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HEK-293/T Cell Bank Testing

HEK-293/HEK-293T (human embryonic kidney) cell lines are frequently used in the biopharmaceutical industry to manufacture viral vectors supporting cell and gene therapy modalities. To support the clinical advancement of these new therapeutics, the HEK cells used for vector production must undergo a formal GMP cell banking program, including production of Master and Working Cell banks and the appropriate panel of GMP release testing.

The regulatory expectations and guidance for characterization testing of cell banks are outlined in various documents from the FDA, EMA, WHO, and ICH. Eurofins BioPharma Product Testing's recommendations for cell line characterization, safety evaluation, and product testing for a HEK derived biopharmaceutical product are summarized in this document. It outlines a testing strategy that should satisfy the latest guidance of global regulatory authorities, including the FDA and EMA.

Like other cell lines, HEK cells are susceptible to a wide variety of contaminants, including microbial, fungal, mycoplasma, and viral adventitious agents (including species specific human viruses). Eurofins BioPharma Product Testing's network of laboratories has validated the methods required to meet domestic and international regulatory requirements to release and characterize the cell banks used for viral vector manufacturing.

Why Choose Eurofins BioPharma Product Testing?

We offer capabilities to prepare and characterize a wide variety of mammalian, insect, and avian cell banks, including master, working, research, bioassay, and ready-to-use cell banks.

Our cGMP-compliant facilities include multiple Grade A/B suites with Animal Origin Free options and ISO 7 clean rooms with ISO 5 critical areas designed to meet current FDA/EMA aseptic processing guidelines.

We also offer a comprehensive package of safety testing services in the areas of microbiology, mycoplasma, genetic stability, viral safety, and biochemistry to support your cell banking needs. All of these services are provided with strict adherence to cGMP requirements and are designed to fully support biopharmaceutical products, including the testing of raw materials, cell lines, unprocessed bulk, purified bulk, and final product.

HEK-293/T Cell Line Characterization

Test Method	MCB	WCB	US Test Code	TAT	US Sample Requirement
Cell Expansion*	X	X	QL4WS	Varies	2 Vials
Sterility Suitability B&F	X		QL1C2	25 Days	7 Vials
Sterility	X	X	QL23J	25 Days	1% of Cell Bank (Rounded to next whole number)
Mycoplasmastasis	X		GPMYK, GPMYL	35 Days	2x25mL, 4x1.5mL > 1x10e^6 cells/mL
Mycoplasma Analysis	X	X	GPMYM, GPMYN	35 Days	2x12mL, 2x1.5mL > 1x10e^6 cells/mL
Identity via CO1	X	X	QL0CJ	14 Days	2x10e^7 cells
in vitro Adventitious Agent - MRC-5	X	X	QL07V	35 Days	7mL at 1x10e^7 cells/mL
in vitro Adventitious Agent - Vero	X	X	QL07W	35 Days	7mL at 1x10e^7 cells/mL
in vitro Adventitious Agent - HEK-293	X	X	QL09X	35 Days	7mL at 1x10e^7 cells/mL
in vivo Inapparent Viruses	X		QL07Z	56 Days	51mL Cell Lysate 1 x10e^7 cells/mL
Bovine 9CFR	X		QL089	35 Days	8mL Cell Lysate at 1x10e^7 cells/mL
Porcine 9CFR	X		QL0B6	35 Days	10mL Cell Lysate at 1x10e^7 cells/mL
"Human PCR Panel HIV I/II, HAV, HBV, HCV, HTLV I/II, EBV, CMV, HHV 6/7/8, HPV 16/18, & B19"	X		QL0FL QL0FR QL0EE QL0EF QL0FY QL0FZ QL0G1 QL0G5 QL0G7 QL0G9 QL0GC QL0GE QL0GG QL0GI	28 Days	5x10e^6 Cell Pellet
TEM	X		QL4YU	40 Days	Fixed Pellet, at least 2x10e^7 cells
F-PERT**	X		QL0BV	14 Days	2x5 mL Supernatant, 2x5 mL of fresh media (if available)
Mycobacterium PCR	X		QL4YE	10 Days	2x2mL (1x10e^7 cells if available)

*Eurofins will expand the cells to perform all of the test methods with the exception of sterility. Sterility should be performed on vials directly from the cell bank.
**If this test is positive, co-cultivation test methods will need to be performed to assess potential for retrovirus contamination.

Contact Us

North America: BioPharmaProductTesting@BPT.EurofinsUS.com
Europe: Information@BPT.EurofinsEU.com
APAC: easl.cserv@BPJP.EurofinsAsia.com
www.Eurofins.com/BPT