Stable cell line for validating next-generation sequencing (NGS) methods for detecting adventitious viruses contaminating biological products

Technology Summary

There is a need to ensure that cells used for the manufacturing of biological products such as viral vaccines, cellular and gene therapy products, and biotherapeutics are free of adventitious viruses. Next-generation sequencing (NGS) methods can be used to determine the presence of adventitious viruses when selecting cells for manufacturing biological products or for use in cellular therapies. A stable human cell line latently infected with a retrovirus has been developed to validate the sensitivity of these NGS methods.

The cell line consists of human A549 cells latently infected with simian foamy virus strain K3T (designated as SFVmmu_K3T). The cells have been well-characterized to demonstrate stable latent infection using molecular and biological assays. The mutation of the viral genome resulting in lack of virus production has been identified. The chromosomal location of the latent viral DNA in the host genome has been determined, and the complete sequence of the viral genome has been published (doi: 10.1128/genomeA.00827-17). The copy number of the viral DNA in the cells has been determined.

Potential Commercial Applications

- Reference standard for validating the sensitivity of next-generation sequencing (NGS) technologies
- Validation of other (non-NGS) assay for adventitious viruses in cells

Competitive Advantages

- Accurate and stable virus genome copy number allows for quantification of NGS viral detection in cell spiking studies
- No virus production required for use in a routine cell culture environment
- Cell line's latent viral genome is well-characterized

Development Stage: Cells are available

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Intellectual Property: Biological material; No patent applications were filed for this technology

Product Area: Biologics testing and manufacturing including but not limited to viral vaccines, biotherapeutics, and cellular and gene therapy products

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