MICROBIAL INTEGRITY
OF FLOWLINX™ SAMPLING SYSTEMS

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STERILE SAMPLING

FlowLinX™ sampling needle assemblies are used to take non-intrusive sterile samples in biopharmaceutical processes, such as cell culture, fermentation, chromatography, and sterile bulk and transfer.

Upon setup for use, the sampling needle assembly does not require sterilization of the sample line for each sample taken. FlowLinX™ sampling needle assemblies can be integrated into a 5-port sampling device for use on various types of reactors and equipment. Available in 1 mm and 2 mm sampling assemblies, the needles are depressed to penetrate a septum into the process stream so that samples can be obtained within a collection container, such as a bag, tube or bottle. Each sampling line can be aseptically crimped for removal of the collection container. FlowLinX™ sampling needle assemblies allow for sterile sampling and aseptic removal up to 5 samples per device.

5-PORT SAMPLING NEEDLE HOLDER
1MM AND 2MM SAMPLING NEEDLES

SAMPLING NEEDLE ASSEMBLY

Sterility Study

A study was conducted using FlowLinX™ sampling needle assemblies and holders to evaluate the performance in maintaining sterility of the sampling process.

A sterile 5-port sampling device, sterile 2 mm sampling needle assemblies and sterile media, BHI broth, were used to conduct the study. To ensure sterility was maintained during the sampling process, the sterile media was added to the sampling device assembly prior to attachment of the 2 mm sampling needle assemblies and collection of samples. The sampling device assembly was incubated at 37°C prior to the removal of samples to ensure a sterile starting environment. The sampling device assembly showed no signs of microbial growth after incubation for 24 hours at 37°C. Additionally, a sample of the sterile media was spiked with *Staphylococcus aureus* to confirm its ability to promote microbial growth. The spiked media sample showed clear signs of microbial growth within 24 hours after incubation at 37°C. Upon confirmation of a sterile starting environment, 2 mm sampling needle assemblies were loaded into the sampling device assembly under a laminar flow hood. A 2 mm sampling needle assembly was actuated, which caused the needle to penetrate through the septum into the fluid path. The liquid media was collected into the 50mL bag of the 2 mm sampling needle assembly and the bag was aseptically disconnected from the sampling line using a pinch pipe and disconnection tool. This process was completed for a total of 10 sample bags. The sample bags were then incubated at 37°C for 72 hours and monitored for microbial growth and turbidity in the media.

No growth was observed in any of the sample bags after incubation at 37°C for 72 hours. All media remained clear and free of turbidity.

Study Conclusions

Results of the study demonstrate the capability of the FlowLinX™ sampling needle assembly and device to take non-intrusive sterile samples. Organizations can successfully implement FlowLinX™ sampling needle assemblies and maintain microbial integrity for their aseptic sampling needs.

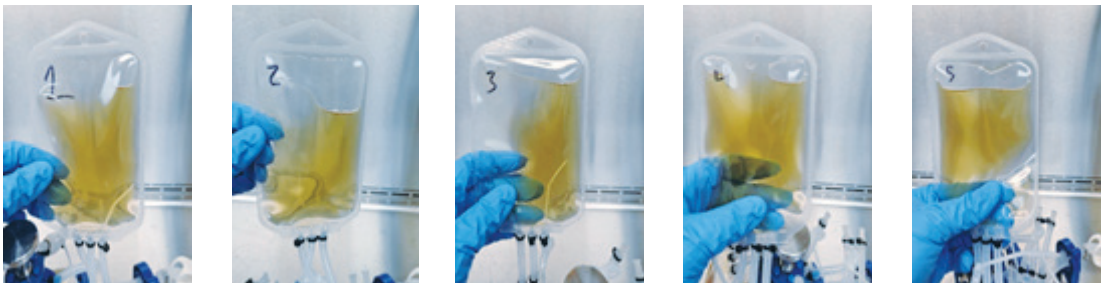

FIGURE 1: SAMPLE BAGS CONTAIN CLEAR NON-TURBID MEDIA AFTER INCUBATION AT 37°C FOR 72 HOURS

Testing was performed by bioX LLC (bioxeng.com) at their Bioprocess Applications Testing Laboratory in Salem, NH. bioX is an independent third-party specializing in single use materials and equipment testing intended for use in the cGMP Manufacturing. All data was generated under controlled laboratory conditions in compliance with a quality management system utilizing NIST traceable measurement devices and standards.