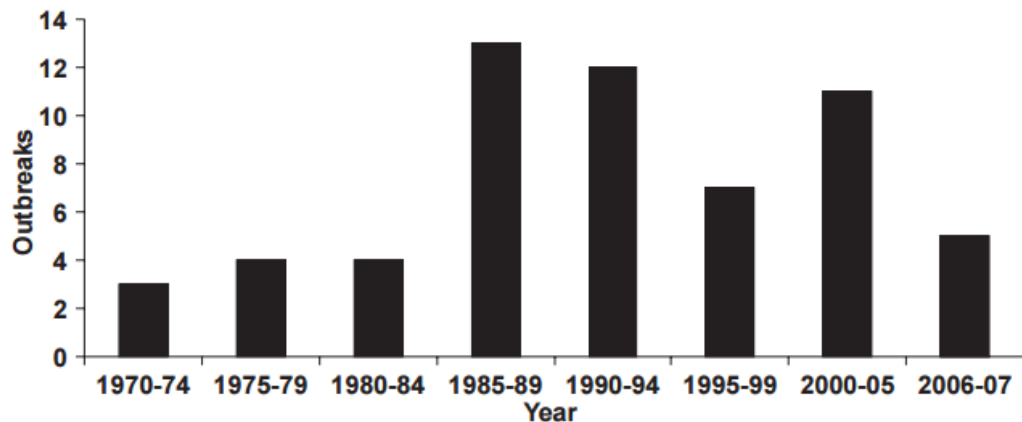
provides defensibility for legal cases

Fungal PCR

- **PCR air sampling**
 - Allows for longer sampling times (3 m³)
 - Focus on *Aspergillus sp.*

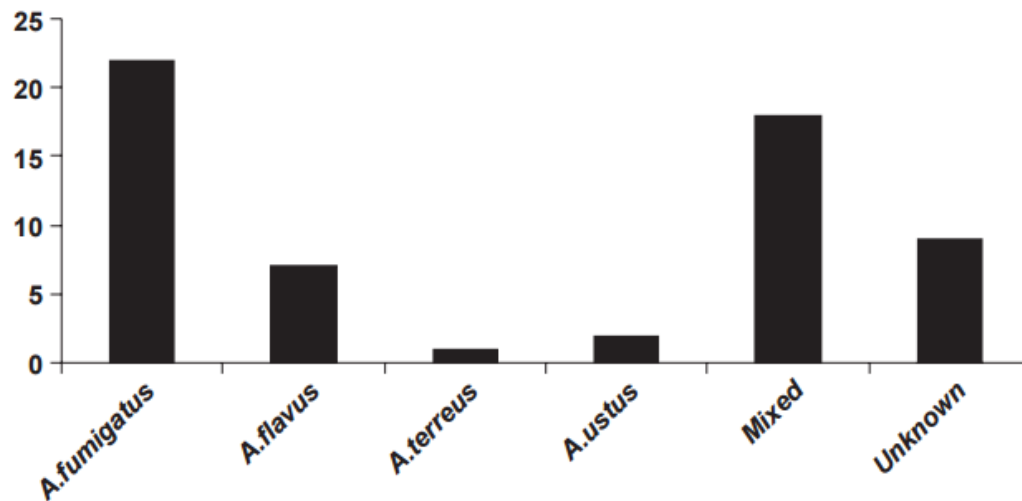


Aspergillosis



Aspergillus outbreaks reported in the English literature, 1970 - 2007 based on year of publication.

Source: Medical Mycology 2009, 47 (Supplement 1), S199 - S209



Distribution of *Aspergillus* species reported in outbreaks, 1967 - 2007.

Source: Medical Mycology 2009, 47 (Supplement 1), S199 - S209

Endotoxin

Biochemical test

- Limulus ameocyte lysate (LAL) – an extract from the blood of the Atlantic horseshoe crab – triggers clotting when reacting with lipopolysaccharide from outer membrane of Gram-negative bacteria
- Good and sensitive test for any bacterial contamination (water, air, dust)
- Commonly applied in pharmaceutical or health-care settings (e.g. hemodialysis water)

Endotoxin

ANSI/AAMI 13959:2014 (Water for hemodialysis and related therapies)

AAMI Microbiological Standards for Dialysis Water

Microbiological Level	New Standard	New Action Level
Colony Forming Units	< 100 cfu/mL	≥ 50 cfu/mL
Endotoxin Units	< 0.25 EU/mL	≥ 0.125 EU/mL

AAMI: Association for the Advancement of Medical Instrumentation (Canada)

Summary

- **Opportunistic pathogens are widespread**
- **Environmental monitoring to control opportunistic pathogens is applicable**
 - When high risk groups are involved
 - In high risk environments (e.g. sterile compounding)
 - Conditions are potentially favorable to reach high concentrations of opportunistic pathogens
 - In some special applications
- **There are few guidelines on microbiological environmental monitoring and sampling**

Continuing Education Units (CEUs)



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- Click on the **survey link** in the “Thank you” email (sent 1 hour after this webinar).
- Complete survey within **24 hours**.
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Thank you for your time!

Questions about Infection Control:
MBerg@emlabpk.com

All other questions:
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Ft. Lauderdale, FL 33309
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CALIFORNIA - San Bernardino
202 E. Airport Road
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San Bernardino, CA 92408
Phone: (909) 370-4707

CALIFORNIA – W. Sacramento
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West Sacramento, CA 95605
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Norcross, GA 30093
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Savannah, GA 31404
phone: (912) 354-7858

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Aiea, HI 96701
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Edison, NJ 08817
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Mt. Laurel, NJ 08054
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phone: (716) 691-2600

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Charlotte, NC 28208
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North Canton, OH 44720
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King of Prussia, PA 19406
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