U.S. FOOD & DRUG ADMINISTRATION

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Duodenoscope Surveillance Sampling and Culturing

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Outline

- Overview of FDA-CDC-ASM duodenoscope surveillance sampling and culturing document
- Sampling method
- Culturing options
- Comparison to CDC's March 2015, Interim Recommendations

Released on February 26th, 2018

- https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf

Who: Working group: FDA, CDC, ASM, duodenoscope manufacturers, and other experts in endoscope sampling and culturing.

What: The document is a tool that can be used by health care facilities that choose to conduct surveillance sampling and culturing of duodenoscopes.

Why: The protocols were developed to provide a standardized, validated method to health care facilities for surveillance sampling and culturing duodenoscopes.

Overview – Background

- Surveillance sampling and culturing is not required by FDA/CDC/ASM.
- These methods require specific resources, training, and expertise.
- Surveillance sampling and culturing is not a substitute for complete adherence to the endoscope manufacturer's recommendations for reprocessing and maintenance.

Overview - Organization of Document

Table of Contents

Overview - Organization of Document

- The document is divided into three sections:
  - The first section provides an overview and introduction to surveillance sampling and culturing.
  - The second section describes the duodenoscope sampling methods.
  - The third section discusses the options for microbiological culturing of samples, and includes suggestions for microbial limits.

Overview- Protocol Implementation

- Health care facilities select the appropriate method for sample collection and culture and interpretation.
- Adopt it to the institutional formatting for standard operating procedures at each individual health care facility.

Overview – Additional Details

- Health care facilities that choose to conduct surveillance sampling and culturing must make a number of decisions regarding these methods, based on their needs and resources.

Sampling Method

- Two staff are required for sampling.
- Staff should be familiar with duodenoscope handling.
- Sampling staff must be trained in aseptic technique and duodenoscope sampling.
- Sampling should be conducted on patient-ready duodenoscopes

Sampling Method

- **One combined sample collected from:**
  - Elevator recess
  - Instrument channel
  - Elevator wire channel (if unsealed)

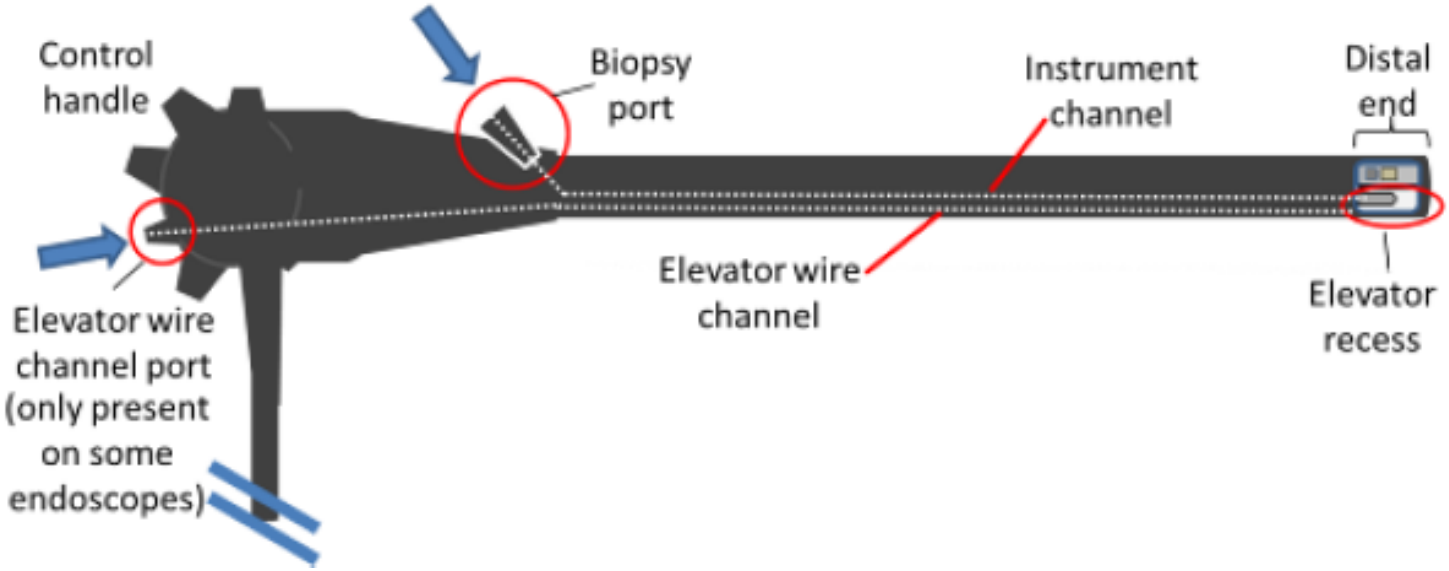


Figure 1: Duodenoscope Diagram

Sampling Method – Elevator Recess

- The seam between the distal end cap (when present) and distal end should be sampled with a swab moistened with sterile water.

- The elevator recess should undergo flushing, brushing, and additional flushing.

Figure 2: Brushing the elevator recess

Sampling Method – Instrument Channel

The channel from the biopsy port to the distal end is flushed with sterile water, brushed, and flushed again. The brush head should be cut off or removed and added to the sample extract.

Figure 3: Brushing the instrument channel

Sampling Method – Elevator Wire Channel

When accessible (i.e. unsealed) on a duodenoscope, this channel should be flushed with sterile water.

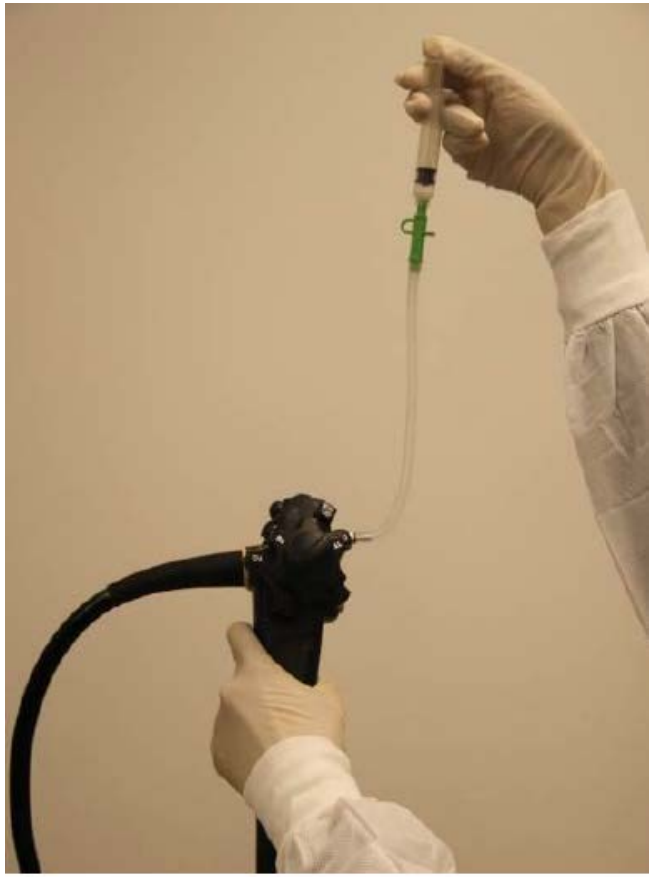


Figure 4: Flushing the elevator wire channel

Sampling Method – Sample Handling

- The extracts (including swab and brush heads) from the elevator recess, instrument channel, and elevator wire channel are combined for microbiological culturing.
- An appropriate neutralizing media (e.g., Dey-Engley) should be added to the sample.
- Sample should be kept on ice or refrigerated prior to microbiological culturing.

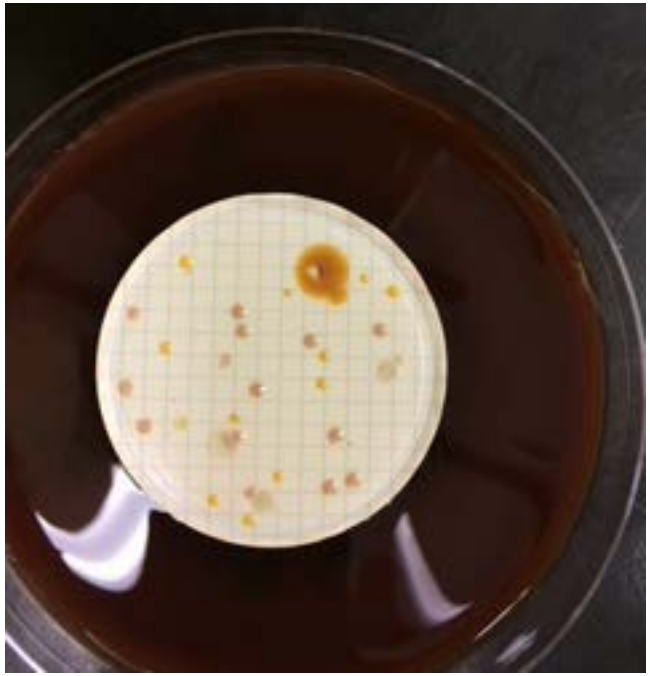
Sampling Method – Endoscope Handling After Sampling

Because the device is handled with sterile implements and sterile water only, reconducting the complete manual cleaning is not necessary.

- Manual high level disinfection
- Processing in an automated endoscope reprocessor
- Drying and sterilization

Culturing Method

Culturing should be conducted by staff who have knowledge and experience with standard microbiological culturing.



Culturing Method - Options

There are four options for culturing. Health care facilities should determine the option most suitable for their needs and resources:

- Membrane filtration and plating *(validated)*
- Centrifugation and plating
- Membrane filtration and liquid culture
- Centrifugation and liquid culture

Culturing Method – Plating Conditions

- The entire endoscope sample should be concentrated (either by membrane filtration or centrifugation).
- The endoscope sample (extract) should be plated on a single blood agar plate.
- Incubate at blood agar plate at 35 - 37°C.
- Identify and document growth at 24, 48 and 72 hours using standard methods.

Culturing Method – Liquid Culture Conditions

- The entire endoscope sample should be concentrated (either by membrane filtration or centrifugation).
- The endoscope sample (extract) should be added to appropriate liquid culture neutralizing media (e.g., Dey-Engley broth).
- Incubate the liquid culture at 35 - 37°C.
- Identify and document no growth/growth at 24, 48 and 72 hours using standard methods.

Culturing Method – Result Reporting

- If growth is observed, Gram staining and other identification methods should be conducted to identify potential high-concern organisms.
- Documentation and notification of relevant culturing information should conform with local regulations, quality management policies, and be traceable within the culturing facility's documents.

Culturing Method – Interpretation

Organism Category	General Criteria	Examples
High-Concern	More often associated with disease.	Gram-negative rods (e.g., *E. coli*, *K. pneumoniae*) *S. aureus*, Beta-hemolytic *Streptococcus*, *Enterococcus* species, and yeasts
Moderate-Concern	Less often associated with disease and commonly found in the oral cavity.	Saprophytic *Neisseria*, viridans group streptococci, and *Moraxella* species
Low-Concern	Less often associated with disease.	*Micrococcus*, coagulase-negative staphylococci (excluding *S. lugdenensis*), *Bacillus*, and diphtheroids

Culturing Method – Potential Responses

Health care facilities should develop their own action plans following culture results.

- Remove duodenoscope from use
- Patient notification
- Review reprocessing methods
- Review sampling and culturing methods
- Repeat reprocessing

Comparison

Methods	FDA/CDC/ASM 2018	CDC 2015 Interim Methods
Sampling		
• Location - Instrument Channel	Flush-brush-flush with sterile water (e.g., DI or RO water)	Flush with sterile water
• Location - Elevator Recess	Brush with water; flush with water	Brush with PBS/Tween-80
• Location - Distal cap seam	Swab the seam between the distal end cap and the distal end	*None specified*
• Sample handling	Samples are combined	Samples are separate (may be combined)
• Neutralization of samples	Neutralizer added to samples	*None specified*

Comparison

Methods	FDA/CDC/ASM	CDC 2015 Interim Methods
Culturing		
• Options	• Plating w/ Membrane Filtration • Plating w/ Centrifugation • Liquid culture w/ Membrane Filtration • Liquid culture w/ Centrifugation	• Plating w/ Membrane Filtration • Plating w/ Centrifugation • Liquid culture w/ Membrane Filtration • Liquid culture w/ Centrifugation
• Plating Method	• 1 Blood agar plate per duodenoscope	Blood and MacConkey agar plates per duodenoscope
• Controls	*None specified (other than routine lab media controls)*	3 controls: positive and 2 negative controls
• Culture incubation conditions	35 - 37°C for 72 hours	35 - 37°C for 48 hours

Summary

The FDC/CDC/ASM Method:

- Sampling: Use of flush-brush-flush for friction
- Neutralization: Reduce false-negatives
- Sample Concentration: Membrane filtration and plating

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Questions?

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http://www.fda.gov/training/cdrhlearn

Under the Heading: Specialty Technical topics; Subheading: Reprocessing