Responding to Positive Microbiological Surveillance Results in the Gastrointestinal Unit

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Acknowledgements

-CALHN Infection & Prevention Control Unit

-Royal Adelaide Hospital GIU Reprocessing Unit

MICROBIOLOGICAL SURVEILLANCE

AFER Final rinse water

Endoscopes with channels

Endoscope storage cabinets

Guidelines and Standards

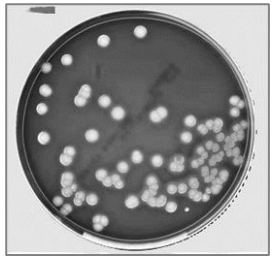
- *Australian Standard AS 5369:2021, Reprocessing of reusable medical devices and other devices in health and non-health related facilities*
- *Infection Prevention and Control in Endoscopy 2021 GENCA guidelines*
- *AAMI Technical Information report (TIR 34)*
- *ISO standards 15883 series*
- *Health Technical Memorandum 01-06: Decontamination of flexible endoscopes Part E: Testing methods*

AFER FINAL RINSE WATER SURVEILLANCE

AS 5369 – *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
(Atypical) *Mycobacterium sp.*	Not detected/100 mL
Chemical purity	In accordance with WD technical specifications
Endotoxin	≤ 30 EU/mL
NOTE For Total viable count (TVC), test methodology should be in accordance with ISO 15883-1 and the Department of Health [UK] (2016) *Health Technical Memorandum* 01-06 series.	



TVC culture as per ISO & HTM
-R2A at 28-32^{0}C for 5 days
≤ 10 cfu/100mL
=
≤ 0.1cfu/mL

GENCA – *Section 10.3.1.3*

Meet the requirements of **AS 4187:2014** (AS 5369)

Table 6 water quality for AER final rinse water:

Substance	Specification	Frequency
Chemical purity	As per manufacturer's instructions	Manufacturer's instructions only
Total viable count	≤10 CFU/100 mL	Monthly
Pseudomonas aeruginosa and atypical *Mycobacterium* species	Nil detected/100 mL	Monthly
Endotoxin	≤30 EU/mL	Annually

Culture on Blood agar at 28^{0}C for 7days

Relevant bacteria

- Non Fermentative Gram-Negative Bacilli
- Atypical *Mycobacterium* species

Refer Figure 8. ***Response to positive cultures from an automated flexible endoscope reprocessor (AFER)***

GENCA Figure 8 - RESPONDING TO POSITIVE AFER FINAL RINSE WATER

Concerning contamination
Any quantity of atypical mycobacteria, gram-negative bacilli, *Enterococcus* spp or viridans streptococci or ≥ 10 colonies of *Staphylococcus aureus*

→ C

Possible contamination of AFER from hospital environment, water supply or filters
Any quantity of atypical mycobacteria, *Pseudomonas* spp or unusual organisms usually found as water or soil contaminants

Low-level contamination
< 10 CFU/mL of all organisms except *Pseudomonas* spp

→ D

High-level contamination
Any quantity of *Pseudomonas* spp or ≥ 10 CFU/mL of other organisms

→ E

100x above the AS 5369 specifications!

LOW LEVEL
< 10cfu/ml
=
< 1000cfu/100ml

HIGH LEVEL
≥ 10cfu/ml
=
≥ 1000cfu/100ml

AS5369 acceptable criteria is
≤ 10cfu/100mls =
≤ 0.1 cfu/ml

C= Withdraw AFER from service
D= Don't use AFER for duodenoscopes
E= Withdraw AFER from service

AFER FINAL RINSE WATER – AS 5369 AND GENCA

AS 5369

- ❑ TVC : ≤ 10cfu/100ml = **≤ 0.1cfu/ml**
  - E.g. Seven colonies of Viridan Strep and two of *E.coli* = acceptable
- ❑ *Pseudomonas* and Atypical *Mycobacterium* species: **NONE** allowed per 100ml of sample
- ❑ Acceptable criteria for TVC is provided as **cfu/100ml**
- ❑ TVC Method as per ISO 15883-1(R2A agar)
- ❑ TVC testing doesn't identify organisms
  - How do we know if it's significant growth?
  - Should we identify growth from a positive TVC?

GENCA

- ❑ **Any growth** other than skin contaminant i.e. Gram-negative bacillus, viridan Strep, *Enterococcus,* high environmental/unusual organism: **withdraw** AFER from service
- ❑ If *Pseudomonas* present = **withdraw** AFER from use
- ❑ If Atypical *Mycobacterium* sp present = Action C, or D/ E
  - Action C&E – **withdraw** AFER from service
  - Action D - continue using the AFER for gastroscopes and colonoscopes only
- ❑ Low level contamination is considered **< 10cfu/ml**
  - Continue to use AFER (except for duodenoscopes)
- ❑ High level contamination is considered **≥ 10cfu/ml**

  This is 100 times above the AS 5369 cutoff of ≤ 0.1cfu/ml
- ❑ Sampling volumes & testing methods differ –use of Blood agar
- ❑ Flowchart responses don't advise on the management of endoscopes or patients
  - Is there a need to reprocess all affected endoscopes and consider a recall?

ACTION LEVELS FOR FINAL RINSE WATER

Available online at www.sciencedirect.com
Journal of Hospital Infection
journal homepage: www.elsevier.com/locate/jhin
Healthcare Infection Society
Guidelines

Final rinse water quality for flexible endoscopy to minimize the risk of post-endoscopic infection. Report from Healthcare Infection Society Working Party

J.T. Walker [a,b], A. Bak [b], G. Marsden [b], W. Spencer [c], H. Griffiths [d], G.A. Stanton [e], C. Williams [b,f], L.J. White [b,g], E. Ross [b,h], G. Sjogren [i], C.R. Bradley [b,j,*], M. Garvey [b,j,*,i]

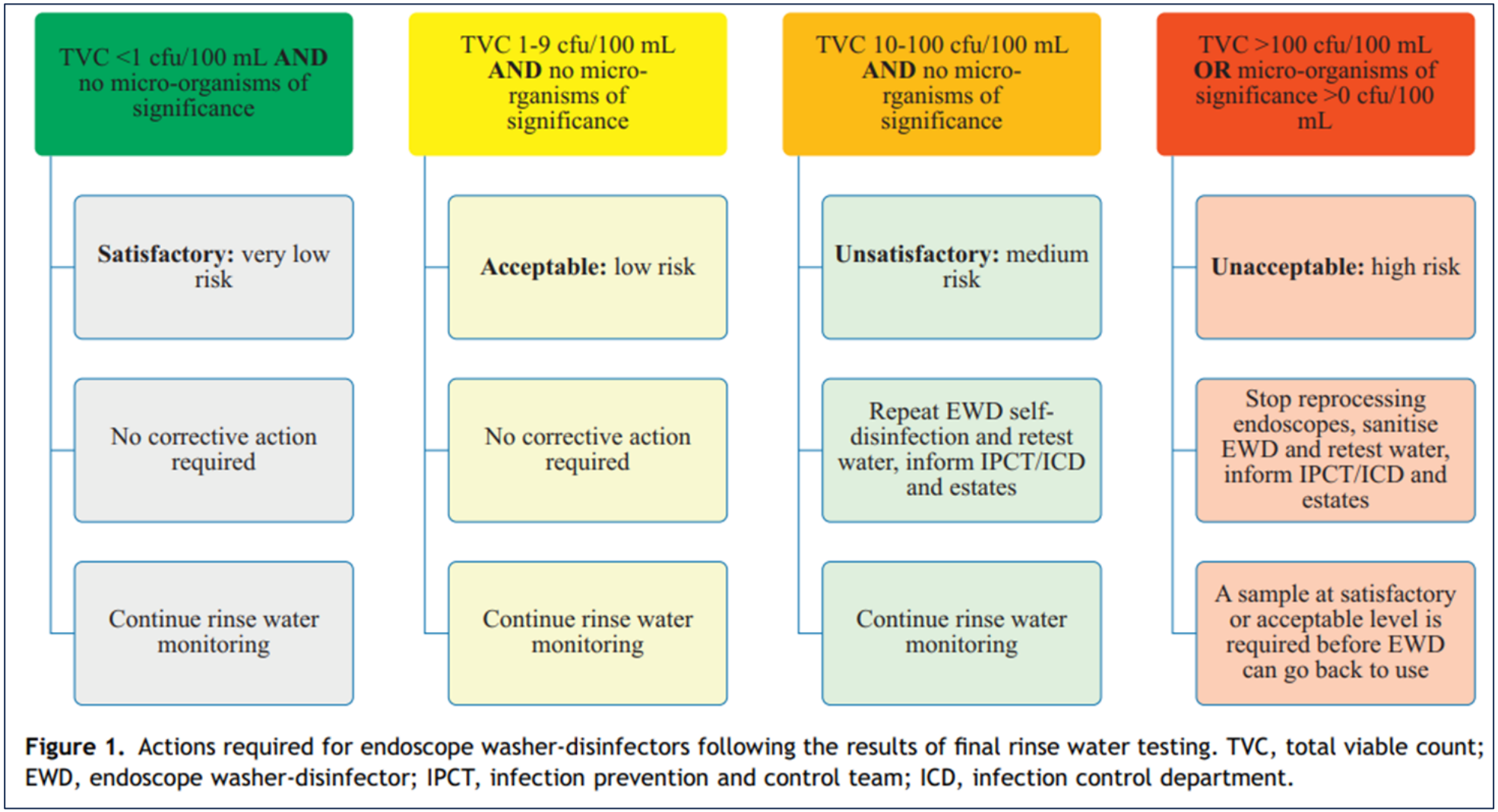


Figure 1. Actions required for endoscope washer-disinfectors following the results of final rinse water testing. TVC, total viable count; EWD, endoscope washer-disinfector; IPCT, infection prevention and control team; ICD, infection control department.

SURVEILLANCE OF FLEXIBLE ENDOSCOPES WITH CHANNELS

AS 5369 – *Section 8.5*

8.5 Microbiological surveillance of flexible endoscopes with channels

Flexible endoscopes with channels shall undergo microbiological surveillance.

Flexible endoscopes not subjected to terminal sterilization shall be tested in accordance with the GENCA Guidelines for Infection Prevention and Control in Endoscope.

Flexible endoscopes with channels that undergo terminal sterilization shall be tested in accordance with the facility's policy.

Loaned flexible endoscopes with channels, or returning from repair, shall undergo microbiological surveillance within 72 h of receipt.

GENCA – *Section 10.2 & 10.3.1.1*

Use of surveillance is:
"recommended as a quality control marker of the adequacy and completeness of the entire cleaning, disinfection and storage process and the structural integrity of the endoscope"

Relevant bacteria

- Oral and enteric organisms
  - Coliforms
  - *Salmonella* and *Shigella*
- Enterococci
- Viridan Streptococci
- Non fermentative Gram-negative bacilli
  - including *Pseudomonas* spp

Refer to Figure 5 & 6. ***Response to positive cultures from a gastroscope or colonoscope or duodenoscope***

POSITIVE SURVEILLANCE CULTURES

Skin and environmental flora

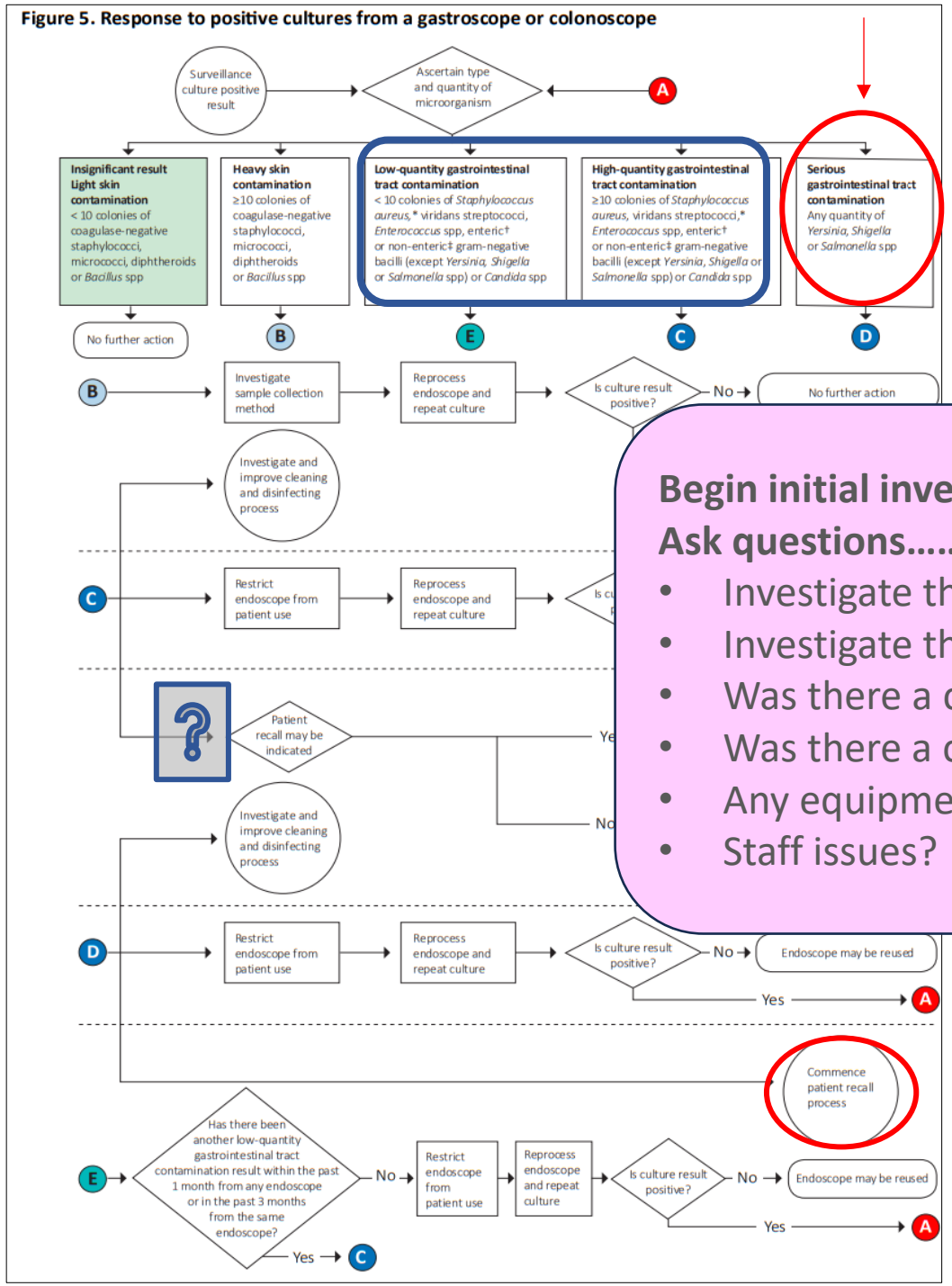
- Coagulase negative *Staph* sp
- *Micrococcus* species
- *Kytococcus* species
- *Bacillus* species

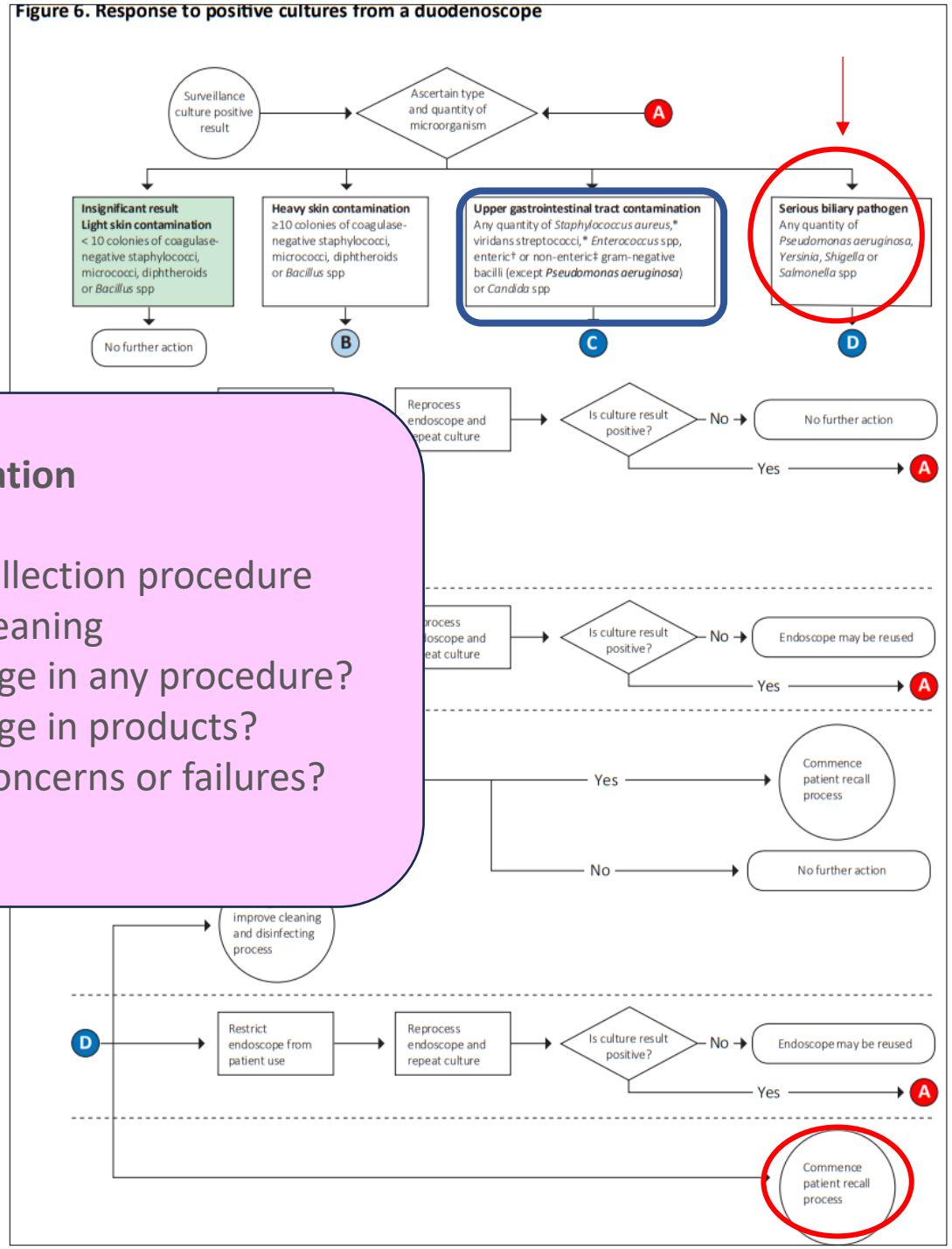
Enteric and oral organisms

- Enteric Gram-negative bacilli
  - *Klebsiella* sp, *Serratia* sp
- *Enterococcus* and Streptococci
- *Pseudomonas aeruginosa*
- *Candida sp*

Environmental organisms

- *Acinetobacter sp*
- *Achromobacter sp*
- *Stenotrophomonas maltophilia*





Begin initial investigation

Ask questions…….

- Investigate the collection procedure
- Investigate the cleaning
- Was there a change in any procedure?
- Was there a change in products?
- Any equipment concerns or failures?
- Staff issues?

INVESTIGATION

Reprocessing lapses or endoscope defects

- Failure to detect a leak in a scope?
- Accidental use of a faulty scope?
- Faulty connectors/accessories?
- Defective batch of disinfectant?
- Insufficient drying time?
- Final rinse water contaminated?

Culture results

- Single organism or mixed culture
- Were there low or high numbers of growth?
- Are they enteric or possible environmental organisms?
- Were sensitivities performed? Could it be an MRO?

Endoscope's history

- Has the scope tested positive previously?
- If so, for same organism/s or different organism/s? How long ago?
- Are there any other scopes with same organism/s?
- Has the scope been recently serviced or overdue for maintenance?
- Is it a higher risk endoscope?

CONSIDERING A PATIENT RECALL

Need to assemble a MD team

Investigation takes time!

Post Exposure Prophylaxis (PEP)

PEP for HIV needs to be given within 72hours!

Would you be able to achieve it?

Would you be able to prevent infection?

What about Hep B ?

Hep C?

Test and monitor with serology?

What about MRO exposure?

Implement Screening ?

How often and for how long?

What do you plan to tell your patients?

Reprocessing lapses or endoscope defects

- Failure to detect a
- Accidental use of a faulty scope
- Faulty connectors/accessories?
- Defective batch of disinfectant?
- Insufficient drying time?
- Final rinse wa… contaminated?

Culture results

- Mixed…
- Were there lo…
- Are they enteric orga…
- Were sensitivities performed?

- Has the scope tested positive previously?
- If so, for same organism/s or different organism/s? How long ago?
- Are there any other scopes with same organism/s?
- Has the scope been recently serviced or …
- Is it a higher risk endoscope?

Endoscope's history

- Time from testing to positive result
- When was the scope last negative?
- Has the endoscope been in use since testing was performed?
- How many patients has the endoscope been used on?
- How far back in time do we go?
- Has cross-contamination occurred?
- Could transmission have occurred?
- ?MRO
- ?Environmental
- ?BBV

ENDOSCOPE STORAGE CABINET SURVEILLANCE

AS 5369 – *Section 7.4.4 & 8.1*

7.4.4 Controlled-environment storage cabinets for thermolabile endoscopes

Performance qualification (PQ) of controlled-environment storage cabinets for processed thermolabile endoscopes shall be conducted in accordance with EN16442.

Table 8.1 — Requirements for routine monitoring and control of cleaning and disinfecting equipment

Test	WD ISO 15883-1 and ISO 15883-2	WD ISO 15883-4	Ultrasonics AS 2773 [e]	Manual chemical disinfection	Drying cabinets AS 5330	Thermolabile endoscope storage cabinet EN 16442
Supply water hardness and chloride	M[a]	M[a]	M[a]	M[a]	B	B
Final rinse water conductivity	M[a]	RM	O	B	B	B
Final rinse water TVC	M[d]	M[b]	B	Q[c]	B	B
Final rinse water Endotoxin	A[a]	A[a]	B	O	B	B
Temperature	EC	EC	RM	RM	D	RM
Chemical dosing volumetric test	Q	EC	RM	B	B	B
Time	EC	EC	RM	EC	RM	EI
Cleaning efficacy/visual inspection	EI	EI	EI	B	B	B

EN 16442:2015 CESC for thermolabile endoscopes

- Section 6.5 Contamination of the inside surfaces of the storage cabinet
- Annex C methods for evaluation of airborne microbial contamination in the storage cabinet
  - Active air sampling or sedimentation

GENCA – *Section 10.6.4.1&2*

Contact plates

- The contamination levels identified should be less than 25 CFU/25 cm^2

Air settle plates

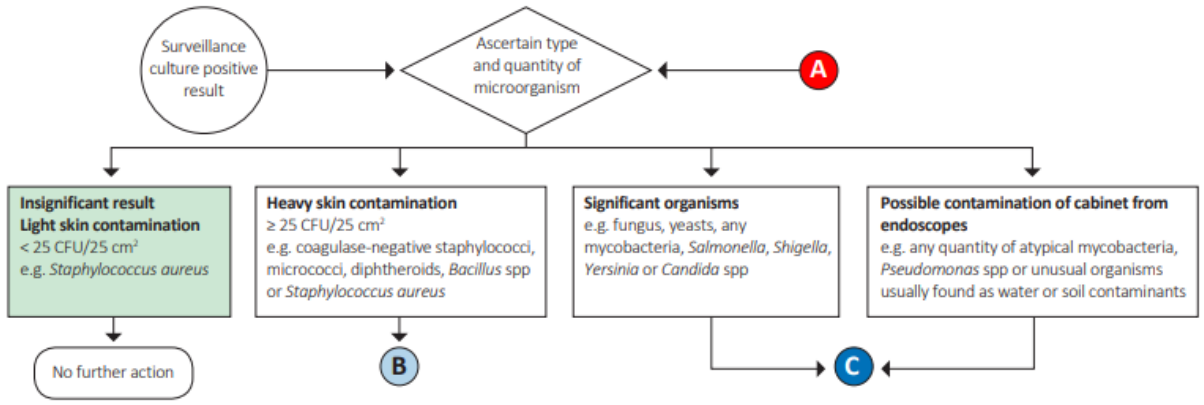
- The tests are considered satisfactory if the total number of colonies on the four agar plates is less than 50 CFU

A contamination level lower than 25/50 CFU **is not satisfactory** if the microorganisms recovered are considered to be **pathogenic** for the intended use of the device

- Refer to Figure 9. ***Response to positive cultures from a controlled-environment storage cabinet***

GENCA FIGURE 9 - RESPONDING TO POSITIVE STORAGE CABINET RESULTS

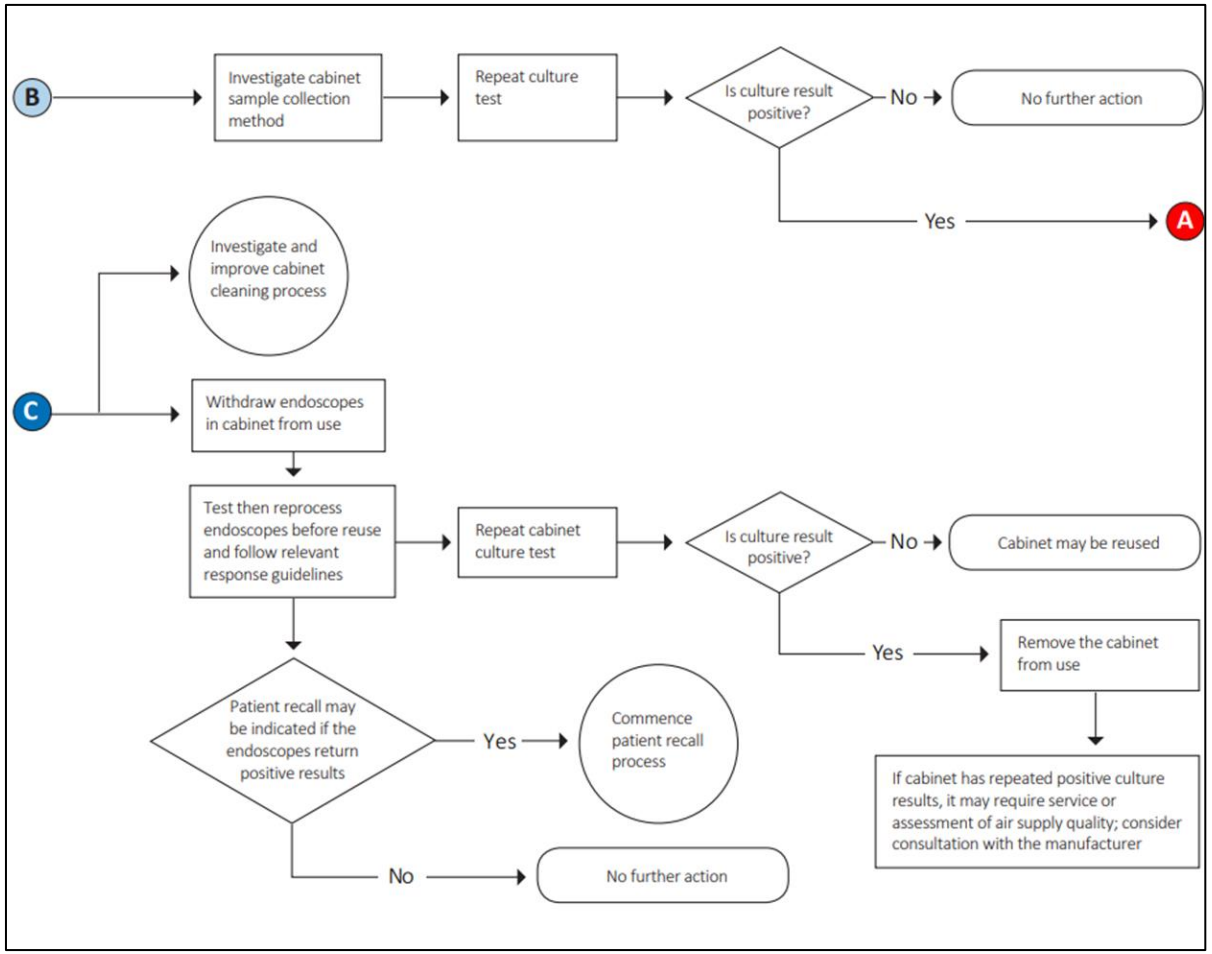
Figure 9. Response to positive cultures from a controlled-environment storage cabinet



No recommendations for air culture results

Contamination = Action C

- Withdraw endoscopes from cabinet
- **Test and reprocess endoscopes**
- **Retest cabinets**
- Patient recall may be indicated if scope positive



Terrabacter ginsenosidmutans
Brachybacterium congloeratum
Psuedomonas lundensis
Rossellomorea sp
Psychrobacter pulmonis

FINAL COMMENTS

- **AFER Final Rinse Water**
  - AS 5369 TVC testing
    - Do we need to identify any growth even if less than 10cfu/100ml?
    - Do we need action levels for unsatisfactory results and what actions to take if endoscopes and patients were put at risk?
  - GENCA Guidelines
    - Do we need to revisit acceptable limits and align the guidelines and standards?

  Do we adopt a traffic light system approach to respond to any positive TVC ?

- **Endoscope surveillance**
  - GIU endoscopes enter body cavities with levels of microbes, 10^7 to 10^{10} cfu/ml
  - Failure to achieve compliance carries the risk of scope to person/s transmission of blood borne viruses e.g. Hep B, Hep C, enteric pathogens e.g. *Salmonella*
  - Reprocessing lapses, culture results and the endoscope's use and history should contribute to the decision-making process
  - Time can be critical if Post Exposure Prophylaxis (PEP) is required

- **Controlled conditions for storage systems**
  - Surveillance is designed to test
    - Cleaning conformity of cabinets - Endoscope cabinets should be cleaned routinely, and scopes should also avoid touching the walls of the cabinet
    - Air quality - Air supply must be as per manufacturer's recommendation and measured at specified intervals

- Responding to positive surveillance in GIU can be a challenge and remedial actions based on the identification and quantity of growth can be difficult
- A multidisciplinary team should be assembled - especially where unusual organisms are encountered, or a patient recall may be indicated
- Epidemiology and distribution of organisms vary – recommendations cannot account for all organisms and exhaustive lists would prove difficult
- Consultation with infectious diseases/microbiologist/lab may be necessary
- Water borne organisms can be resistant to disinfectants and persist in water supplies
- GIU Services may be affected - Repeat testing is usually necessary, time and staffing resources are required to undertake recommended actions
- Is there a greater risk to patients if procedures are delayed?