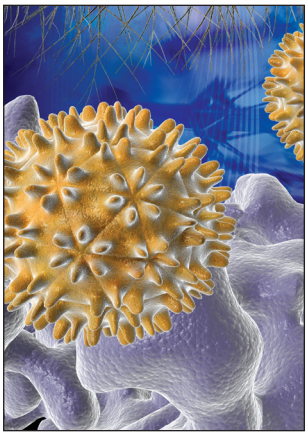
BioReliance

Biologics Safety Testing Services

Pinnacle Q-PCR™ Human Virus Panel I



Safety Testing For Human-derived Cells Used In Manufacturing Processes

Biotechnology products ("biologicals") manufactured in eukaryotic cell lines carry the risk of viral contamination by endogenous viruses or from viruses introduced during manufacturing processes. Quite often, raw materials (including cell substrates) can be the route through which viruses of known (or unknown) origin are inadvertently introduced in to a manufacturing system. Regulatory authorities therefore recommend that both biological therapeutics (e.g. proteins, monoclonal antibodies, vaccines, etc.) and the raw materials used during manufacturing of them undergo rigorous safety testing prior to release. These concerns are heightened when the cell substrate to be used during manufacturing is of human origin (e.g. HEK293). Human cells should be tested for the presence of known pathogens prior to being used in a manufacturing process or when developed as a stand-alone therapeutic product.

Pinnacle Q-PCR™ - An Advanced Platform for Testing Biologic Product Safety

BioReliance has been testing biological product safety using polymerase chain reaction (PCR) based methods for over a decade. In fact, we pioneered of the use of quantitative (or qualitative) PCR base nucleic acid detection methods in biosafety testing. Our next innovation in nucleic acid testing – Pinnacle Q-PCR™ is now available.

Pinnacle Q-PCR™ combines the precision and reproducibility of automation with the sensitivity and accuracy of advanced assay design (including bioinformatics and reagent optimization) to offer a superior service for testing your critical biological product. All virus targets are extensively analyzed to ensure that the amplification primer design incorporates the broadest genomic sequence coverage while maintaining a high signal-to-noise ratio. Pinnacle Q-PCR™ assays also incorporate automated nucleic acid extraction and assay set-up methods. Finally, Pinnacle Q-PCR™ assays include all necessary internal controls to ensure a valid test result. When combined, these features make Pinnacle Q-PCR™ assays exquisitely sensitive and robust.

The Pinnacle Q-PCR™ Human Panel Tests for 14 Known Viral Pathogens

The Human Panel I includes 14 assays for the detection of viral nucleic acids in a test sample using real-time PCR (Q-PCR) technology. Of the 14 assays, 11 assays target detection of viral DNA (HSV 1/2, B19, EBV, SV40, HHV5 (CMV), HHV6, HHV7, HHV8, HBV) or proviral DNA (HIV-I and HIV-II) and 3 assays target detection of viral RNA (HTLV 1/2, HCV, HAV). Individual virus assays using Pinnacle Q-PCR™ technology are also available.

Semi-automated, GMP compliant qualitative real-time PCR assay

Engineered to provide the highest sensitivity and reproducibility for all 14 viruses detected

Provides assurance of a human-derived cell line's suitability for manufacturing

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The following table details both the genomic coverage and sensitivity of each assay:

Virus Target	Assay Coverage of Known Genomes	Assay Limit of Detection
HSV 1/2 (Herpes Simplex Virus Type 1 & 2)	100%	10 copies
B19 (Parvovirus B19)	100%	10 copies
EBV (Epstein-Barr Virus)	100%	10 copies
SV40 (Simian Virus 40)	94.4%	10 copies
hCMV / hHV5 (Human Cytomegalovirus / Human Herpes Type 5)	85.8%	10 copies
hHV6 (Human Herpesvirus Type 6)	100%	10 copies
hHV7 (Human Herpesvirus Type 7)	100%	20 copies
hHV8 (Human Herpesvirus Type 8)	100%	20 copies
HTLV 1/2 (Human T-Cell Leukemia Viruses Type 1 & 2)	100%	10 copies
HCV (Hepatitis C Virus)	93.7%	10 copies
hHAV (Human Hepatitis A Virus)	70%	10 copies
HBV (Hepatitis B Virus)	79.8%	100 copies
HIV-I (Human Immunodeficiency Virus Type 1)	82.7%	100 copies
HIV-II (Human Immunodeficiency Virus Type 2)	74.1%	100 copies

Ordering Information

Assay Number	Assay Description	Regulatory Compliance	Sample Requirements
300100GMP.BSV	Pinnacle Q-PCR™ Human Virus Panel I Assays for detection of 14 Viral Nucleic Acids ("Human Panel I")	GMP	Cell pellets – Qty. six (6) of 1 x 10^7 cells (per mL if in suspension)
300100AGMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of 12 Viral Nucleic Acids (Human Panel, excluding HSVI/II And SV40)	GMP	Cell based samples: 2-3 vials of 2 x 10^7 cells per vial (3 vials for >5 DNA assays) Non-cell based samples: 2-3 vials of 0.5 mL per vial
300101GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of HSV 1/2	GMP	
300102GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of B19	GMP	
300103GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of EBV	GMP	
300104GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of SV40	GMP	
300105GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of hHV5/HCMV	GMP	
300106GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of hHV6	GMP	
300107GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of hHV7	GMP	
300108GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of hHV8	GMP	
300109GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of HIV-I	GMP	
300110GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of HIV-II	GMP	
300111GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of HBV	GMP	
300115GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of HIV-I/II	GMP	
300112GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of HCV	GMP	Cell based samples only: 2-3 vials of 1 x 10^7 cells per vial. (3 vials are needed when 3 RNA assays are ordered)
300113GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of HTLV	GMP	
300114GMP.BSV	Qualitative Polymerase Chain Reaction (PCR) Assays for detection of HHAV	GMP	

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