International Alliance for Biological Standardization

4th Conference on Next Generation Sequencing for Adventitious Virus Detection in Biologics for Humans and Animal

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Transcriptomic NGS assay of cells as a substitute for conventional virus testing techniques

Testing for viruses in cells employed in cell therapy and biomanufacturing is detailed in various monographs and guidelines. Traditionally, this involves the use of PCR techniques to detect human viruses, animal tests such as HAP, MAP, and RAP tests for rodent cells, in vitro assays in a variety of indicator cell lines, and immunofluorescence techniques (9CFR) for bovine or porcine cells or using raw materials from these species.
We will show how an NGS transcriptomic analysis of cells can effectively replace these conventional methods, supported by data showcasing its sensitivity, capacity to detect viral replication signatures, and broad detection range. We will also explore additional applications, such as bulk testing when cells are readily available, and in cell therapy, where its ability to distinguish between latent herpes viruses and replicating viruses provides a significant advantage.