Rapid Bacteria | Fungi Swab Test for Medical Devices

Introduction

Medical devices can improve the quality and even extend a patient's life. Continuous microbiological testing during manufacturing is crucial to ensure consistent, reliable product quality and more importantly, patient safety. Methods and solutions to determine the microbial load on all or part of your medical device's surface, are of high relevance in the medical device industry.

We provide a rapid solution for Bacteria | Fungi testing. Our Microsart® ATMP Bacteria and ATMP Fungi PCR kits are highly sensitive in detecting bacterial and fungal contaminants. One option to determine the microbial contamination level on the surface of medical devices is taking samples with the help of medical swabs. But the majority of commercially available medical swabs would cause positive signals in universal bacterial PCR reactions, especially if a sterilization method other than ETO gassing was used to sterilize the swab. In contrast to fungal DNA, bacterial DNA is ubiquitous and hard to eliminate completely, because even minor residuals of bacterial DNA can cause positive signals in a broad range bacterial PCR assay.

In this study the following question was addressed: Are sterile medical swabs completely free of detectable bacterial DNA and can be used in combination with the Microsart® ATMP Bacteria kit? Three ETO-sterilized medical swabs were identified to be suitable for this application and can be considered to be free of bacterial DNA.

Experimental Set Up

All experimental steps were carried out in a biosafety cabinet. ETO-sterilized medical swabs (Table 1) were unpacked and rinsed in 1 mL of UltraPure™ water (Invitrogen,No. 10977-035) already prepared in microbial DNA-free 1.5 mL tubes (Sarstedt, No. 72.706.200) for three minutes including rotating each swab every minute multiple times. All swab types were processed in triplicates. The washing water of each swab was tested for the presence of bacterial DNA using the Microsart® ATMP Bacteria kit (Sartorius, No. SMB95-1008) according to the instructions for use. Each replicate was measured in duplicates in the PCR assay. The PCR run was performed using a QuantStudio™ 5 PCR cycler (Thermo Fisher).

Table 1: *Specifications of Swabs Used for Microsart® ATMP Bacteria Compatibility Test*

Swab	Supplier	Product number	LOT	Description
Forensic Swab L	Sarstedt	80.630	3053321	Forensic swab, round, in the tube with ventilation membrane, ISO 18385, 85 mm, viscose, single pack
Sterile Medical Swabs	Boettger	09-119-9100	(10)1220	Wood, 2.3/150 mm, Ø 4 – 5.5 mm, single peel pack
PurFlock Ultra 6" Sterile DNA-Free Standard Flock Swab	Puritan	25-3306-U TT FDNA	8919	DNA-Free Regular Tip Applicator with Polystyrene Handle in Transport Tube, Ø 5.08 mm, 153.4 mm

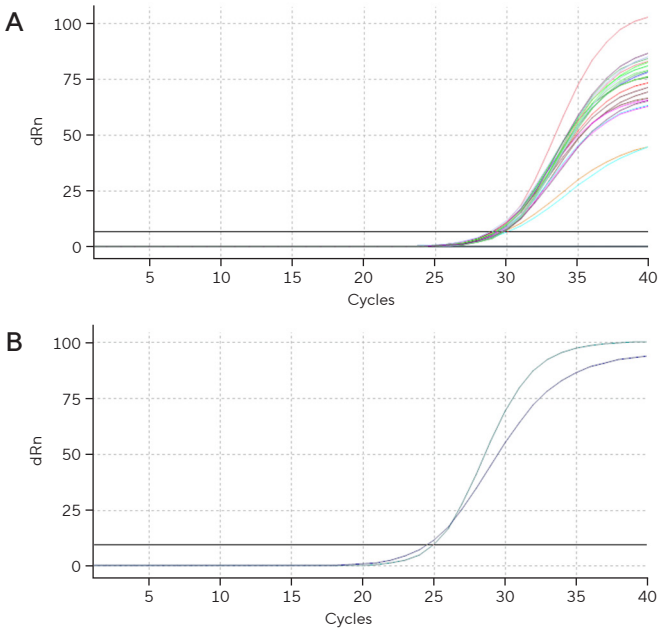
Results

None of the tested ETO-sterilized medical swabs revealed a signal for the bacterial target (FAM™ channel). This in return means that the swabs are free from bacterial contaminants or DNA, enabling reliably tracing of potential positive signals back to contamination of the medical device and not to the swabs themselves. Additionally, no PCR inhibition was observed since all samples showed a good amplification of the Internal Control (ROX™ channel Figure 1A). The Positive Control reactions were functional, and all tested medical swabs did not generate any positive signal in the FAM™ channel (Figure 1B), thus the tests are considered as valid. Concrete Ct values are listed in Table 2.

Table 2: *Generated CT Values for FAM™ and ROX™ Channel of Medical Swabs Rinsed in PCR-Grade Water and Measured Using the Microsart® ATMP Bacteria Kit*

	Replicate	Ct_{FAM}	Ct_{ROX}
Sarstedt	1	No Ct	29.4
	2	No Ct	29.8
	3	No Ct	29.7
Boettger	1	No Ct	29.1
	2	No Ct	29.8
	3	No Ct	29.4
Puritan	1	No Ct	29.3
	2	No Ct	29.3
	3	No Ct	29.6
Positive Control	1	25.1	28.7
	2	24.6	29.4

Figure 1: *Amplification Curves of Medical Swabs Rinsed in PCR-Grade Water as well as Curves for PCR Positive Control Reactions; A) Amplification Curves ROX™ Channel (Internal Control Amplification), B) Amplification Curve FAM™ Channel (Target Amplification)*



Conclusion

All three ETO-sterilized medical swab types which have been tested in this study are suitable to swab medical devices and subsequently perform a PCR-based microbial contamination test with Sartorius´ Microsart® ATMP Bacteria and ATMP Fungi kits. None of the medical swabs tested show a risk of production-related contamination by bacteria or respective DNA.

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