



PORCINE CIRCOVIRUS (PCV) TESTING BY qPCR

In 2010, a press release from the US FDA reported the presence of Porcine circovirus DNA in the products of major biopharmaceutical companies. At least one vaccine maker confirmed its presence in both the cell bank and the virus seed from which the vaccine is derived, suggesting its presence from the early stages of vaccine development.

PCV is a non-enveloped, single-stranded DNA virus with a non-segmented circular genome. The viral capsid is icosahedral and approximately 17 nm in diameter. It is robust and difficult to remove or inactivate by physico-chemical means, including gamma irradiation.

Studies have shown that human and primate cell lines can be infected with Porcine circovirus type 1 (PCV-1) and Porcine circovirus type 2 (PCV-2). Infected by PCV-1 was observed with Vero, HEK 293 and Hela cells. While PCV-1 can persist in cell lines without causing any visible changes, while PCV-2 transfected cells can show a cytopathogenic effect. PCV contamination could possibly occur from the use of porcine trypsin in a cell line's history. Since most cell lines have been exposed to this reagent, the screening of all such cell substrates used for manufacture of clinical material is recommended.

GLP/cGMP COMPLIANT qPCR ASSAYS

To assist biotech companies in ensuring the absence of PCV-1 and PCV-2, SGS's team of qPCR experts offer a highly sensitive, fully validated, cGMP compliant, routine nucleic acid-based test with proven ability for detecting PCV-1, PCV-2 and Bovine circovirus in biological samples to a sensitivity of fewer than 30 copies of PCV genomes per μg of cell line DNA.

SGS provides an extensive range of qPCR testing services, including assay development, validation and assay transfer to client GMP facilities, to meet your preclinical and clinical requirements. All qPCR assays are performed according to cGMP compliance and are validated to ICHQ2 guidelines on ABI 7900HT instruments using TaqMan technology, in accordance with criteria required for maintaining 21CFR part 11 compliance.

OTHER GLP/CGMP COMPLIANT qPCR ASSAYS	RETROVIRAL PERT ASSAYS	EQUIPMENT & LABORATORIES
<ul style="list-style-type: none">• Mycobacterium• Insect and Avian viruses• Murine and Human viruses• Porcine and Bovine viruses (incl. 9CFR)	<ul style="list-style-type: none">• Qualitative (F-PERT)• Quantitative (Q-PERT)	<ul style="list-style-type: none">• IQ, OQ & PQ• Validated ABI 7900HT Systems• Test Item and Material Segregation• Client Cell Culture Laboratories• Segregated Virus Culture

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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