

Policy

# Clinical Guideline

## Microbiological Testing of Endoscopes Clinical Guideline

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**Policy developed by:** Infection Control Service, CDCB

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**Summary** The Microbiological Testing of Endoscopes Clinical Guideline outlines the procedures for quality assurance of the reprocessing of gastrointestinal endoscopes and bronchoscopes using microbiological sampling and culture. The instructions contained within this guideline are based on the Gastroenterological Society of Australia (GESA) Guidelines for Infection Control in Endoscopy

**Keywords** Microbiological testing of endoscopes clinical guideline, endoscope, endoscopy, microbiology, culture, sampling, contamination, validation, quality assurance

**Policy history** Is this a new policy? **Y**  
Does this policy amend or update an existing policy? **N**  
Does this policy replace an existing policy? **N**  
If so, which policies?

**Applies to** CALHN, SALHN, NALHN, CHSALHN, WCHN

**Staff impact** All Clinical, Medical, Nursing, Emergency, Pathology staff involved in endoscopy and endoscope reprocessing.

**PDS reference** CG259

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### Version control and change history

Version	Date from	Date to	Amendment
1.0	22/03/2017	Current	Original version

Clinical Guideline for  
microbiological testing  
of endoscopes

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### **Disclaimer**

This guideline provides advice of a general nature. This statewide guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach. The guideline is based on a review of published evidence and expert opinion.

Information in this statewide guideline is current at the time of publication.

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Health practitioners in the South Australian public health sector are expected to review specific details of each patient and professionally assess the applicability of the relevant guideline to that clinical situation.

If for good clinical reasons, a decision is made to depart from the guideline, the responsible clinician must document in the patient's medical record, the decision made, by whom and detailed reasons for the departure from the guideline.

This statewide guideline does not address all the elements of clinical practice and assumes that the individual clinicians are responsible for:

- discussing care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes the use of interpreter services where necessary,
- advising consumers of their choice and ensure informed consent is obtained.
- providing care within scope of practice, meeting all legislative requirements and maintaining standards of professional conduct and
- documenting all care in accordance with mandatory and local requirements.

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## Introduction

This guideline outlines the procedures for quality assurance of the reprocessing of gastrointestinal endoscopes and bronchoscopes using microbiological sampling and culture. The instructions contained within this guideline are based on the Gastroenterological Society of Australia (GESA) *Guidelines for Infection Control in Endoscopy*.<sup>1</sup>

## Background

Microbiological testing of endoscopes, such as duodenoscopes, colonoscopes, bronchoscopes, and of automated flexible endoscope reprocessors (AFERs), is performed as a quality control measure to verify cleaning and sterilisation processes and the integrity of the internal channels of the endoscope. It has been shown that isolation of bacteria from the internal channels of processed endoscopes is an indicator of either inadequate cleaning prior to high level disinfection, a failure of the disinfection/sterilisation process, or a structural defect within the endoscope that enables biofilm to form.<sup>2 3</sup>

Bacteria of interest include enteric, respiratory and some environmental organisms (such as rapidly growing mycobacteria), as isolation of these organisms may indicate a breakdown of the cleaning and sterilisation processes of the instruments or inadequate filtering of water used to clean the devices. Additionally, isolation of organisms such as staphylococci, micrococci and occasionally viridans streptococci may indicate contamination during the sample collection process.

## Definitions

**AFER means:** automated flexible endoscope reprocessors

**CNS means:** coagulase-negative staphylococci

**GESA means:** Gastroenterological Society of Australia

**MTB means:** *Mycobacterium tuberculosis*

## Standards

The following National Safety and Quality Health Service Standards (NSQHSS) standards apply:

Standard 3 - Preventing and Controlling Healthcare Associated Infections, in particular managing patients with infection or colonisations:

- > Criterion 3.1 - Developing and implementing governance systems for effective infection prevention and control to minimise the risks to patients of healthcare associated infections.
- > Criterion 3.16 – Reprocessing reusable medical equipment, instruments and devices in accordance with relevant national or international standards and manufacturers' instructions.

## Principles of the standards

Standard 3 aims to prevent patients from acquiring preventable healthcare associated infections and effectively manage infections when they occur by using evidence-based strategies that are based on the risk to both patients and staff.

## Frequency of testing

Because of differential risks of infection transmission, recommendations on the frequency of testing vary with both the proposed use of the endoscopes and with the method of disinfection. [Appendix 1](#) summarises recommendations from the GESA guidelines.<sup>1</sup>

Further microbiological screening should be undertaken in consultation with a clinical microbiologist/infection control professional in the following circumstances:

- > there is a clinical suspicion of cross-infection related to endoscopy
- > in response to positive surveillance cultures
- > where new staff are performing endoscope reprocessing
- > where alterations are made to the plumbing of the endoscopy reprocessing area
- > with the introduction of new models of equipment (endoscope or AFER).

## Sampling of instruments

Instruments should be sampled after usual processing and following storage for at least 12 hours, except in the case of rigid endoscopes that have undergone sterilisation and are already stored in a wrapped state. These should be removed from the packaging and tested at the interval indicated in table 1 or as per agreed endoscopy unit protocol. Detailed recommended methods for instrument or AFER sample collection are available in the GESA guidelines.<sup>1</sup>

All samples should be pooled in a single container which is labelled and sent with a request form detailing the following:

- > type of scope sampled and serial number
- > name of person to whom the report should be sent
- > test requested (e.g. routine infection control surveillance; TB - after a positive bronchoscopy clinical sample; repeat testing after previous positive surveillance culture).

In the event of a significant positive surveillance culture, testing should be repeated. Each individual channel will need to be sampled and the rinse fluid placed into separate collection containers.

## Microbiological testing

Bacterial cultures are reported semi-quantitatively and should be interpreted and acted upon according to guidelines established in individual endoscopy units in consultation with local infection control staff. The type of organism isolated e.g. environmental or skin organisms (e.g. *Bacillus* spp., coagulase-negative staphylococci, micrococci) versus gastrointestinal organisms (e.g. *E. coli*, *Salmonella*, *Proteus* spp.) are factors used in assessing whether any action is necessary. Growth is evaluated to quantify the level of bacterial contamination and may be reported according to the scheme below:

Growth quantitation	Approximate colony counts per agar plate
+	< 10
++	10 – 100
+++	> 100

Each endoscopy unit must determine its own interpretative scheme; that described in the GESA guidelines is the most frequently used. Suggested interpretation of cultures and actions are summarised in appendices 1 and 2.

## Summary of interpretation of microbiology results according to GESA guidelines:

- > Pathogens in any numbers, such as *S. aureus*, *Salmonella* spp., *E. coli*, *P. aeruginosa*, *Mycobacterium* spp. indicate that there is a problem with the cleaning/disinfection process, with potential for cross-infection. Immediate further investigation is needed and endoscopes should be removed from patient use until investigations are complete. Microbiological testing of the AFER (e.g. Steris and Soluscope) and disinfecting equipment, in addition to retesting of endoscopes, is indicated in order to identify the problem.
- > Low numbers (<10 colonies) of skin commensals or environmental-type organisms e.g. coagulase negative staphylococci (CNS), micrococci, *Bacillus* spp., etc., are most likely derived from the sample collection process and are not considered significant. Isolation of skin contaminants or environmental organisms **does not require** the endoscope to be removed from patient use whilst waiting for results of repeat cultures.
- > Repeated isolation of an environmental organism, such as some species of *Acinetobacter*, *Bacillus* species, *Stenotrophomonas* species and related organisms, may indicate problems associated with insufficient drying of endoscope channels post-processing or improper storage conditions.
- > When unfamiliar organisms are reported, advice may be sought from SA Health's Infection Control Service, or the processing laboratory, to ascertain whether these are potential pathogens or environmental organisms.

## Workforce implications

All staff responsible for reprocessing of endoscopes must have undergone the relevant competency-based training, and maintain the currency of their skills by attendance at relevant update courses or training provided by the endoscope manufacturers.

## Quality, safety and risk management

Failures of reprocessing identified by microbiological culture or other means should be reported on the SA Health Safety Learning System, and a root cause analysis undertaken.

In the event of a positive culture with a significant pathogenic microorganism a risk assessment should be undertaken in conjunction with Infection Control personnel to determine whether a patient look-back should be undertaken. For further guidance, refer to the SA Health Lookback Review Policy Directive, available at: <http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/clinical+resources/safety+and+quality/governance+for+safety+and+quality/patient+incident+management+and+open+disclosure/lookback+review?contentIDR=0b5aea804e28bcf99fd9bfe0fb06cb83&useDefaultText=1&useDefaultDesc=1>

## Eligibility Criteria

### Inclusions

All lumened endoscopic instruments that are manually cleaned and reprocessed by using a liquid chemical sterilant or high level disinfectant by either manual soaking or by an AFER.

### Exclusion

Non-lumened probes or other instruments used in body cavities.

## Reporting

All significant positive cultures should be reported to the local Infection Control Coordinator, the SA Health Infection Control Service and on the SA Health Safety Learning System.

## Appendices

Appendix 1: Recommended frequency of endoscope and reprocessor testing and microorganisms of interest

Appendix 2: Recommendations based on testing results

## References

1. Gastroenterological Society of Australia. (2010). Infection Control in Endoscopy 3rd edit.
2. Rutala, W. A. & Weber, D. J. (2016). Outbreaks of carbapenem-resistant Enterobacteriaceae infections associated with duodenoscopes: What can we do to prevent infections? *Am J Infect Control* **44**, 5 Suppl: e47-51.
3. O'Horo, J. C., Farrell, A., Sohail, M. R., *et al.* (2016). Carbapenem-resistant Enterobacteriaceae and endoscopy: An evolving threat. *Am J Infect Control* **44**, 9: 1032-6.



## Appendix 1: Recommended frequency of endoscope and reprocessor testing and microorganisms of interest

Adapted from: *Infection Control in Endoscopy, Gastroenterological Society of Australia, Third Edition 2010.*

Device/scope	Recommended frequency of testing	Microorganisms of interest	Comments
Automatic flexible endoscope reprocessors (AFERs)	Monthly	Non-fermentative Gram-negative bacilli (including <i>Pseudomonas</i> spp.) and rapid-growing mycobacteria	
Duodenoscopes	Monthly	coliforms (including <i>Salmonella</i> spp.), enterococci and viridans streptococci; non-fermentative Gram-negative bacilli (including <i>Pseudomonas</i> spp.).	
Bronchoscopes	Monthly	As for duodenoscopes plus rapid-growing mycobacteria	Culture to identify <i>M. tuberculosis</i> is not included in routine surveillance but should be performed on the next scheduled sampling from a bronchoscope that has been used on a patient who has a positive MTB culture.
Linear endoscopic ultrasound instruments	Monthly	As for duodenoscopes	
Other gastrointestinal scopes	3-monthly	As for duodenoscopes	
Processed endoscopes stored in wrapped state	3-monthly	As for duodenoscopes	
Water supply for manual rinsing	Monthly if no filter 3-monthly if 0.2 micron filter in place	Non-fermentative Gram-negative bacilli (including <i>Pseudomonas</i> spp.) and rapid-growing mycobacteria	
Loan instruments	Within 72 hours of receipt and then on routine schedule	As for duodenoscopes / bronchoscopes	

\* Enteric bacteria: *E coli*, *Klebsiella*, *Enterobacter*, *Serratia*, *Citrobacter*, *Morganella*, *Proteus* spp.  
Non-enteric bacteria: *Pseudomonas* spp. (including *P. aeruginosa*), *Alcaligenes*, *Flavobacterium*, *Stenotrophomonas* and *Acinetobacter* spp. (common examples).

## Appendix 2: Recommendations based on testing results

### 1. Bronchoscopes

Culture classification	Culture result	Interpretation	Action
Light skin contamination	<10 colonies skin flora (CNS, <i>Bacillus</i> spp, diphtheroids, micrococci)	Insignificant result	No further action required Educate staff on sample collection if repeated problem.
Heavy skin contamination	≥10 colonies skin flora (CNS, <i>Bacillus</i> spp, diphtheroids, micrococci)	Probable contamination during sample collection	<ul style="list-style-type: none"> <li>&gt; investigate sample collection procedure</li> <li>&gt; reprocess endoscope and re-culture</li> <li>&gt; if re-culture is negative, no further action</li> <li>&gt; if positive on re-culture, consult.</li> </ul>
Upper respiratory tract contamination	Any quantity of <i>Staphylococcus aureus</i> , viridans streptococci, non-tuberculous mycobacteria, enteric or non-enteric Gram-negatives* (except <i>P.aeruginosa</i> , <i>Burkholderia cepacia</i> or <i>Acinetobacter baumannii</i> , which are considered significant) or <i>Candida</i> species.	Breaches in cleaning or disinfection process	<ul style="list-style-type: none"> <li>&gt; investigate and improve cleaning and disinfecting procedure</li> <li>&gt; remove endoscope from patient use</li> <li>&gt; reprocess endoscope and re-culture</li> <li>&gt; if re-culture is negative, scope may be reused</li> <li>&gt; if positive with same organisms on re-culture, manage as per high quantity gastrointestinal contamination of colonoscopes.</li> </ul>
Serious pulmonary pathogen	Any growth of <i>Mycobacterium tuberculosis</i> , <i>P.aeruginosa</i> , <i>Burkholderia cepacia</i> or <i>Acinetobacter baumannii</i>	Major breach in cleaning or disinfection process	<ul style="list-style-type: none"> <li>&gt; investigate and improve cleaning and disinfecting procedure</li> <li>&gt; remove endoscope from patient use</li> <li>&gt; <b>initiate patient recall</b><sup>#</sup></li> <li>&gt; reprocess endoscope and re-culture</li> <li>&gt; if culture negative, scope may be reused</li> <li>&gt; if positive on re-culture, retest and consult.</li> </ul>

\* Enteric bacteria: *E coli*, *Klebsiella*, *Enterobacter*, *Serratia*, *Citrobacter*, *Morganella*, *Proteus* spp.

Non-enteric bacteria: *Pseudomonas* spp. (excluding *P. aeruginosa*), *Alcaligenes*, *Flavobacterium*, *Stenotrophomonas* and *Acinetobacter* spp. (common examples).

CNS: coagulase-negative staphylococci

<sup>#</sup> Refer to [SA Health Lookback Review Policy Directive](#).

## 2. Duodenoscopes

Culture classification	Culture result	Interpretation	Action
Light skin contamination	< 10 colonies skin flora (CNS, <i>Bacillus</i> spp, diphtheroids, micrococci)	Insignificant result	No further action required/educate staff on sample collection technique if repeated problem
Heavy skin contamination	≥10 colonies skin flora (CNS, <i>Bacillus</i> spp, diphtheroids, micrococci)	Probable contamination during sample collection	<ul style="list-style-type: none"> <li>&gt; investigate sample collection procedure</li> <li>&gt; reprocess endoscope and re-culture</li> <li>&gt; if repeat culture negative no further action</li> <li>&gt; if positive on re-culture, consult.</li> </ul>
Upper gastrointestinal tract contamination	Any quantity of <i>Staphylococcus aureus</i> , viridans streptococci, <i>Enterococcus</i> sp. , enteric or non-enteric Gram-negatives* (except <i>P.aeruginosa</i> ), or <i>Candida</i> species	Upper gastrointestinal tract contamination, indicative of incomplete cleaning or disinfection	<ul style="list-style-type: none"> <li>&gt; investigate and improve cleaning and disinfecting procedure</li> <li>&gt; restrict endoscope from patient use</li> <li>&gt; <b>patient recall may be indicated</b></li> <li>&gt; reprocess endoscope and re-culture</li> <li>&gt; if repeat culture negative, scope may be reused</li> <li>&gt; if positive on re-culture, consider structural fault in scope; consult.</li> </ul>
Serious biliary pathogen	Any quantity of <i>P.aeruginosa</i> , <i>Yersinia</i> , <i>Shigella</i> or <i>Salmonella</i> spp.	Serious biliary pathogen, indicative of incomplete cleaning or disinfection	<ul style="list-style-type: none"> <li>&gt; investigate and improve cleaning and disinfecting procedure</li> <li>&gt; restrict endoscope from patient use</li> <li>&gt; <b>initiate patient recall</b><sup>#</sup></li> <li>&gt; reprocess endoscope and re-culture</li> <li>&gt; if repeat culture negative scope may be reused</li> <li>&gt; if positive on re-culture, consider structural fault in scope – send to manufacturer for testing.</li> </ul>

\* Enteric bacteria: *E coli*, *Klebsiella*, *Enterobacter*, *Serratia*, *Citrobacter*, *Morganella*, *Proteus* spp.

Non-enteric bacteria: *Pseudomonas* spp. (excluding *P. aeruginosa*), *Alcaligenes*, *Flavobacterium*, *Stenotrophomonas* and *Acinetobacter* spp. (common examples).

CNS: coagulase-negative staphylococci

<sup>#</sup> Refer to [SA Health Lookback Review Policy Directive](#)

### 3. Gastrosopes and colonoscopes

Culture classification	Culture result	Interpretation	Action
Light skin contamination	< 10 colonies skin flora (CNS, <i>Bacillus</i> spp, diphtheroids, micrococci)	Insignificant result	No further action/educate staff on sample collection technique if repeated problem
Heavy skin contamination	≥10 colonies skin flora (CNS, <i>Bacillus</i> spp, diphtheroids, micrococci)	Probable contamination during sample collection	<ul style="list-style-type: none"> <li>&gt; investigate sample collection procedure.</li> <li>&gt; reprocess endoscope and re-culture</li> <li>&gt; if culture negative no further action</li> <li>&gt; if positive on re-culture, consult.</li> </ul>
Low quantity gastrointestinal contamination	<10 colonies <i>Staphylococcus aureus</i> , <i>Enterococcus</i> spp., viridans streptococci, enteric or non-enteric Gram-negatives* (except <i>Yersinia</i> , <i>Salmonella</i> or <i>Shigella</i> spp.), <i>Candida</i> species	Breaches in cleaning or disinfection	<ul style="list-style-type: none"> <li>&gt; investigate and improve cleaning and disinfecting procedure</li> <li>&gt; restrict endoscope from patient use</li> <li>&gt; reprocess endoscope and re-culture</li> <li>&gt; if repeat culture negative, scope may be reused</li> <li>&gt; if repeat culture positive, manage as per high quantity gastrointestinal contamination below.</li> </ul>
High quantity gastrointestinal contamination	≥ 10 colonies <i>Staphylococcus aureus</i> , <i>Enterococcus</i> spp., viridans streptococci, enteric or non-enteric Gram-negatives* (except <i>Yersinia</i> , <i>Salmonella</i> or <i>Shigella</i> sp.), <i>Candida</i> species	Significant breach in cleaning and or disinfecting process	<ul style="list-style-type: none"> <li>&gt; investigate and improve cleaning and disinfecting procedure</li> <li>&gt; restrict endoscope from patient use</li> <li>&gt; <b>patient recall may be indicated</b></li> <li>&gt; reprocess endoscope and re-culture</li> <li>&gt; if repeat culture negative scope may be reused</li> <li>&gt; if repeat culture positive, consider structural fault in scope.</li> </ul>
Serious gastrointestinal pathogen contamination	Any quantity of <i>Yersinia</i> , <i>Salmonella</i> or <i>Shigella</i> spp.	Major breach in cleaning or disinfection process	<ul style="list-style-type: none"> <li>&gt; investigate and improve cleaning and disinfecting procedure</li> <li>&gt; restrict endoscope from patient use</li> <li>&gt; <b>initiate patient recall<sup>#</sup></b></li> <li>&gt; reprocess endoscope and re-culture</li> <li>&gt; if culture negative scope may be reused</li> <li>&gt; if repeat culture positive; consider structural fault in scope</li> </ul>

\* Enteric bacteria: *E coli*, *Klebsiella*, *Enterobacter*, *Serratia*, *Citrobacter*, *Morganella*, *Proteus* spp.  
 Non-enteric bacteria: *Pseudomonas* spp. (excluding *P. aeruginosa*), *Alcaligenes*, *Flavobacterium*, *Stenotrophomonas* and *Acinetobacter* spp. (common examples).  
 CNS: coagulase-negative staphylococci

<sup>#</sup> Refer to [SA Health Lookback Review Policy Directive](#)

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