healthmark

Flexible Endoscope Sampling Kit

Mary Ann Drosnock, MS, CIC, CFER, RM (NRCM), FAPIC

Background: Outbreaks of bacterial infection associated with endoscopes are often attributed to improperly reprocessed endoscopes. However, recent reports have identified carbapenem-resistant Enterobacteriaceae (CRE) transmission associated with persistently contaminated duodenoscopes for which no breaches in reprocessing were identified[1]. Endoscope manufacturers, regulatory bodies & healthcare facilities are increasingly concerned about the spread of communicable diseases, including clinically relevant microorganisms, on reprocessed medical devices. Since it is well-known that flexible endoscopes are challenging to clean and disinfect or sterilize, Healthmark Industries & Nelson Laboratories have partnered to create an endoscope sampling kit for the purpose of monitoring and reporting objective results from clinical scopes.

The Endoscope Sampling Kit is intended to be used as a proficiency assessment for healthcare practices and not as a safety assessment for the reprocessed scope (not a "fitness for use" test). This surveillance assessment is important to help the clinical user determine if their scope is safe for use, requires additional reprocessing, requires additional testing or should be quarantined. As such, the kit is intended as another process to assess the adequacy of healthcare facility endoscope reprocessing. Although there are no requirements for endoscope sampling at this time, current standards and guidelines such as AAMI ST91, SGNA and AORN do discuss the value of conducting endoscope sampling as a means to identify reprocessing issues for endoscopes and as a feedback mechanism to determine if there is a robust system in place. Endoscopes sampling has been successful at identifying quality issues in facilities.[2,3,4]

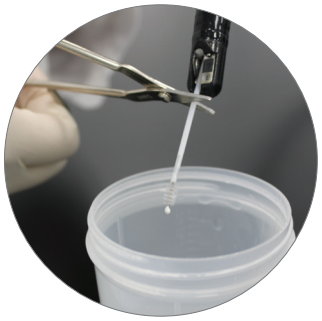
Process: Ideally, according to the FDA/CDC/ASM method, the endoscope sample should be obtained after the scope has been reprocessed and dried. A sample should at least be taken from the instrument channel and the forceps elevator/distal end of the scope (if applicable). The sample is then shipped to Nelson Labs for independent testing of the sample for the presence of any microorganisms. If present, the organisms will be quantified and up to 2 organisms will be identified. Additional identifications, if necessary, can be conducted for additional purchase. All items necessary to collect & send a sample from a reprocessed endoscope are provided in the kit with the exception of PPE and sterile water. The Flexible Endoscope Sampling Kit is offered with either the 3.7mm diameter brush (for extraction of samples from the instrument channel of most duodenoscopes) that comes with the CK-374 or the 2.5mm diameter brush (for extraction of samples from smaller diameter duodenoscopes) that comes with the CK-250. Other kit configurations are available for different types of endoscopes.

A sampling protocol based on the FDA/CDC/ASM Sampling and Culture Method is included with the kit. The sample taken from the instrument/suction channel is obtained by a Flush-Brush-Flush method where sterile water is flushed through the channel, which is then brushed and flushed again with sterile water. The effluent is collected into a sterile container to which D/E Neutralizing Fluid is added. Additionally, a sample of the elevator recesses is taken, if applicable.[5] The FDA protocol advises a 72-hour incubation period.

Validation: According to the FDA method, since the surveillance sampling and culturing protocols are intended to monitor that the facility-specific procedures for reprocessing duodenoscopes render the devices properly reprocessed, and not that a particular duodenoscope is free of microbes, and because samples from duodenoscopes are not clinical specimens from patients and are not used for diagnostic purposes, it is not necessary for healthcare facilities to validate that they can successfully carry out the protocols and meet pre-determined acceptance criteria. While the current instructions apply primarily for duodenoscopes, they can also be implemented for other flexible endoscopes such as ultrasound scopes and bronchoscopes.[1]

Results interpretation: The FDA states that a negative culture does not completely exclude the possibility of a contaminated duodenoscope. However, positive culture results should lead to some action as described below.[1] Any endoscope found to be contaminated with any level of high-concern organisms or unacceptable level of low-concern organisms should be reprocessed again with repeat post-reprocessing cultures obtained. The endoscope should not be used again until it has been demonstrated to be free of high-concern organisms and has an acceptable level of low-concern organisms.

Discussion: According to the CDC, a negative culture does not completely exclude the possibility of a contaminated duodenoscope. However, positive culture results should lead to some action as described below.[1] Any endoscope found to be contaminated with any level of high-concern organisms or unacceptable level of low-concern organisms should be reprocessed again with repeat post-reprocessing cultures obtained. The endoscope should not be used again until it has been demonstrated to be free of high-concern organisms and has an acceptable level of low-concern organisms.



Instrument Channel Brush

Distal Tip Brush

Sample Collection Container

Shipment to Nelson Labs

References:
1: FDA Duodenoscope Sampling and Culture Method, Feb 2018, Accessed 7/30/18. https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ReprocessingofReusableMedicalDevices/UCM597949.pdf
2: ANSI/AAMI ST91:2015; Flexible and semi-rigid endoscope processing in health care facilities.
3: SGNA Standards of Infection Prevention in Reprocessing of Flexible Gastrointestinal Endoscopes, 2016. Accessed 6/5/17. http://www.sgna.org/Portals/0/Standards%20for%20reprocessing%20endoscopes_FINAL.pdf
4: AORN. Guideline for Processing Flexible Endoscopes. Guidelines for Perioperative Practice. February 2016.
5: Flexible Endoscope Sampling Kit IFU. Accessed 6/5/17. http://www.healthmark.info/CleaningVerification/SamplingKit/Flexible_Endoscope_Sampling_Kit_IFU_2016-07-13.pdf

NELSON LABORATORIES