

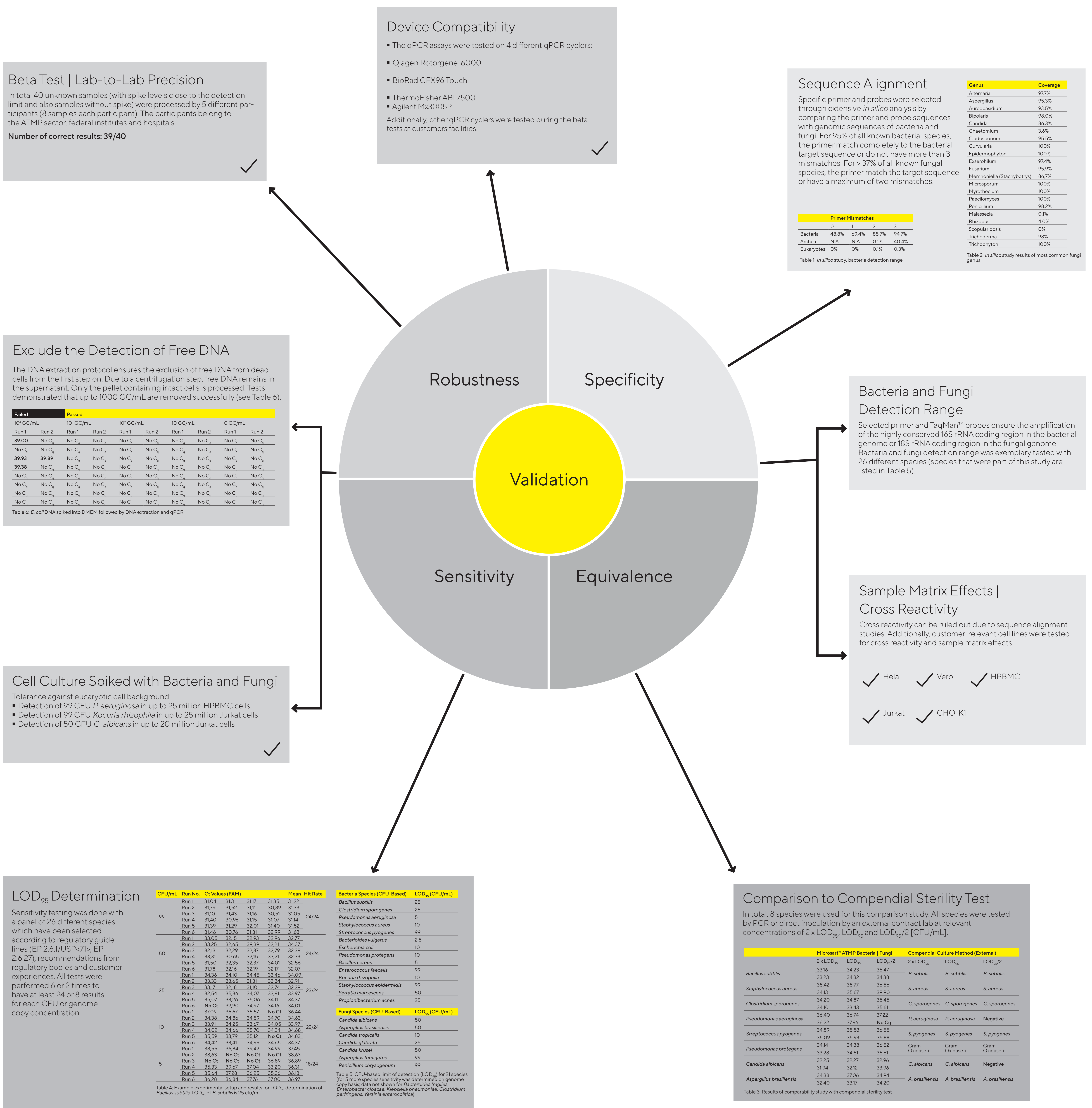
# First Final Release Test of ATMPs Prior to Treatment Validation of a qPCR-Based Rapid Sterility Test

Dr. Alexandra Mueller-Scholz<sup>1</sup>, Dr. Diana Patzelt<sup>1</sup>, Dr. Kai Neemann<sup>2</sup>  
<sup>1</sup> Research and Development Department, Sartorius Stedim Biotech, Göttingen, Germany  
<sup>2</sup> Department Microbiology, Sartorius Lab Instruments, Göttingen, Germany  
 Correspondence Email: PCR@Sartorius.com

Sterility is a critical quality attribute (CQA) of cellular therapeutics. Since microbial contamination of cell therapy products can potentially result in the deaths of the recipients, sterility testing is a critical component of the release testing for any cell therapy product. The current compendial sterility test takes 14 days before contamination can be ruled out with certainty, which is too long for short shelf-life cellular therapeutics and especially for autologous cell therapies intended to treat terminally ill patients. As a result, there is an increasing demand for growth-independent rapid assays. Therefore, a detection system consisting of the highly efficient DNA extraction protocol Microsart® ATMP Extraction followed by the real time PCR assay Microsart® ATMP Bacteria | Fungi (or the combination product Microsart® ATMP Sterile Release) has been developed. A validation study was designed to evaluate the bacterial and fungal detection capability. The study was set up to fulfill the European Pharmacopeia chapter 5.1.6 and the USP chapter <122> as well as the guidance chapter USP <107>.

## Summary and Outlook

The described procedures and results give a good impression of the complexity of the assay validation required for a presence | absence test for bacteria and fungi as sterility test for cellular therapeutics. This enables the detection of such contaminants in cellular therapies with short shelf lives, and especially autologous cell therapies urgently needed for administration to terminally ill patients.



Correspondence Email: PCR@Sartorius.com