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LABORATORY MEDICINE WA

Understanding the Microbiological Requirements of AS 4187:2014 Amd 2:2019

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20th November 2019

Case Study:
When to call it quits and Commission a new AFER
(aka how can anything take this long)

AFER = Automated Flexible Endoscope Reprocessor
AER = Automated Endoscope Reprocessor

Soluscope

Medivator

STERIS Reliance EPS…

Aims for this Workshop session

- Describe a real life scenario
- Address the AS 4187:2014 and relevant guidelines
- Demystify
  - Test requirements
  - Microbiological rationale
  - Laboratory aspects
- Bring some level of comfort to
  - Tackling an out-of-specification result
  - Commissioning a new AFER

Telephone call/email

I'm calling from the endoscopy clinic. The lab has just told us we have 2cfus of *Pseudomonas aeruginosa* in our latest Soluscope sample!

What should we do?

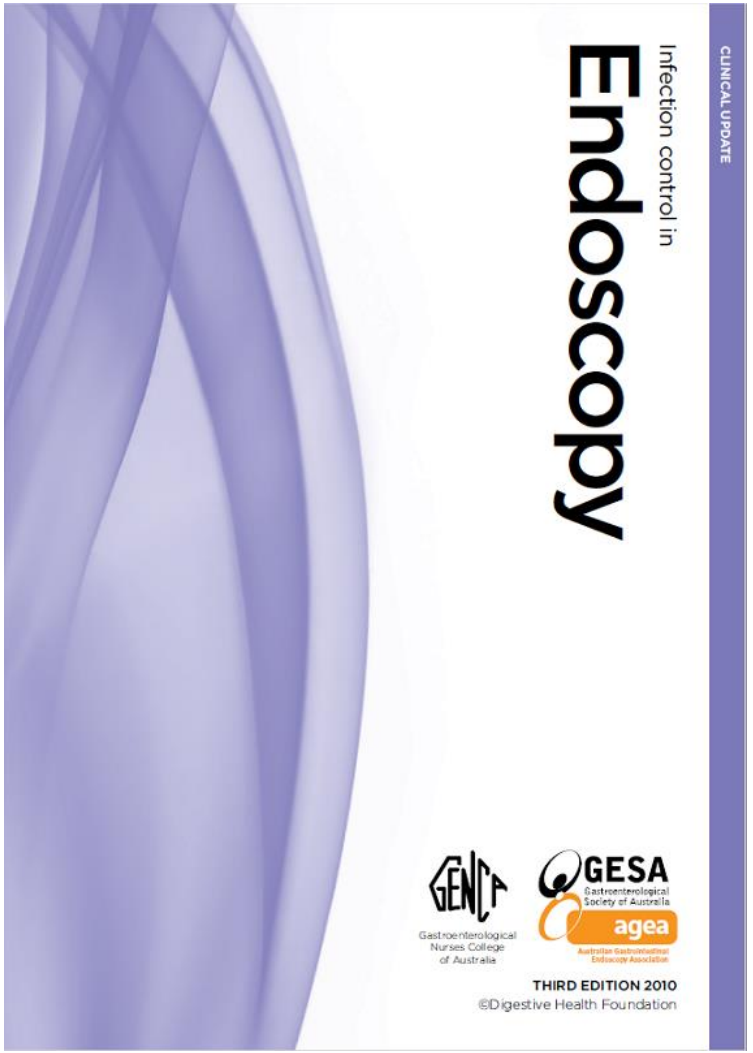
Yikes….

- What's a Soluscope? What does it do?
- Is *Pseudomonas aeruginosa* bad?
- 2 cfus…is that good?
- What are they expecting from me as Infection Control?
- It's their machine, shouldn't they know what to do?

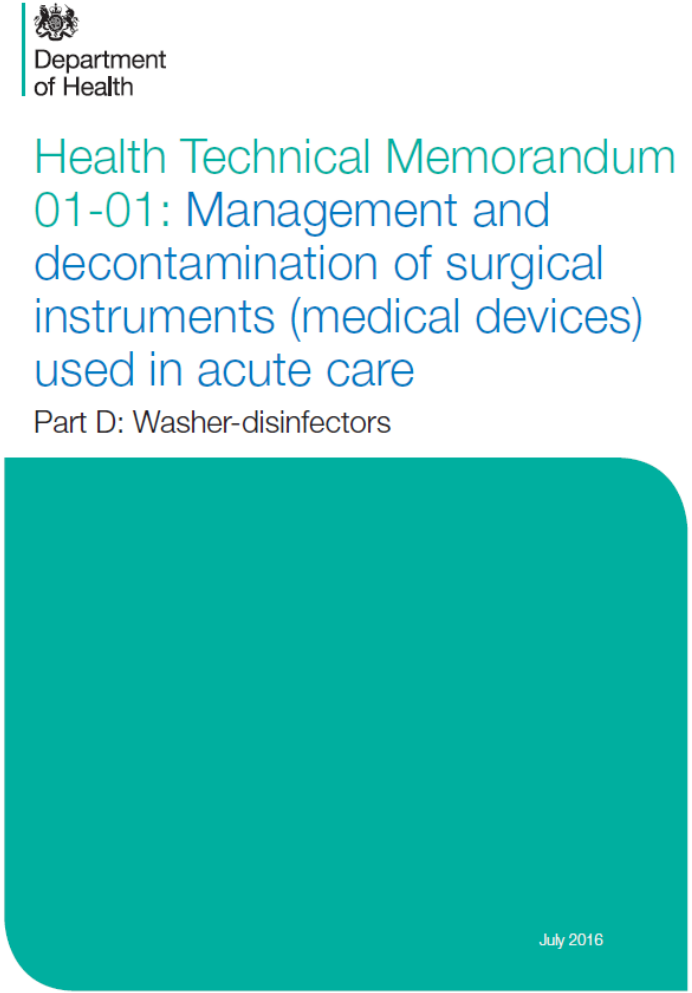
Hmmmmm….

- That’s not good
- What does the GENCA say about this?
- How does this fit with the new AS?
- What did I do last time? And the time before that….?

- Infection control in Endoscopy 2010
  - Gastroenterological Nurses College of Australia (GENCA)
  - Gastroenterological Society of Australia (GESA)



- Public Health England
  - Health Technical Memorandum
  - Series HTM 01-01
  - Decontamination of surgical instruments
  - Part D: Washer-disinfectors



Australian/New Zealand Standard™

Reprocessing of reusable medical devices in health service organizations

STANDARDS Australia

STANDARDS NEW ZEALAND

TABLE 7.3

FINAL RINSE WATER—WASHER-DISINFECTORS IN ACCORDANCE WITH ISO 15883-4 FOR THERMOLABILE ENDOSCOPES

Substance	Specifications
Total viable count (see Note)	≤ 10 cfu/100 mL
Pseudomonas aeruginosa	Not detected/100 mL
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Endotoxin	≤ 30 EU/mL

NOTE: For TVC, test methodology should be in accordance with ISO 15883-1 and the HTM 01-06 series.

TABLE 7.2

FINAL RINSE WATER—MANUAL CLEANING MANUAL DISINFECTION AND WASHER-DISINFECTORS

Substance	Specifications
pH	5.5–8.0
Conductivity at 20°C	≤ 30 µS/cm
Total hardness	≤ 10 mg $CaCO_3$/L
Chloride	≤ 10 mg/L
Iron	≤ 0.2 mg/L
Phosphates (molybdate reactive)	≤ 0.2 mg/L
Silicates (molybdate reactive)	≤ 1.0 mg/L
Total viable count (see Note)	≤ 100 cfu/100 mL
Endotoxin	≤ 0.25 EU/mL

NOTES:

1 Table 7.2 applies to the quality of water used in the types of washer-disinfectors included under the scopes of ISO 15883-1 and ISO 15883-2.

2 ISO 15883-1 is the umbrella (i.e. horizontal) standard that applies to all WDs. Specific or altered requirements are given in each of its subsequent parts (i.e. vertical standards) for different types of WD. See Table 7.3 for specific requirements for WDs used to reprocess thermolabile endoscopes.

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- Followed by sterilisation
- Instruments into sterile body sites and bloodstream

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- Final product
- GIT/Respiratory tract

Other Guidance:

- That local hospital's infection control/CSSD protocols
- Senior colleagues
- Hospital engineer/Facilities Management
- The Clinical Microbiologist
- The lab scientists
- The tertiary hospital infection control service
- Department of Health
- Private Infection Control Practitioners

What does AS 4187 say about my result?

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FAILED

What does GENCA about my result?

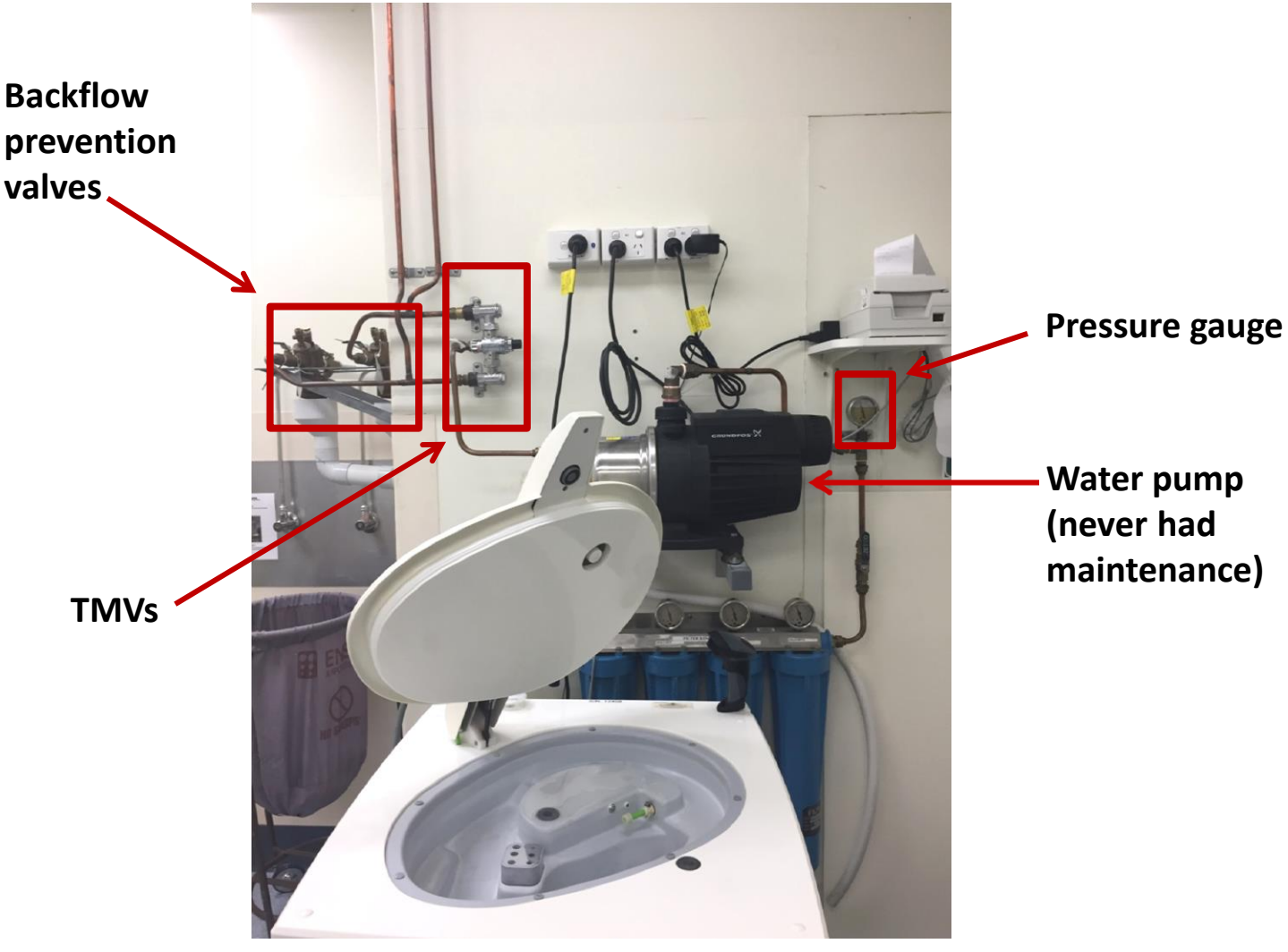
"A growth of *Pseudomonas* spp. or other nonfermentative gram-negative bacilli from a duodenoscope, bronchoscope or an AFER that processes duodenoscopes or bronchoscopes would be cause for serious and immediate concern"

Immediate response:

- Remove the AFER from service; arrange alternative reprocessing in CSSD
- Ask a few questions around any changes to the clinic, staff using the AFER or re-processing the scopes or performing the test
- Contact Technical Service
- Notify Infection Control Officer
- Determine last filter change:
  - *Wall filters changed 6 monthly (in 3 months time)*
  - *On board air and water filters changed 3 monthly (due in one month) – changed early*
- Re-run disinfection cycle and re-test

Next:

- Followup test result: Count went up >10cfu/100ml = FAILED
- Organism cultured was *Pseudomonas alcaligenes* (environmental non-fermenter)
- Time to go take a look

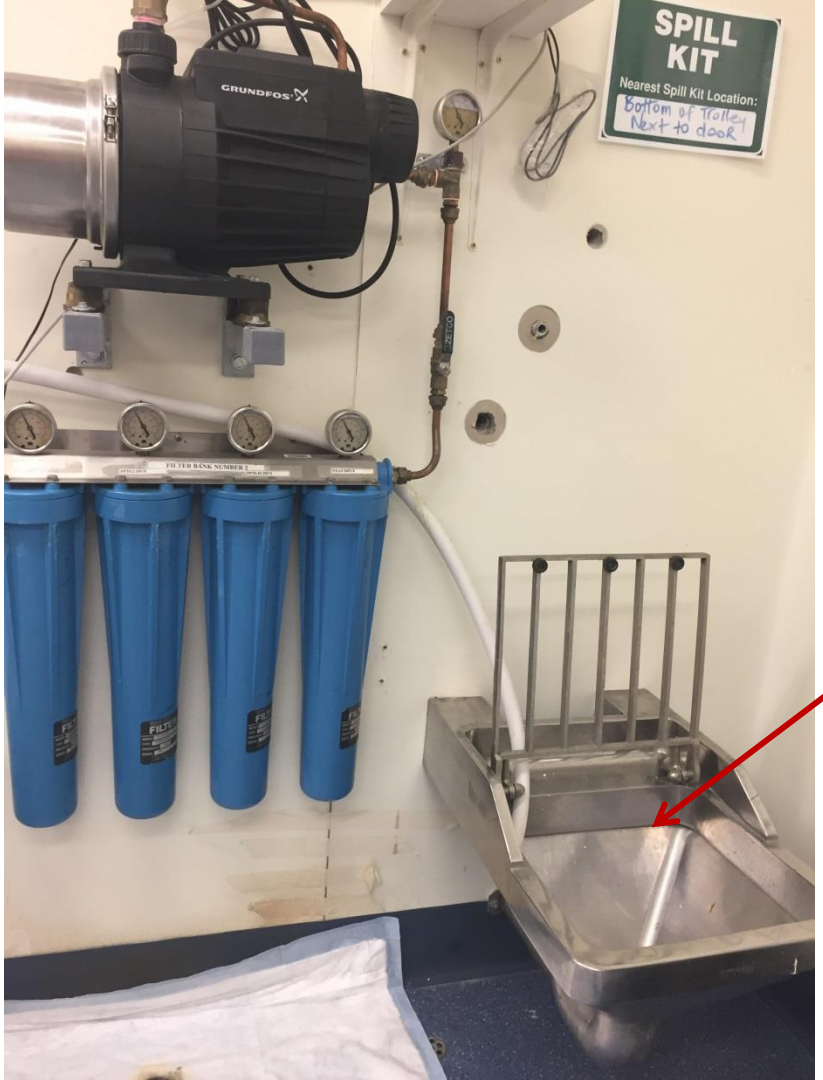

Backflow prevention valves
Pressure gauge
Water pump (never had maintenance)
TMVs

Old filter bank

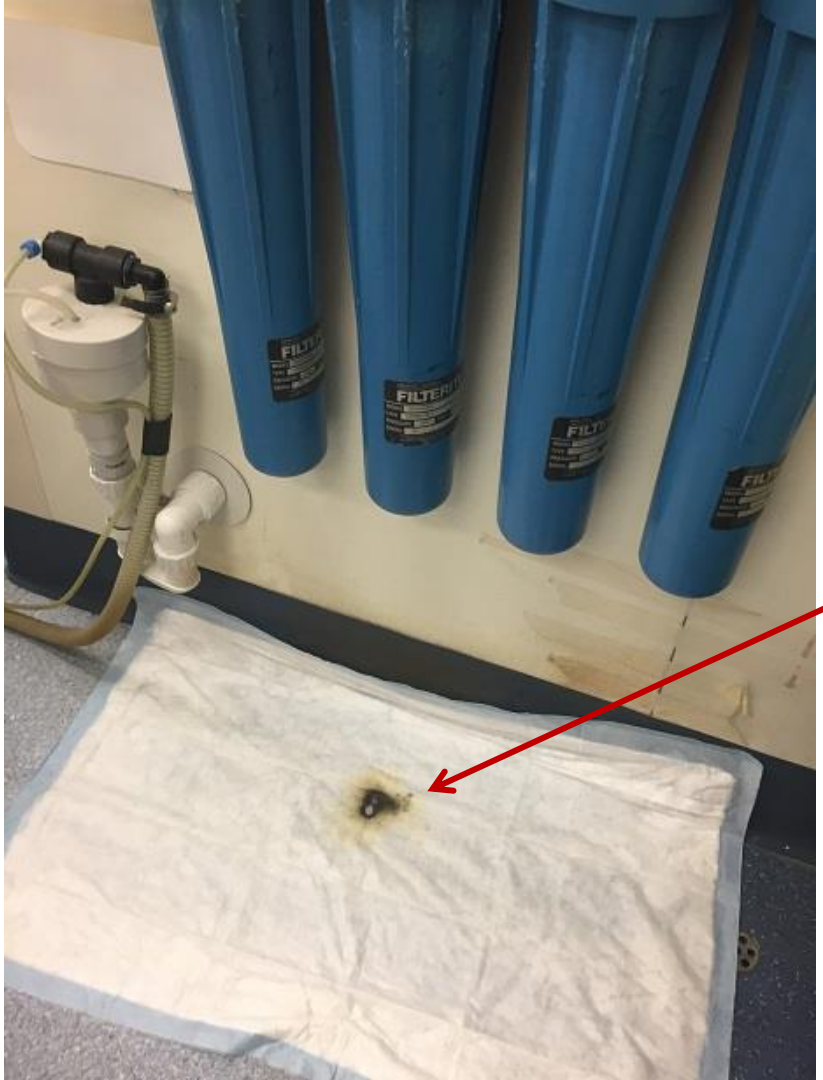
In coarse to fine sequence

Filter flushing pipe

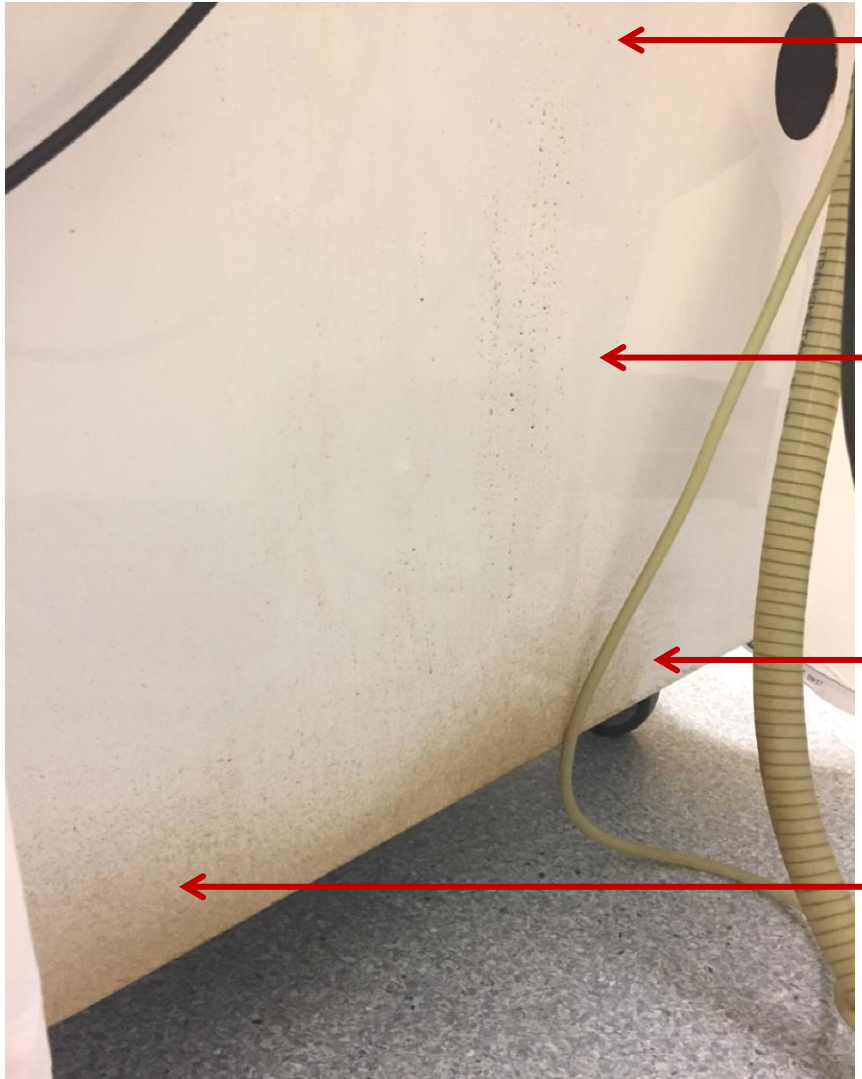
To waste where?


SPILL KIT
Nearest Spill Kit Location:
Bottom of Trolley Next to door
GRUNDFOS
FILTER BANK NUMBER 1

Old sluice




Drip from
water pump

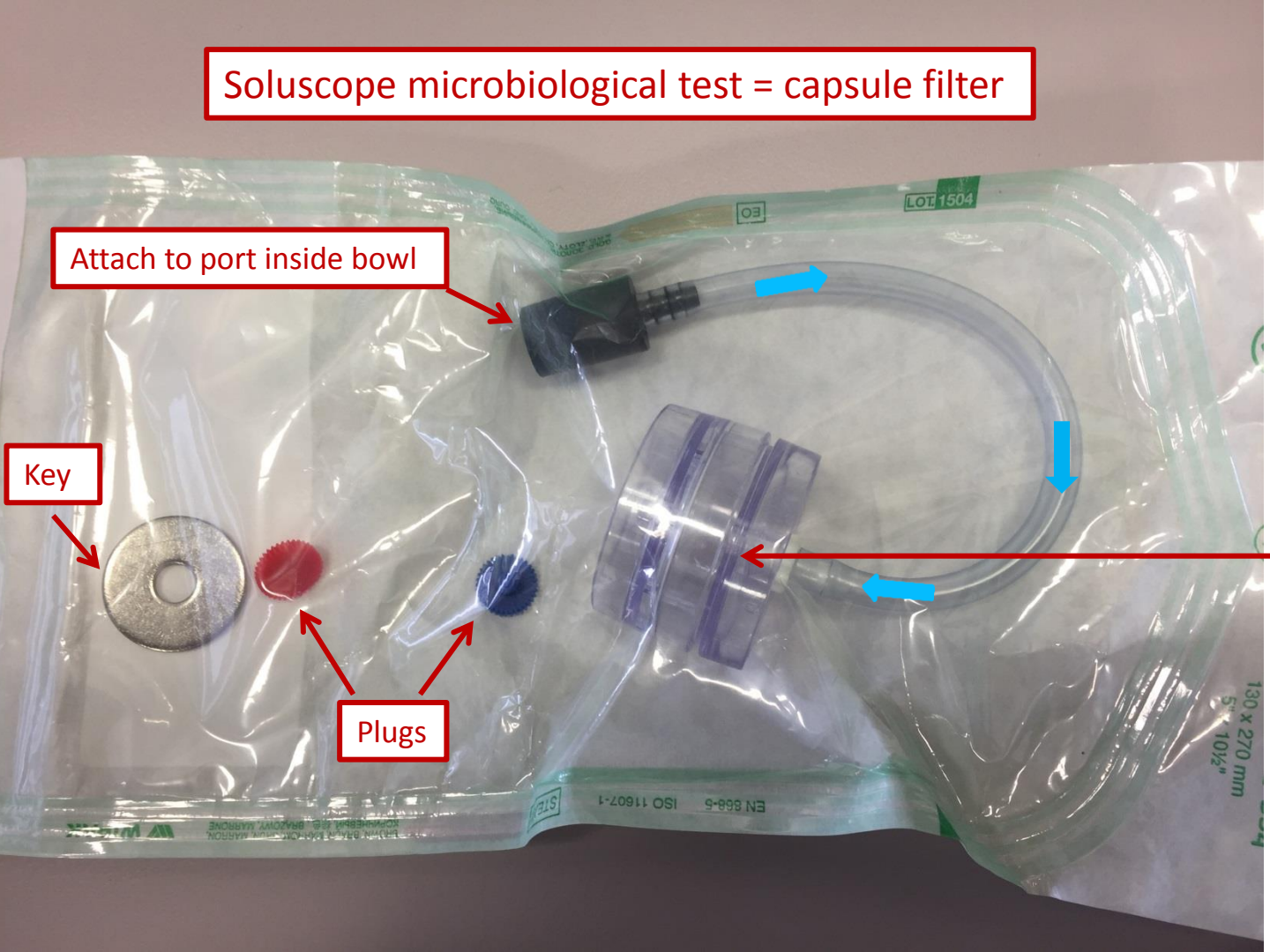


Dripping from water
Pump and splashing
Onto
Soluscope

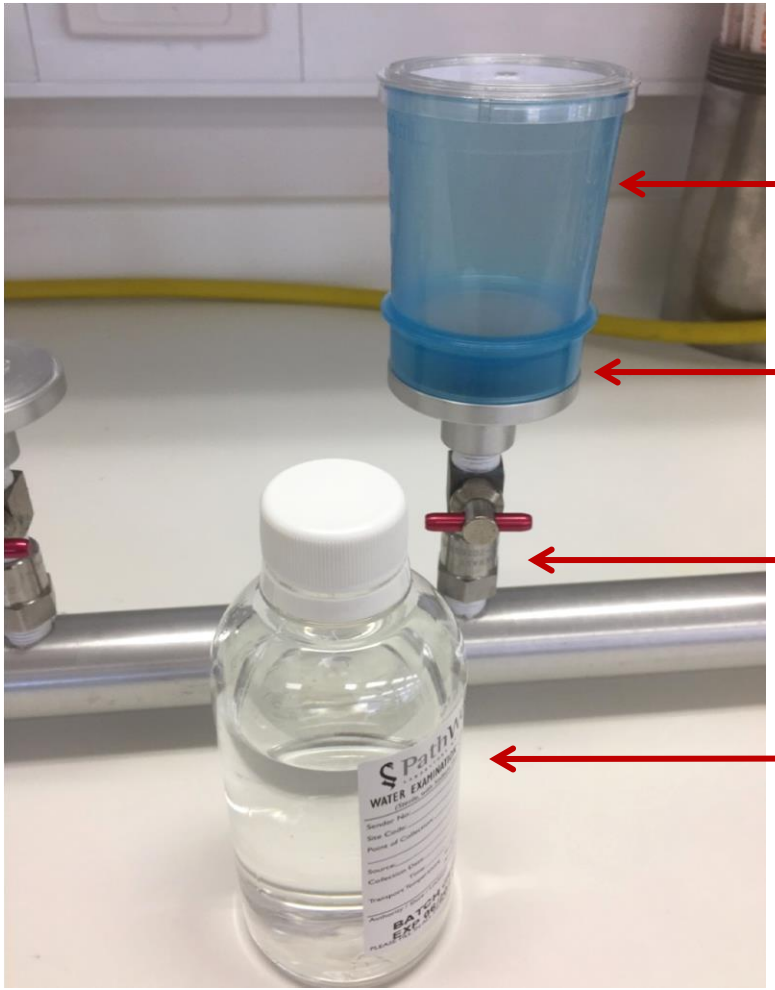
Then:

- Room had a full disinfection clean
- Full service by the Technician
- Replaced all wall filters and cleaned canisters
- Remove the sluice
- Review the sample collection technique and re-test

Soluscope microbiological test = capsule filter



Membrane filtration

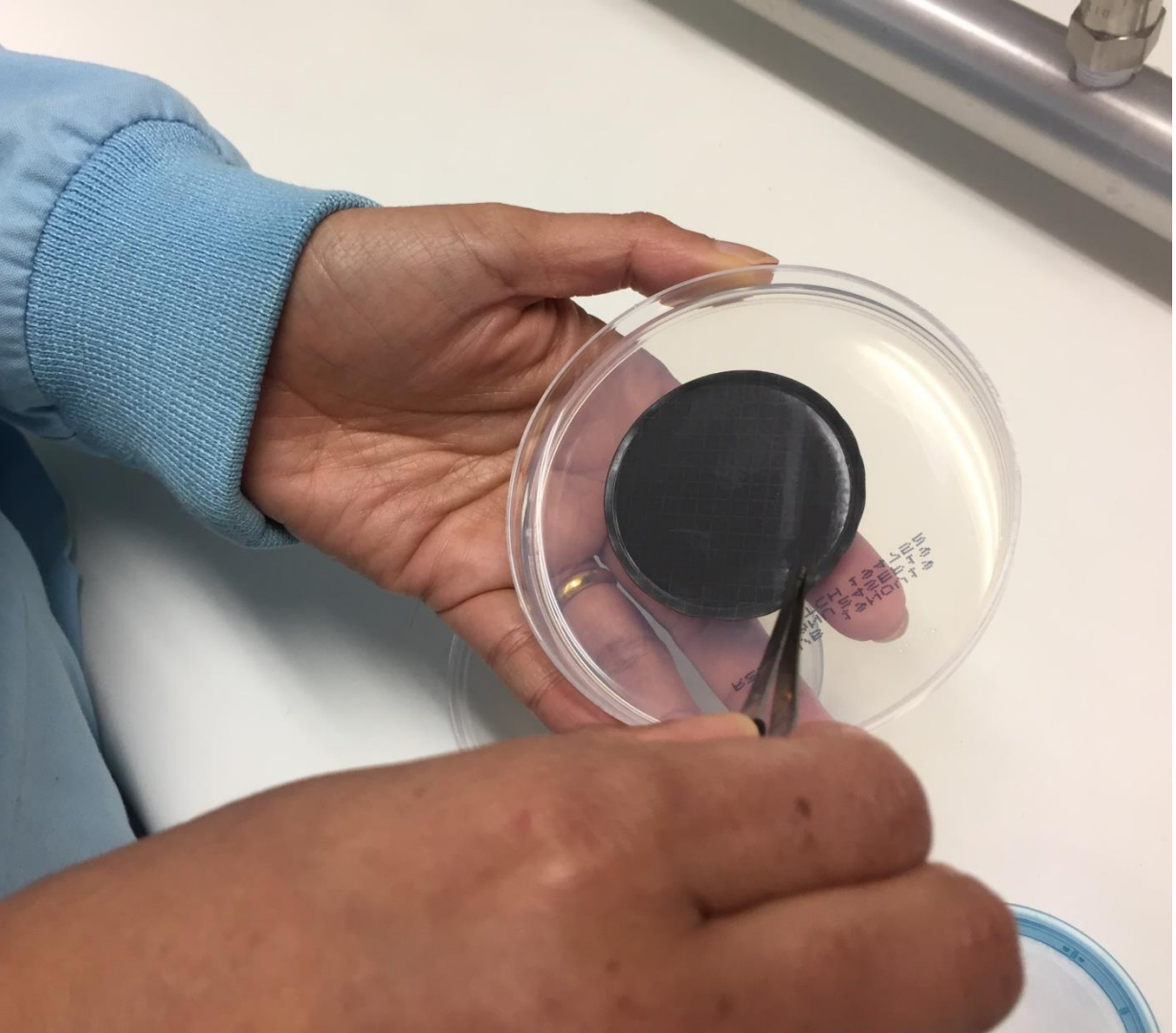


Sterile cup

Membrane filter
bottom of cup

Manifold

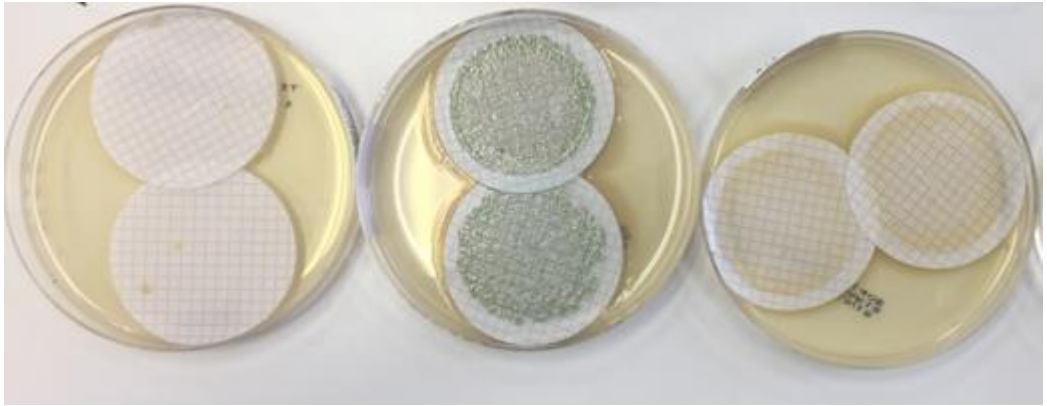
Water sample (250 ml)



After filtration, membrane is aseptically placed on the surface of the agar plate

Follow-up tests:

- Technician's test FAILED
- Sampling back in the water supply chain:



Pre-pump **Post-pump** **Post-filter bank**

Decision time

- Pump remediated
- Wall filters flushed – never got above 60^{o}C
- Further soluscope tests - FAILED
- Likely unreachable biofilm in damaged internal mechanisms

- Consider options
  - Re-process elsewhere
  - Buy a replacement AFER
    - New Soluscope

- Supply water to comply with AS 4187 before commissioning

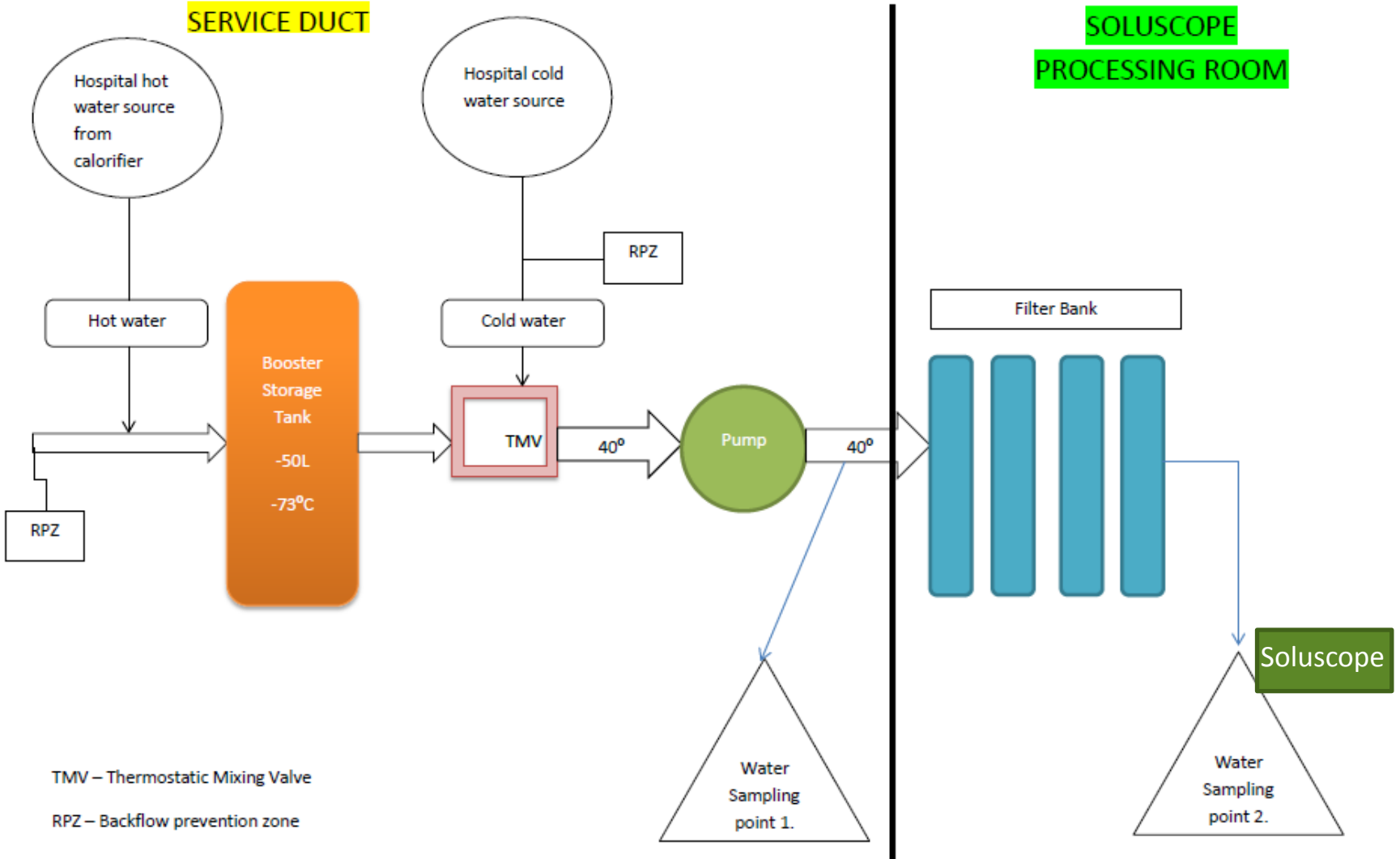
Planning

- Multidisciplinary team meetings
  - staffing issues within Facilities Management, stalled project
- Serendipitously, a senior experienced hospital engineer who had installed systems elsewhere became involved
- Who’s cost centre?

…and waiting

- An external plumbing company was sub-contracted
  - some disadvantages
- Finally obtained schematic diagram
- The new plumbing was likely acceptable **except** for the failure to install water sample points at nominated critical sites in the pipes.


Rheem


SERVICE DUCT
SOLUSCOPE PROCESSING ROOM
Hospital hot water source from calorifier
Hospital cold water source
RPZ
Hot water
Cold water
Booster Storage Tank
-50L
-73°C
RPZ
TMV
40°
Pump
40°
Filter Bank
Soluscope
Water Sampling point 1.
Water Sampling point 2.
TMV – Thermostatic Mixing Valve
RPZ – Backflow prevention zone

Supply water before commissioning

- First test: FAILED
  - Very high TVC and *Pseudomonas aeruginosa*

- The new locally installed hot water tank was not turned on
  - Water stagnating in tank, forming biofilm

Supply water before commissioning

- The tank turned on
  - hot water supply reached 73^{o}C constantly
  - The supply water PASSED

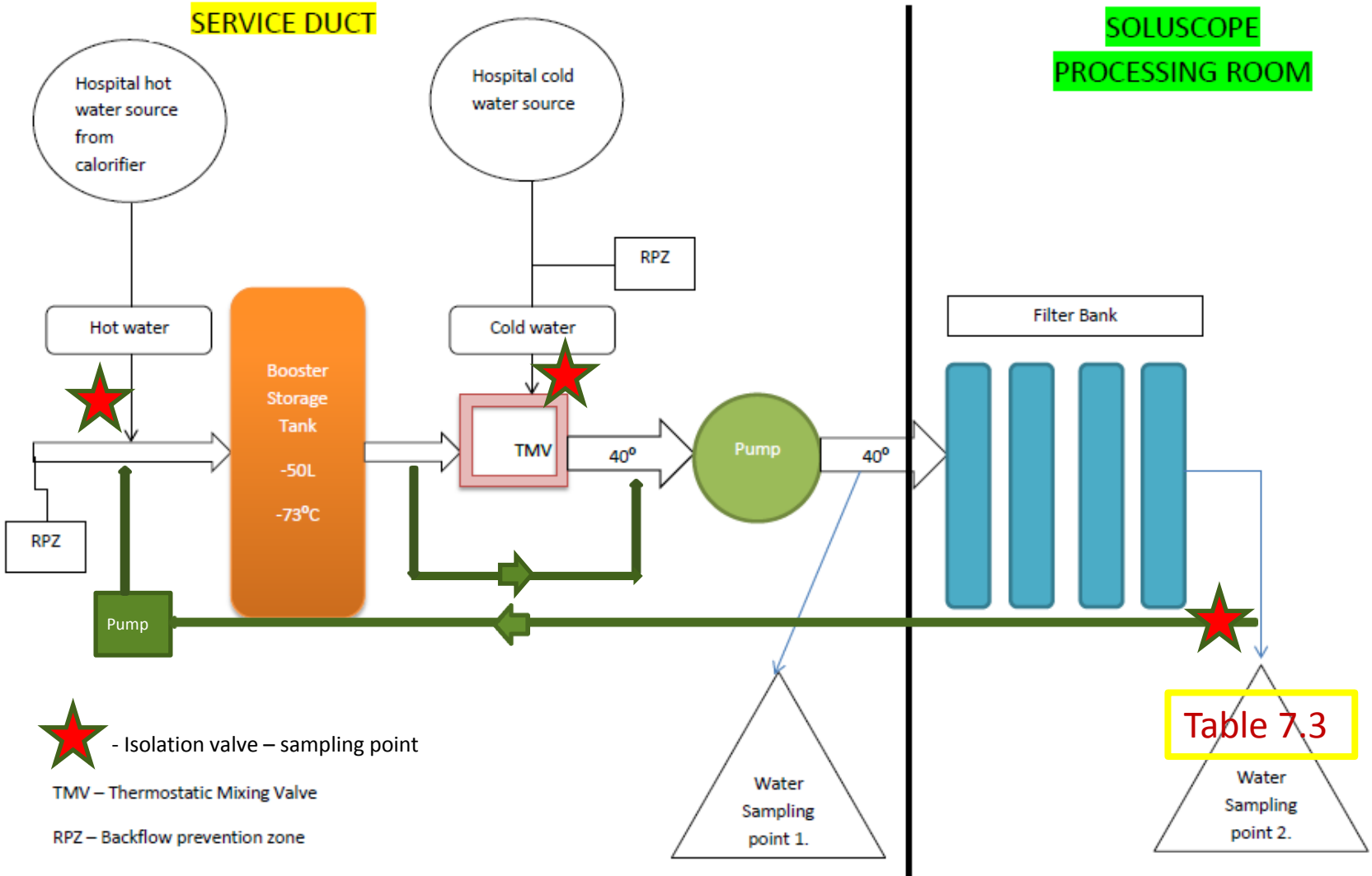
- Are we ready to install the Soluscope? Not quite…

- Issue: water lying fallow over expected periods of inactivity
- Soluscope typically last used on Thursday or Friday afternoon, and then not used again until Monday morning.
  - A test of the stagnant water supply after a mimicked 3 and ½ day period: TVC >100cfu/100ml (but no *Pseudomonas*) = FAILED

Supply water before commissioning

- Cold water supply sub-standard
  - overwhelm the filter bank
  - possibly overwhelm the on board filters

- Solution: pasteurise the system each Sunday night


SERVICE DUCT
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Hospital hot water source from calorifier
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-50L
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Filter Bank
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40°
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40°
RPZ
Pump
- Isolation valve – sampling point
TMV – Thermostatic Mixing Valve
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Water Sampling point 1.
Water Sampling point 2.
Table 7.3

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What is a Total Viable Count?

- Total Viable Count (TVC) = Heterotrophic Plate Count (HPC) = Standard Plate Count (SPC) = Total Bacterial Count = Water Plate Count = Aerobic Mesophilic Viable Count….

- All microorganisms that use organic nutrients for growth
  - Universally present in all types of water, food, soil, vegetation, air
  - Encompasses bacteria, yeasts and moulds

Why is the TVC method important?

- No single method or medium will recover or enumerate all organisms in the water being analysed
- Many bacteria present in the water are not even culturable

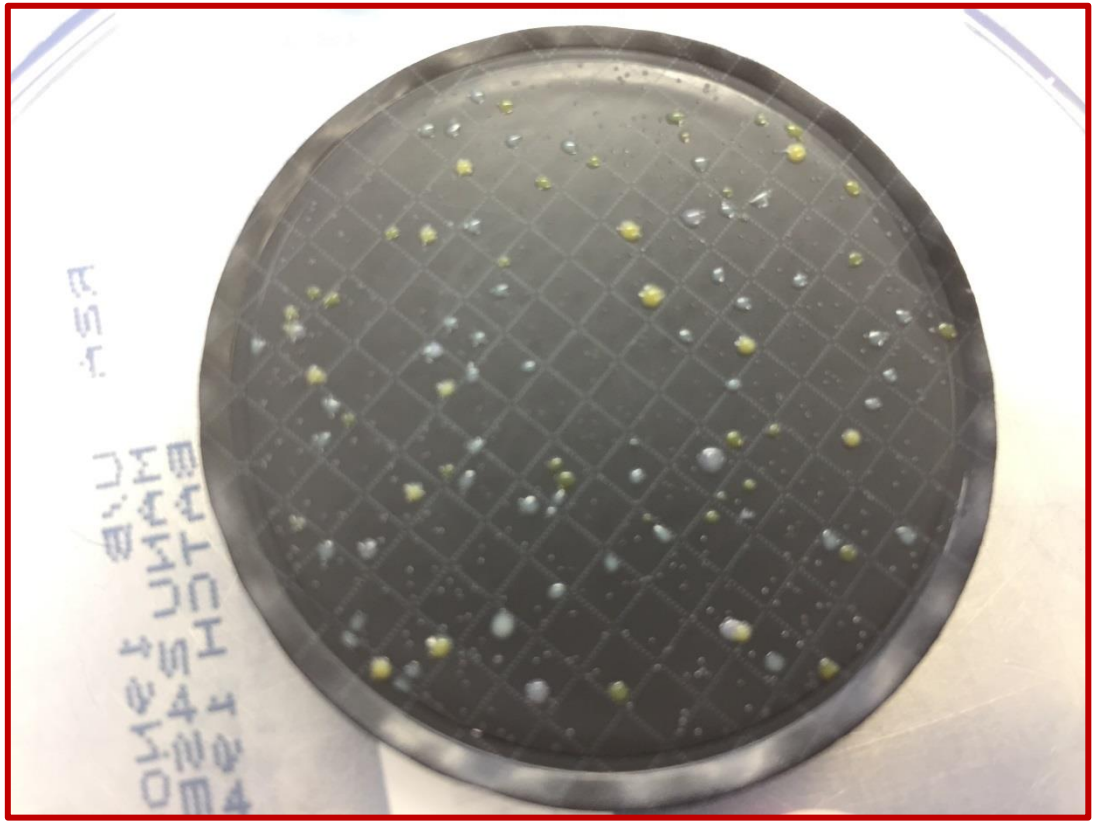
- High-nutrient media with higher temperatures are better for enumeration of bacteria from animals and humans
- Low-nutrient media with lower temperatures are better for enumeration of water-based bacteria (autochthonous) found in aquatic systems, including drinking water

TVC Method in AS/ISO

- Sample method (**Membrane filtration**)
  - more flexible than spread/pour plate
  - any sample volume >1.0ml
  - efficient method for 100ml of water

- **R2A** – low-nutrient, low-ionic strength formulation to culture organisms that have a water-based, rather than mammalian lifestyle

- Incubation conditions (**28-32ºC for 5 days**)
  - High-temperature (35-37ºC) and short incubation time (34-48 hours) favour growth of bacteria from animals and humans
  - Low-temperature incubation (20-28ºC) and longer incubation time (5-7 days) favour growth of aquatic bacteria



Mycobacteria and Legionella will **not** grow

TVC

- AFERs = final product ≤10cfu/100ml
- Batch-Washers and manual rinse water = pre-sterilisation ≤100cfu/100ml
- Not possible/necessary to differentiate which microorganisms are potentially pathogenic (except *Pseudomonas aeruginosa*)

Will knowing the organism name/s help me?

- Skin – Coagulase negative staphylococci, Micrococci, diphtheroids, Corynebacteria, Bacillus, *Staphylococcus aureus*
- Gastrointestinal tract – viridans group Streptococci (oral streps), *Staphylococcus aureus*, Enterococci, Enterobacteriaceae (coliforms), Candida, other gram-negative bacilli (non-fermenters)
- Respiratory tract – viridans streptococci, Enterobacteriaeceae (coliforms), other gram-negative bacilli (non-fermenters), *Staphylococcus aureus,* Candida
- Environmental – Bacillus, fungi, non-fermenters, mycobacteria, some Enterobacteriaceae

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What are non-fermenters and why are they important?

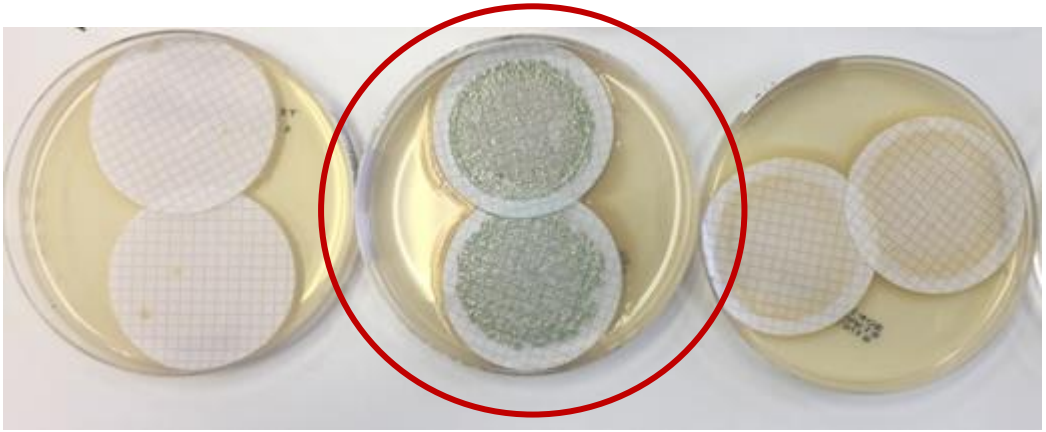
- Gram negatives, oxidase positive, can't catabolise glucose
- Ubiquitous in the environment, moist areas
- Important opportunistic and nosocomial pathogens, biofilm formation in plumbing, AFERs, endoscopes
- Intrinsically resistant and acquire multi-resistance to antibiotics, resistance to disinfectants
- Have differing virulence potential:
    - Higher : *Pseudomonas aeruginosa*, *Acinetobacter baumannii, Stenotrophomonas maltophila, Burkholderia cepacia, Chryseobacterium, Shewanella…*
    - Lower: *Blastomonas, Brevundimonas, Cupriavidus…*

https://www.google.com.au/search?q=pseudomonas+biofilm+picture&tbm=isch&source=hp&sa=X&ved=2ahUKEwiN1_Spu9zlAhWUguYKHVD4DbkQsAR6BAgGEAE&biw=1920&bih=951#imgdii=UWkpCRR0kX_8aM:&imgrc=TEEKVZUDN-nl_M:&spf=1573279630790

Pseudomonas outbreaks

- Shimono N, Takuma T, Tsuchimochi N, Shiose A, Murata M, Kanamoto Y. An outbreak of Pseudomonas aeruginosa infections following thoracic surgeries occurring via the contamination of bronchoscopes and an automatic endoscope reprocessor. *J Infect Chemother* 2008; 14: 418-423.
- Allen JI, Allen MO, Olson MM, Gerding DN, Shanholtzer CJ, Meier PB. Pseudomonas infection of the biliary system resulting from use of a contaminated endoscope. *Gastroenterol* 1987; 92: 759-763.
- Alvarado CJ, Stolz SM, Maki DG. Nosocomial infections from contaminated endoscopes: a flawed automated endoscope washer. An investigation using molecular epidemiology. *Am J* Med 1991; 91: 272S-280S.
- Classen DC, Jacobson JA, Burke JP, Jacobson JT, Evans RS. Serious Pseudomonas infections associated with endoscopic retrograde cholangiopancreatography. *Am J Med* 1988; 84: 590-596.
- Fraser TG, Reiner S, Malczynski M, Yarnold PR, Warren J, Noskin GA. Multidrug-resistant Pseudomonas aeruginosa cholangitis after endoscopic retrograde cholangiopancreatography: failure of routine endoscope cultures to prevent an outbreak. *Infect Control Hosp Epidemiol* 2004; 25: 856-859.

Pseudomonas aeruginosa



Will grow in the TVC method; can use specialised media if Pseudomonas problem

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Atypical Mycobacteria (NTM)

- 'Atypical' = Non-tuberculous *mycobacteria (*NTM*)*
- Free-living in environment, water-borne
- Can grow in potable and distilled water
- Hardy, cells walls contain waxy mycolic acid (acid-fast bacilli, ZN stain)

- Rapid growers (RGM) – 7 days, routine media
  - *M.fortuitum, M.chelonae, M.abscessus*

- Slow growers – up to 8-12 weeks, specialised media
  - *M.avium-intracellulare, M.gordonae, M.marinum*

Atypical Mycobacteria (NTM)

- *Mycobacterium chimaera* in Heater Cooler Units (slow grower)
- Resist the activity of commonly used disinfectants (organomercurials, chlorine, 2% concentrations of formaldehyde and alkaline glutaraldehyde) AND thrive at high temperatures
- Nosocomial outbreaks and pseudo-outbreaks caused by the nontuberculous mycobacteria (NTM) in AFERs/endoscopes
- Review Article: Kovaleva et al,Transmission of Infection by Flexible Gastrointestinal Endoscopy and Bronchoscopy, *Clinical Microbiology Reviews* Apr 2013, 26(2) 231-254

Atypical Mycobacteria (NTM)

- Will *not* grow on the TVC media
- ISO requires both rapid **and** slow-growing mycobacteria
- Takes 28 days for a negative result
- Need to send 200ml of water to comply (membrane filtration, required to be performed in duplicate)

- More difficult test to source
  - within the remit of highly specialised clinical microbiology labs
  - expensive

Growth of *Mycobacterium* isolated on a plate of culture medium. (Photo: Stacey Pfaller, EPA)

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What is Endotoxin?

- A type of lipopolysaccharide (LPS)
- Major component of the outer membrane of gram negative bacteria
- High doses in blood (500pg/ml) cause ‘cytokine storm’, septic shock and death
- Chronic low level endotoxin associated with atherosclerosis, peridontitis, amyotrophic lateral sclerosis, cirrhosis, Alzheimer’s disease, HIV infection, neurodegeneration….

Where is Endotoxin?

- Gram negative bacteria are found in high numbers in mammalian large bowel, saliva, dental plaque, skin, respiratory tract and urinary tract
  - ~1gm of endotoxin in human gut
  - 1 to 50 picogram/ml in plasma of healthy humans (0.01 and 0.5 EU/ml)
- Also in environment, including water
- Humans are orders of magnitude more sensitive to endotoxin than other mammals (mice models)
- Structure and antigenicity varies according to species
  - Single *E.coli* cell contains ~ 2 million LPS molecules per cell

What is Endotoxin?

- Soluble endotoxin is released when
  - bacteria are destroyed AND during active cell growth

- Heat-stable, highly resistant to routine disinfection and sterilisation processes
  - glassware is rendered pyrogen-free by heating at 200-220^{o}C for 2-3 hours
  - plastics – gamma-irradiation
  - fluids - ultrafiltration

Illustration courtesy Charles River Endosafe, SC

How do we measure Endotoxin?

- In vivo test: Rabbit pyrogen
- In vitro test: *Limulus* amoebocyte lysate (LAL assays)
- Dependent on the blue-blooded Horseshoe crab donating haemolymph (“living fossils”)

vs Recombinant assays
- viable synthetic alternative
- crab-sparing, environmentally sustainable,
- decreased batch to batch variation and no false positives from activation of alternative pathway by fungi/peptidoglycans

Endotoxin test result

- Pass or Fail (original gel clot LAL method)
  - Lab needs to know the limit is 30 EU/ml
- Quantitative (including Recombinant)
  - Point of care
  - NATA accredited laboratory
  - how much did I fail by?

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Substance	Specifications
pH	5.5–8.0
Conductivity at 20°C	≤ 30 µS/cm
Total hardness	≤ 10 mg $CaCO_3$/L
Chloride	≤ 10 mg/L
Iron	≤ 0.2 mg/L
Phosphates (molybdate reactive)	≤ 0.2 mg/L
Silicates (molybdate reactive)	≤ 1.0 mg/L
Total viable count (see Note)	≤ 100 cfu/100 mL
Endotoxin	≤ 0.25 EU/mL

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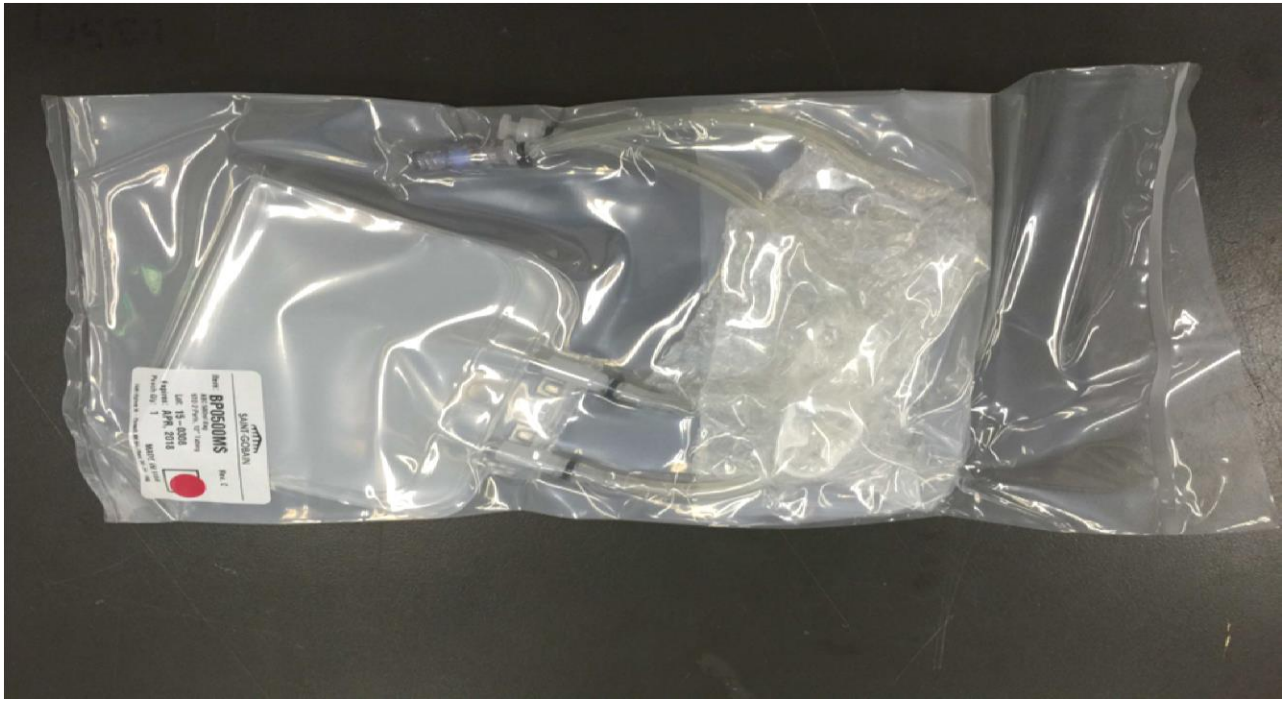
Machine	Frequency	Required Tests	Test Frequency Reference	Required Test Reference
Supply Water **AFER**	On commissioning	TVC ≤ 10cfu/100ml *Pseudomonas aeruginosa* ND/100ml (Atypical) Mycobacterium ND/100ml Endotoxin <= 30 EU/ml ND=not detected	AS 4187 Amd2 Clause 7.2.3.1	AS 4187 Amd2 Table 7.3
	Not Required - regular quarterly testing of supply water for AFERs has been removed from AS 4187 Table 10.3			AS 4187 Amd2 Table 10.3
Final Rinse Water **AFER**	Monthly	TVC ≤ 10cfu/100ml *Pseudomonas aeruginosa* ND/100ml (Atypical) Mycobacterium ND/100ml	AS 4187 Amd2 Table 8.1	AS 4187 Amd2 Table 7.3
	Annually	Endotoxin ≤ 30 EU/ml		

Additional sampling tips

- Medivators, Reliance EPS, others
  - Water is collected straight from the outlet in the bowl into a sterile container
  - Possibility of contamination of inside of container or lid
  - Certified endotoxin free container if performing endotoxin
  - Volume is greater under the new AS
    - 100ml for the TVC
    - 200ml for the mycobacteria (duplicate)
    - +/- 100ml Pseudomonas aeruginosa
    - ~10mls for Endotoxin

Additional sampling tips



Soluscopes

- 500ml water collection bags that fit into the bowl instead
- Pyrogen-free bags for annual endotoxin test

Commissioning an AFER

- Multidisciplinary team in the same room (several times)
  - hospital engineers, water filtration experts, clinical microbiologists, AFER representatives, infection control officers, and endoscopy unit staff
- Clear diagram of the plumbing and sample points
- Be prepared to spend some money (but perhaps not as much money as you thought)
- Laboratory expertise and understanding of the new AS requirements

Acknowledgements

- Endoscopy staff
- Infection Control Officer and nursing staff
- Soluscope Technical Service
- PathWest Laboratory Medicine – Environmental Microbiology Unit, Pharmaceutical Testing Facility, Microbial Contamination Testing Laboratory
- Hospital engineer

Thank you

What you need from your laboratory

High Quality Service Delivery

- NATA Accredited 17025 (environmental laboratory)
- NATA Accredited culture and endotoxin methods (or working towards)
- Clear understanding of the test requirements and limits
  - Endotoxin detection range needs to cover 0.25 to 30 EU/ml
  - May wish to have a quantitative method
- Correct referenced methods (or other methods verified as equivalent)

What you need from your laboratory

High Quality Service Delivery

- Contactable during your full working day (interstate time differences)
- Early notification of out-of-specification results (needs to be negotiated as some labs may only send you a final report)
- Assistance with troubleshooting out-of-specification results, including specific media for specific organisms, epidemiological typing

What you need from your laboratory

Straight-forward practical procedures

- Step-by-step instructions on collection technique
- Easy access to sample bottles
- Sample bottles used for endotoxin testing must be endotoxin free (check with the manufacturer)
- Unambiguous request forms
- Reports get sent to the right people (you?)
- Quick turn around time
    - Onsite identification of organisms
    - Access to mycobacterial laboratory