

RETROVIRAL ASSAY SERVICES

Regulatory guidance advises the use of reverse transcriptase activity as a marker for the detection of extracellular retrovirus particles and the presence of retrovirus contamination. These reverse transcriptase (RT) assays (also described in the literature as Amp-RT, PBRT and PERT) detect the conversion of RNA template to cDNA (due to the presence of RT enzyme when retroviruses are present in the test sample). The development of these RT-dependent assays led to the requirement for QF-PERT testing on cell banks and/or viral vaccine products originating from mammalian & avian cell substrates (Lovatt et al., 1999).

QF-PERT, CO-CULTIVATION AND CELL SUBSTRATE INDUCTION ASSAYS

Retrovirus testing using QF-PERT assays should be performed on cell-free culture medium to detect retroviruses. QF-PERT assays can detect all infectious retroviruses since they encode and contain a functional RT enzyme. The material that is tested includes, cell substrates, viral seeds, and/or harvests of all viral vaccines produced in mammalian cell substrates. SGS's QF-PERT assays are highly sensitive since they include sample concentration and cellular DNA polymerase suppressant. This, together with an additional ultracentrifugation step for the concentration of retroviral particles, ensures specific detection of retroviral RT activity, and that optimal conditions are used for each test sample.

Co-cultivation or infectivity tests may also be augmented with sensitive QF-PERT assays. Under some circumstances, it may be appropriate to pre-treat cells with chemical agents known to induce reactivation or replication of endogenous or latent viruses.

Subsequent co-cultivation or transmissibility assays with cells susceptible to a wide range of retroviruses, combined with the QF-PERT and Transmission Electron Microscopy (TEM) systems are used to confirm the absence of detectable virus (e.g. co-cultivation with HEK 293 cells, followed by TEM and QF-PERT to detect latent retroviruses capable of infecting human cells).

SGS offers a wide range of adventitious agent tests, including co-cultivation, infectivity and QF-PERT assays, in combination with multiple detector cell lines, Q-PCR virus detection packages, etc.

QF-PERT ASSAYS	EQUIPMENT & LABORATORIES
<ul style="list-style-type: none">• SP-M.8001 Quantitative (Q-PERT)• SP-M.8002 Qualitative (F-PERT)• SP-V.2100 Co-cultivation HEK293	<ul style="list-style-type: none">• IQ, OQ, PQ• Dedicated PERT laboratories• Validated ABI 7900HT machines• Biosafety Level 2 cabinets• Dedicated culture facilities• TEM laboratories and expertise

ABOUT SGS

Part of the SGS Group, SGS Life Science Services is a leading contract service organization providing analytical development, biologics characterization, biosafety, quality control testing and clinical research. Operating 25 facilities in 13 countries across Europe, the Americas and Asia, with 1,600 employees, SGS represents the world's largest, state-of-the-art network of GMP compliant laboratories.

SGS provides a comprehensive range of biosafety services such as: virology, cell and molecular biology as well as microbiology and electron microscopy. Health Authorities, including the US FDA and the EMA, require companies to undergo safety testing to demonstrate that all cell banks, viral banks, raw materials of animal origin, bulk harvests, and batches of clinical drug are free of bacteria, fungi, mycoplasma, viruses and other potential contaminants. SGS helps clients by ensuring product safety in satisfying these regulatory requirements through a large range of validated assays and develops new services in the following areas:

- Cell bank and virus seeds characterization per the major compendia, regulatory and ICH guidelines
- Raw material and bulk harvest testing (sterility, mycoplasma, viruses and other potential biological contaminants)
- Final product testing for residual DNA and other process related impurities
- Regulatory and safety consultancy services
- Custom development of assays

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