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Tips, Tricks and Insights for Implementation and Management of an Endoscope Sampling and Culturing Program

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Introduction

Sampling and culturing of flexible endoscopes involves obtaining a sample from an endoscope and sending it to a laboratory to determine if any microorganisms are present. The purpose of this procedure is to detect microbial contamination that may be present on the endoscope after reprocessing is performed.[1] This is most often performed on duodenoscopes, though many facilities express interest in using this method for the detection of possible post-reprocessing contamination on other models of endoscopes.

While it may sound simple enough, implementing endoscope sampling and culturing as a regular quality assurance activity is a multi-step process that requires input from a variety of sources; it is a learning experience. There are several scientific publications available on this topic as well as an invaluable resource from the FDA which will be discussed in this article. However, facilities may still experience some confusion on how to get started down this path and what exactly it entails.

"This article pulls on the experience obtained and lessons learned by Olympus during this study in hopes that it will provide insight to those wishing to implement or improve upon an endoscope sampling and culturing program."

Olympus is one of three endoscope manufacturers who performed post-market surveillance studies on duodenoscope reprocessing over the past couple of years. During this project, Olympus collected over 2,000 samples from 21 different study sites and gained a wealth of knowledge on this topic. This article pulls on the experience obtained and lessons learned by Olympus during this study with the hope that it will provide insight to those wishing to implement or improve upon an endoscope sampling and culturing program.

There are two main components to sampling and culturing, the first of which is the sampling portion. Sampling is performed at the healthcare facility by facility staff and is the physical act of collecting a sample or samples from the endoscope. Culturing is the second part of this process, and this is performed by a microbiology laboratory, where testing is performed to detect the presence or absence of microorganisms in collected samples.

Be aware that culturing will not typically detect all microorganisms that may be present in a sample as different organisms have differing requirements for growth and some may not be able to flourish in a laboratory environment. Variables such as the sampling medium, use of a neutralization broth, shipping speed and laboratory methods may also impact the sensitivity of the culturing methods.

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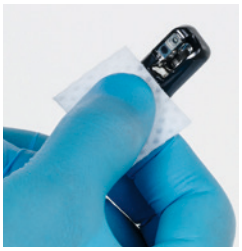
Tips, Tricks and Insights for Implementation and Management of an Endoscope Sampling and Culturing Program (Continued)



The use of the protocol described in this article, which was developed as a collaboration between the FDA, CDC, American Society for Microbiology and other experts, was designed to be able to detect most organisms that could potentially be of concern to patient safety.[1]

The implementation of a sampling and culturing program within a healthcare facility may help mitigate risks involved with the reprocessing of reusable medical devices. Furthermore, when the data obtained from sampling and culturing endoscopes is used to its full potential, it can provide insight into potential staff, device, equipment or environmental deficiencies.

This article will focus on the aspects healthcare facilities will be most involved in - obtaining a sample from the endoscope and the interpretation of laboratory results.

This publication is intended to be used as a potential educational resource for facilities that are considering or are engaging in a sampling and culturing program. It is not an official guideline or instruction manual but rather an overview of topics to consider before or during the implementation of a sampling and culturing program, and includes some tips on what may be encountered. A sampling and culturing program is a multi-faceted process that should be reviewed and considered by the relevant subject matter experts at a specific healthcare facility. Please note that the information within this publication refers to routine sampling and culturing for quality assurance purposes. In outbreak situations a different process may need to be applied. It is our hope that our healthcare partners will find this publication helpful, and can refer to the references herein for official guidance.

Pros and Cons to Implementing an Endoscope Sampling & Culturing Program

PROS

Before implementing an endoscope sampling and culturing program, the pros and cons should first be considered. Perhaps the most obvious pro is the ability to **help detect endoscope contamination before the endoscope is used on a patient**. For this goal to be successful, the endoscope must remain in quarantined storage until the sample is cultured by the laboratory and the final report is received and reviewed.

Without quarantine measures, the quarantined endoscope has the possibility of being used on one or more patients between the time of sampling and the receipt of results. If the results show there was a presence of potentially harmful microorganisms on the endoscope, then all the patients on which the endoscope was used since the time of sampling may have been exposed.

Errors or oversight in reprocessing equipment maintenance may also be able to be detected by analyzing endoscope culturing results. For instance, if waterborne pathogens are consistently seen in culture reports, the facility may want to ensure proper (AER) maintenance has been performed. Additionally, sampling of the facility water source itself might prove useful in investigating the source of endoscope contamination with certain microorganisms.

Environmental contamination, or contamination of the reprocessing and/or sampling areas themselves, could show up in laboratory reports as well. As sampling is not a strictly sterile process, the potential for environmental

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contamination of the sample itself is reasonably high. If organisms such as molds or fungi are present in the sample, the facility may want to consider the possibility that the source could be from the room(s) where the endoscopes are reprocessed and/or sampled rather than from the endoscope itself.

Sampling and culturing may **help identify errors or oversights in reprocessing**. Contamination of endoscopes may be a direct result of incorrect reprocessing. Reprocessing is a multi-step process and all steps must be performed correctly for effective disinfection to be achieved. Studies have shown that endoscope reprocessing technicians often skip or perform steps incorrectly when they are not directly observed and that compliance with reprocessing IFUs varies greatly between facilities.[2-4] Sampling endoscopes is a line of defense against accidental use of incorrectly reprocessed endoscopes. Patterns may also begin to emerge when looking at culture data. For instance, one may begin to see that endoscopes reprocessed by a certain technician, in a certain location, or during a certain shift have higher contamination rates than others. This information can be used to improve processes and increase the training and education of staff.

Sampling may also **help detect endoscope damage**. This may be recognizable when persistent positive cultures are seen with a single endoscope, especially if the same microorganism(s) is seen in consecutive results. If damage to the device is in an area that is difficult to visualize with current inspection techniques, it may be able to harbor microorganisms that could evade exposure to manual cleaning methods, high-level disinfection chemistries, or sterilization modalities.

CONS

Cost is one recognized negative aspect of implementing a sampling and culturing program. In addition to existing costs of endoscope reprocessing equipment and materials, sampling requires specific products that may not already be available within the healthcare facility. Numerous items used for sampling must be sterile which may also add additional costs. Laboratory fees must also be paid, and these costs can vary based on the laboratory selected but should be taken into consideration when determining a budget.

Additional employee resources are also needed as performing the sampling procedure typically requires two staff members. When staff members are still new to the sampling process a third person is often a great help; they can read the protocol out loud, ensure the sterile field is maintained, give the samplers supplies that may be out of reach and perform other simple tasks that will be required less as the samplers become more experienced. Employees that are chosen to perform sampling will also require additional training and periodic competency testing to ensure samples are collected properly.

Record keeping is also an essential part of a sampling and culturing program, which while important, adds more tasks to an already busy schedule. Information such as endoscope model and serial number, name of employees performing sampling, lot numbers of sampling materials used, shipping information if applicable, culture results and a record of endoscopes released from quarantine or other disposition should be maintained. This information is necessary if data obtained from sampling and culturing is to be analyzed and used to its fullest potential.

Endoscope downtime, or time in quarantine, must also be taken into consideration. Endoscopes should be kept in quarantine after sampling until the laboratory releases the final test report and it is reviewed by the selected personnel at the healthcare facility. Endoscopes can be in quarantine for 48 hours (at a minimum) and up to 10+ days depending upon whethe contamination is found in the sample or not. This downtime may result in the need to increase the number of endoscopes in inventory to maintain procedure volume.

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A con that can greatly impact the number of endoscopes in quarantine is the **possibility of inaccurate culture results due to human error**. As stated earlier, personnel performing sampling must be trained on the protocol. Even after training is complete, there is a learning curve where there may be a higher occurrence of environmental contamination until samplers become proficient at the task. Although environmental contamination of samples does not necessarily reflect the usability of the sampled endoscope, it will result in some endoscopes remaining in quarantine longer than if the sample had been collected competently. Keep in mind that while it is common to see environmental contamination in samples even when samplers are skilled, the occurrence can be decreased when samplers are well trained and competency is ensured.

Available Resource: Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection

If a decision is made to move forward after careful consideration of the pros and cons, examining the logistics of implementing a sampling and culturing program is the next step. A sampling protocol must be chosen or developed, but luckily such a protocol already exists. In February 2018, the FDA together with the CDC, American Society for Microbiology and other leading experts published a document titled *Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection.*[1] This document can be considered as the current gold standard on duodenoscope sampling and provides the user direction on everything from what supplies are required to how the laboratory should process the samples.

Although this document is intended specifically for duodenoscope culturing, it it may also amended to help guide the user in how to collect samples from other models of endoscopes. For example, to culture a colonoscope the steps for sampling the elevator forceps area can be replaced with sampling around the distal tip. In European countries, sampling and culturing of multiple types of flexible endoscopes is a well-established practice. Additional information can be found in the ESGE–ESGENA guideline on microbiological surveillance testing in endoscopy.[5]

Olympus utilized this protocol for the FDA-mandated duodenoscope post-market surveillance study, and the information within this article is based largely on the contents of this protocol.

At the time of publication of this article, *Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection* was available on the FDA's website to the public at no cost.

Obtaining a Quality Sample from a Flexible Endoscope

The FDA's duodenoscope sampling protocol recommends obtaining samples from two primary areas on the duodenoscope - the instrument channel and the elevator recess/distal end. For endoscopes with an elevator wire channel, a sample from that location should be collected as well.

The basic method for sampling these areas is a flush-brush-flush method. This approach has been shown to be efficient at collecting microorganisms that may remain on endoscope surfaces after reprocessing.[6] The initial flush rinses easily detachable microorganisms and soils into the sample collection container. The subsequent brushing provides a mechanical way to dislodge more difficult to detach contamination, and the final rinse flushes this dislodged material into the collection container. Brush heads are also typically collected within the same collection container as the rinse fluids.

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Aseptic Technique

For many, the most arduous component of implementing a sampling and culturing program is perfecting the sampling procedure itself. In our experience at Olympus, one of the biggest hurdles was training our sampling staff in aseptic technique. To nurses, physicians, microbiologists and other healthcare staff, aseptic technique is an ingrained habit that eventually becomes second nature. However, reprocessing technicians or other staff who may be asked to take samples from endoscopes might never have had this type of training.

Teaching good aseptic technique is not a task that can be completed in one session. Once the initial training has been completed, facilities may consider assigning a staff member with a deep understanding of aseptic and sterile techniques to observe the samplers on a regular basis and offer help and corrections. Endoscope sampling is difficult to perform with strict by-the-book sterile technique but maintaining a sterile field as best as possible will help decrease environmental contamination and increase sample quality. Samplers should gradually become proficient at the task.

Equipment and Supply Selection

Equipment, consumables and materials used in collecting samples from endoscopes should be sterile whenever possible. The use of non-sterile supplies can increase the instances of environmental contamination of samples to a notable degree. Any reusable materials should be sterilized (if compatible with sterilization) between each sampling and disposable/single-use items should be purchased pre-sterilized whenever possible. Endoscope cleaning brushes are typically required for sample collection. Contact your endoscope manufacturer for guidance on how to sterilize brushes if no appropriate pre-sterilized brushes are available.

Be cautious of items that come in pre-sterilized multipacks. For example, the FDA's sampling protocol calls for the use of sterile pipettes or sterile plastic transfer bulbs. If your facility decides to use micropipettes with sterile tips, the tips used should be sterile. The micropipette itself also needs to be kept as clean and as free of contamination as possible. These are challenges that can be mitigated by using an individually wrapped sterile plastic transfer bulb instead of a micropipette with racked tips. Though it may be more costly, consider using single-use disposable pre-sterilized or sterilizable items to reduce the risk of environmental contamination. Doing so may help save on laboratory fees from potentially unnecessary microorganism identification testing as well as help reduce the time endoscopes are in quarantine.

Personal Protective Equipment

Much like sampling supplies, the personal protective equipment (PPE) used should also be sterile when possible as the use of non-sterile PPE can increase the risk of environmental contamination. In addition to keeping individually packaged sterile gowns and sterile gloves in stock, sampling personnel must be trained on how to don such PPE. Staff may not know how to put on sterile gloves or gowns with appropriate techniques. These methods should be incorporated into initial training as well as reviewed in periodic competency checks. Bouffant caps and face/eye protection must also be worn during sampling, but it is more important for the gloves and gown to be sterile than it is for these items to be as they should not come in direct contact with the endoscope or sampling supplies.

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Sampling Environment

Sampling should be performed in an area that decreases the risk of environmental contamination while providing enough space to physically collect the sample. There should be an adequately sized surface area available so the endoscope can be laid flat while loosely coiled and the required supplies can be placed around it. This surface should be able to be easily cleaned and disinfected. The sampling space should not be in heavily trafficked location and personnel other than those involved in the sampling should be instructed to keep some distance. Placement of the sampling location directly below heating, ventilation, and air conditioning (HVAC) venting should be avoided if possible. If possible, the area should also be close to the location where endoscopes are high-level disinfected so the endoscopes can be removed from the AER or basin and taken directly to the sampling area with minimal risk for damage or contamination. Ensure endoscopes are sampled on the clean side of the reprocessing area to further minimize risk of environmental contamination.

Remember that endoscope sampling is not a strictly sterile process. When sampling larger endoscopes such as duodenoscopes, colonoscope, and gastroscopes, their length may complicate the retrieval of a sample from the instrument channel while the endoscope remains on a sterile drape or in the sterile field. The process should be kept as sterile as possible while understanding that total sterility may not be feasible.

When handling the endoscope during the sampling process, care should be taken to not contaminate the sterile gloves with outside sources. While the endoscope itself is not sterile at this point, touching of non-sterile items such as skin, wrappings from sterile items used during sampling, or other sources should be avoided. Sterile gloves that become contaminated should be replaced before resuming with the sampling procedure.

Sample Packaging and Shipping

Once the sample is collected it should be clearly labeled, packaged and shipped (if applicable) to the chosen laboratory for culturing. The laboratory should provide direction on appropriate storage and shipping methods. The sample should be transported in a nutrient broth to keep microorganisms alive until they reach the laboratory. Careful consideration should be taken when choosing an appropriate nutrient broth. Broths should support bacterial survival during transport and neutralize any potential remaining residual disinfectant. Consult with your chosen testing laboratory for recommended broth type(s).

Be aware that the laboratory may have a time threshold where the sample must be received within a certain number of hours after collection. This time limit will help determine what method of shipping is used. Some laboratories will provide shipping kits with pre-printed labels adhering to Department of Transportation requirements. If the laboratory does not offer this service, ensure samples are shipped in containers which maintain a refrigerated temperature. This is usually achieved by packing the sample container within a cooler containing ice packs. The shipping container must be labeled in such a way to adhere to local, state and national shipping regulations.

Laboratory Selection

There are options to consider when selecting a laboratory to perform sample culturing. These samples are from endoscopes and not from patients, are not used to diagnose or treat patients and are not used to certify an endoscope as sterile (a point that is sometimes misunderstood). For these reasons and because endoscope culturing is considered to be a quality indicator, these tests are not subject to Clinical Laboratory Improvement Amendments (CLIA) oversight or FDA review.[1] Any laboratory that has the appropriate expertise may be used. Facilities with access

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to on-site or in-network laboratories with microbiology experience may want to explore this option as fees, shipping costs and turnaround time may be decreased.

If no on-site laboratory is available or if the on-site lab is not capable of performing these tests, a reference or offsite lab may be the method of choice. Ensure the chosen reference laboratory has the knowledge and experience required to perform microbiological culturing. As mentioned previously, review laboratory requirements for nutrient broths and/or sample neutralizers, shipping containers, transport conditions, shipping time and any other requirements to ensure the sample arrives at the laboratory safely.

FDA's *Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection* document does include laboratory protocols. Providing this document to your laboratory of choice may help laboratory management determine if their facility can perform this type of testing as indicated. It is also a valuable resource for laboratories who have the required staff expertise to perform culturing but have not done so previously.

Understanding and Interpreting Laboratory Reports

Presence or Absence of Microorganisms

Once received by the laboratory, the sample is concentrated and placed into growth media – either on a culture plate or suspended in liquid culture broth. The samples are incubated at a specific temperature for a specific time and the presence or absence of microbiological contamination is then assessed.

If the collected sample was placed onto a culture plate, the first result a facility might receive is a colony-forming unit (CFU) count. This is a quantitative estimate of the number of viable (living and able to multiply into colonies) bacterial or fungal cells present in the sample. After incubation, a laboratory technician will remove the culture plate from the incubator and count the number of CFUs, which look like small dots, present on the growth medium. The results may be anywhere from zero CFU (absence of microorganisms) to "too numerous to count", often abbreviated as TNTC. A result of TNTC indicates the presence of so many CFUs that they were unable to be counted.

If the sample was placed into liquid growth media, the first laboratory result may be a simple "positive" or "negative" indication of the presence of microbiological growth.

If this first laboratory report indicates no presence of microorganisms in the sample with either a zero CFU or a negative culture result, no additional action is needed. Culturing has confirmed there is a low probability that potentially harmful microorganisms were present in the sample. The laboratory report should be reviewed by internal personnel with the expertise to determine if the endoscope is safe to release from quarantine, such as an infection preventionist or clinical microbiologist.

If any amount of contamination is found within the sample as indicated by a >0 CFU or positive culture result, additional testing should be performed to determine what microorganisms are present in the sample. The presence of microorganisms within the sample alone does not offer enough information to decide if the endoscope is safe or unsafe for patient use. A positive culture does not indicate the presence of harmful or clinically significant endoscope contamination – it only informs you if there are or are not microorganisms within the sample.

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Identification of Microorganisms

The number of microorganisms along with knowledge of which microorganism(s) is present are both needed to determine potential next steps. There are several methods to determine the type of microorganisms within a sample, including microbiological techniques like Gram staining and observation of defining characteristics of the culture plate growth (colony form, elevation, margin, opacity, etc.). Other possible methods include DNA-based approaches and MALDI-TOF mass spectrometry, which can generate results that are often at the species level. No matter what method of identification is used, it must be able to generate results specific enough to differentiate between organisms that are potentially harmful and those that are not.

Microorganism Identification

The number of microorganisms along with knowledge of which specific microorganism is present are both needed to determine potential next steps. Additionally, identification of organisms is required to differentiate between environmental contamination and microorganisms of clinical significance.

A microorganism identification lab report should list the names of all microorganisms that were able to be identified with some degree of confidence. Depending on the method used, this may typically consist of at least the bacterial and/or fungal genus name (i.e. *Bacillus*). If the laboratory was able to identify the specific species of microorganism, this will also be noted (i.e. *Bacillus megaterium*). In some cases, a microorganism may be unable to be identified and this will be indicated. If this occurs, it may be a good idea to consult with an internal expert such as an infectious disease physician, a clinical microbiologist, or an infection preventionist for guidance. If there are ever questions regarding laboratory report content, contact the laboratory for more information.

For the specific task of sampling duodenoscopes, the FDA has suggested grouping microorganisms found in sampling results into one of three categories: high concern, moderate concern and low concern. The FDA has assigned the following definitions to these terms:

LOW/MODERATE CONCERN ORGANISM	**Organisms that are less often associated with disease;** their presence could result from environmental contamination during sample collection. Examples of low-concern organisms include many species of Gram-positive bacteria such as Micrococcus, coagulase-negative staphylococci (*excluding Staphylococcus lugdunensis*), as well as Bacillus and diphtheroids or other Gram-positive bacilli whose presence on a duodenoscope could be attributed to environmental contamination during sampling or culturing. Moderate-concern organisms consist of those commonly found in the oral cavity (*e.g., saprophytic Neisseria, viridans group streptococci, and Moraxella species*).
HIGH CONCERN ORGANISM	**Organisms that are more often associated with disease.** Examples of high-concern organisms include Gram-negative rods (*e.g., Escherichia coli, Klebsiella pneumoniae or other Enterobacteriaceae as well as Pseudomonas aeruginosa*) Gram-positive organisms including Staphylococcus aureus, Beta-hemolytic Streptococcus, Enterococcus species, and yeasts.

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Tips, Tricks and Insights for Implementation and Management of an Endoscope Sampling and Culturing Program (Continued)

These definitions are taken directly from *Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection* and they give general guidance on which organisms could trigger remedial actions and which are of minimal concern. There is no straightforward and absolute guide that lists all species of microorganisms and into which category they fall. Each facility should work closely with their internal infection prevention & control experts when categorizing microorganisms.

Each organism found in a sample should be analyzed with endoscopic procedures in mind; for example, a bacterial species considered to be low concern for endoscopy may be highly concerning in a surgical situation. Each specific facility may also have an evolving list of high concern organisms to consider as well. For example, if there is an outbreak of a normally low concern organism in your area or facility, it may become high concern for a period.

ORGANISMS THAT MAY BE ENCOUNTERED DURING ENDOSCOPE SAMPLING & CULTURING

LOW CONCERN

Genus	Example species*	Description[7,8]	Source[7,8]
Bacillus	*licheniformis, pumilis, simplex, megaterium, circulans*	Gram-Positive Rod	Environment, Livestock
Brevibacterium	*casei, luteolum*	Gram-Positive Rod	Human Skin, Dairy Products
Corynebacterium	*tuberculostearicum, afermentans*	Gram-Positive Rod	Skin, Mucous Membranes, Environment
Micrococcus	*luteus*	Gram-Positive Cocci	Environment, Skin/Mucosa
Staphylococcus (Coagulase-Negative, excluding *S. lugdunensis*)	*epidermidis, hominis, haemolyticus*	Gram-Positive Cocci	Skin, Mucous Membranes

HIGH CONCERN

Genus	Example species*	Description[7,8]	Source[7,8]
Acinetobacter	*calcoaceticus, radioresistens*	Gram-Negative Rod	Environment, Sewage
Enterococcus	*faecalis, faecium*	Gram-Positive Cocci	Environment, Gi Tract
Escherichia	*coli*	Gram-Negative Rod	Gi Tract
Klebsiella	*pneumoniae, oxytoca*	Gram-Negative Rod	Gi Tract, Environment
Pseudomonas	*aeruginosa, stutzeri*	Gram-Negative Rod	Environment
Staphylococcus (disease-associated species)	*aureus, lugdunensis*	Gram-Positive Cocci	Skin, Mucous Membranes

*not an exhaustive list

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Determining Potential Responses Based on Laboratory Results

Appropriate next steps can be considered once the DNA identification report is back from the laboratory and your facility has determined in which FDA-guided category the microorganism(s) belong. One of the benefits of having your chosen laboratory culture endoscope samples on culture plates instead of in liquid broth is the extra information the CFU count result provides.

I have a low/moderate concern result. Now what?

When determining the next steps for low/moderate concern organisms, the CFU count should help guide if remedial action should be taken or if the endoscope can be released from quarantine.

For any DNA identification report, one or multiple microorganisms may be found. If all organisms are determined to be low/moderate concern, look back at the CFU count report for the total CFU count for all organisms combined. A low CFU count of low/moderate concern organisms may not require any additional steps: refer to the below table for more information.

I have a high concern result. Now what?

Any instance of a high concern organism within a sample requires remedial action. Even a single CFU of a high concern organism should trigger an active response.

I have a mixture of low/moderate and high concern organisms in my DNA identification report. Now what?

Any high concern result within a sample requires remedial action, even if there are low/moderate concern organisms present within the same sample. In these cases, defer to the suggested responses for the high concern organism result.

What percentage of cultures that are positive for high-concern organisms is considered “normal”?

While some regulatory bodies and professional societies recommend the implementation of an endoscope sampling and culturing program, it is not currently required by any organization or manufacturer. No national benchmarks exist that indicate what percentage of high-concern or highly contaminated results are normal or abnormal. While best practice suggests to always strive for a 0% positive culture rate, facilities should analyze their data and form internal benchmarks as this procedure is incorporated into a quality assurance program.

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Tips, Tricks and Insights for Implementation and Management of an Endoscope Sampling and Culturing Program (Continued)

SUGGESTED NEXT STEPS/REMEDIAL ACTIONS BASED ON CFU COUNT AND DNA IDENTIFICATION RESULTS

CFU Count (total)	LOW/MODERATE CONCERN ORGANISM(S)	HIGH CONCERN ORGANISM(S)
0	No action required. Release endoscope from quarantine. If required by internal policy, reprocess endoscope before returning into clinical rotation.	**No action required.** Release endoscope from quarantine. If required by internal policy, reprocess endoscope before returning into clinical rotation.
1 to 10	No action required due to low CFU count. Release endoscope from quarantine. If required by internal policy, reprocess endoscope before returning into clinical rotation.	**Action required.** Remove duodenoscope from use and consider actions such as conducting a risk/safety management response, reviewing staff reprocessing practices, reviewing sampling procedures with sampling staff, and re-training staff as needed. Consider repeating reprocessing, sampling and culturing to see if issue is resolved.
11-100	Consider actions such as reviewing staff reprocessing practices, reviewing sampling procedures with sampling staff, and re-training staff as needed. Release endoscope from quarantine. If required by internal policy, reprocess endoscope before returning into clinical rotation.	**Action required.** Remove duodenoscope from use and consider actions such as conducting a risk/safety management response, reviewing staff reprocessing practices, reviewing sampling procedures with sampling staff, and re-training staff as needed. Consider repeating reprocessing, sampling, and culturing to see if issue is resolved.
>100	**Action required.** Remove duodenoscope from use and consider actions such as conducting a risk/safety management response, reviewing staff reprocessing practices, reviewing sampling procedures with sampling staff and re-training staff as needed. Consider repeating reprocessing, sampling and culturing to see if issue is resolved.	**Action required.** Remove duodenoscope from use and consider actions such as conducting a risk/safety management response, reviewing staff reprocessing practices, reviewing sampling procedures with sampling staff and re-training staff as needed. Consider repeating reprocessing, sampling and culturing to see if issue is resolved.

Source: Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection.[1]

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Interpretation of Results from Repeated Sampling and Culturing

In cases of high concern organisms or a high microbial load of low/moderate concern organisms, a facility may decide to repeat sampling and culturing on the contaminated endoscope. If this repeated culture comes back negative, or positive but only for low/moderate concern organisms at <100CFU, then the issue could be considered resolved and the endoscope may be able to be released according to internal procedures. If the repeated culture comes back positive for high-concern organisms once more (especially the same high-concern organism that was present in the initial testing) or is again positive for low/moderate concern organisms at >100CFU, then further actions should be taken.

Repeated instances of concerning results may be an indicator of an issue such as inadequate or incorrect reprocessing practices, endoscope damage, water source contamination, or another problem. The facility should carefully consider what type of microorganism(s) is being recovered. If waterborne pathogens are being detected, the water source that supplies the reprocessing areas and AERs should be tested. Additionally, ensure the AER water filters have been replaced with the correct filter and according to the AER manufacturer's recommendations. Facilities performing high volumes of endoscopy procedures may want to consider changing AER filters on an even more frequent basis. Several contamination issues have occurred in facilities due to lapses in water quality monitoring and failure to install and/or maintain AER filters appropriately.[9-11]

If organisms found during culturing are enteric then this could be an indicator of inadequate reprocessing practices or possible endoscope damage. Ensure reprocessing and sampling procedures are being performed correctly. If no errors are observed, consider sending the endoscope for repair, and then fully reprocess and re-culture upon return. If the reoccurring organism is known to have the ability to form biofilms, then endoscope repair, replacement of parts, or other actions may need to be considered. Biofilm formation on medical devices is a subject currently undergoing intense study, and more information on how to resolve these issues will hopefully become available in the future.

Conclusion

Implementing sampling and culturing of endoscopes is a great way to boost an internal quality assurance program. However, it is a complex task that requires a great deal of forethought and understanding. The sampling procedure itself requires changes in staff training and scheduling in addition to the need for materials and supplies that may not already be available within a facility. Laboratory selection should be carefully considered in order to ensure quality and cost-effective testing is performed. Additionally, the logistics of maintaining available endoscope inventory for use in clinical procedures while sampled devices are in quarantine needs to be taken into consideration.

Consider bringing together a multidisciplinary core team to facilitate sampling activities as well as to assist in the interpretation of results. Personnel working in the reprocessing area may not have the expertise required to interpret the culture results received from the laboratory. Microbiologists, laboratory directors and/or infection preventionists should be regularly consulted when deciding if an endoscope should be released from quarantine or if remedial actions should take place.

While the challenges should be considered, the overall benefit to implementing an endoscope sampling and culturing program can be significant. The ability to detect the presence of potentially harmful contamination before an endoscope is used on a patient is only one of the advantages. Data obtained can be used to help identify incorrect reprocessing practices, uncover environmental or water source contamination, and detect potential endoscope damage. Patient safety is always the number one priority and the addition of endoscope sampling and culturing can be one part of a robust quality assurance program designed to combat preventable infections.

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References

1. FDA/CDC/ASM Working Group on Duodenoscope Culturing. Duodenoscope Surveillance Sampling & Culturing: Reducing the Risks of Infection. U.S. Food and Drug Administration, February 2018. https://www.fda.gov/media/111081/download

2. Armellino D, Cifu K, Wallace M et al. Implementation of remote video auditing with feedback and compliance for manual-cleaning protocols of endoscopic retrograde cholangiopancreatography endoscopes. Am J Infect Control. May 2018;46(5):594-596.

3. Chang WK, Liu TC, Liu TL, Peng CL, Wang HP. Enhanced manual cleaning efficacy of duodenoscope in endoscopy units: Results of a multicenter comprehensive quality control program. Am J Infect Control. Oct 2019;47(10):1233-1239.

4. Ofstead CL, Wetzler HP, Snyder AK, Horton RA. Endoscope reprocessing methods: a prospective study on the impact of human factors and automation. Gastroenterol Nurs. 2010;33:304-11.

5. Beilenhoff U et al. ESGE–ESGENA guideline for quality assurance in reprocessing: Microbiological surveillance testing in endoscopy. Endoscopy 2007; 39: 175–181.

6. Alfa MJ, Singh H, Nugent Z et al. Sterile Reverse Osmosis Water Combined with Friction Are Optimal for Channel and Lever Cavity Sample Collection of Flexible Duodenoscopes. Front Med. Nov 2017;4(191).

7. Brooks, K. Ready Reference for Microbes, 3rd edition. Association for Professionals in Infection Control and Epidemiology; 2012.

8. Holt JG, Krieg NR, Sneath PHA, Staley JT, Williams ST. Bergey's Manual of Determinative Bacteriology, 9th ed. Philadelphia, PA: Lippincott Williams & Wilkins; 2000.

9. Campos-Gutiérrez S, Ramos-Real MJ, Abreu R, Jiménez MS, Lecuona M. Pseudo-outbreak of Mycobacterium fortuitum in a hospital bronchoscopy unit. Am J Infect Control. Article in press, available online 24 December 2019.

10. Seidelman JL, Wallace RJ, Iakhiaeva E et al. Mycobacterium avium pseudo-outbreak associated with an outpatient bronchoscopy clinic: Lessons for reprocessing. Infect Control Hosp Epidemiol. Jan 2019;40(1):106-108.

11. Rosengarten D, Block C, Hidalgo-Grass C et al. Cluster of pseudoinfections with Burkholderia cepacia associated with a contaminated washer-disinfector in a bronchoscopy unit. Infect Control Hosp Epidemiol. Jul 2010;31(7):769-771 doi:10.1164/rccm.201902-0383OC.

G00016EN · 02/23 · GMA

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