

AGE1.CR.pIX® - The Vaccine ProDUCKtion Platform

AGE1.CR.pIX®: Avian Cell Line Platform for Industrial Viral Vaccine Manufacturing

AGE1.CR.pIX® is a continuous cell line derived from primary cells of a Muscovy duck embryo. The cell line was created as a universal platform to replace primary chicken cells for the industrial production of a broad range of virus-based vaccines. As opposed to chicken cells, the AGE1.CR.pIX® cells are free of active endogenous retroviruses in highly sensitive assays against these adventitious agents.

The AGE1.CR.pIX® cell line is designed to meet health regulatory guidelines and the 'defined risk' concept. Immortalization is achieved by the expression of E1 genes from human adenovirus type 5 as a pharmaceutically safe and well characterized approach. AGE1.CR.pIX® was generated in a dedicated clean room suite. A complete documentation describes the source and isolation of primary cells, the passage history and all raw materials used in the generation the AGE1.CR.pIX. Master Cell Banks of the cell line have been demonstrated not to harbor adventitious agents in an exhaustive spectrum of assays.

The AGE1.CR.pIX® cells proliferate in suspension in commercially available, chemically defined medium free of animal-derived components. The formulation of the medium was developed by ProBioGen and is therefore not locked-in to a single specific manufacturer or geographic region. Robust AGE1.CR.pIX® upstream processes include cell growth shake flasks, WAVE and stirred-tank bioreactors (including continuous cultivation by perfusion).

An additional feature of the AGE1.CR.pIX® cells is their ability to be excellent hosts for the generation of trans-complementing helper or packaging cell lines to support efficient production of replication-restricted viral vectors.

The cell line is licensed to a number of international clients. First vaccine produced in AGE1.CR.pIX is on the market since 2014.

Properties of ProBioGen's AGE1.CR.pIX® cell line:

- Fully-documented and free of adventitious agents including active endogenous retroviruses
- Robust and fully-scalable proliferation in suspension in different bioreactor systems in chemically defined medium
- Highly susceptible to a range of viruses, such as pox-, adeno-, orthomyxo-, rhabdo-, paramyxo- and togaviruses
- Readily transferrable for flexible, local GMP manufacturing with small footprint
- Cost-saving over manufacturing in CEFs

For references see next page

Literature:

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