PathoQuest

SIMPLIFY AND SECURE YOUR BIOSAFETY QUALITY CONTROL WITH NEXT GENERATION SEQUENCING (NGS)

Vaccines

COMPLIANT, FASTER, ANIMAL-FREE

GMP GOOD MANUFACTURING PRACTICE CERTIFIED

iDTECT®

Adventitious Agent Testing | Identity Confirmation

SIMPLIFIED VIRAL SAFETY TESTING

No neutralization needed:
Consistent and reproducible results that work the first time

Faster:
Comprehensive adventitious viral agent detection and identification in a single assay step

Safer:
Comprehensive viral breadth of detection

Animal-Free:
3Rs compliant

UNMATCHED PRECISION FOR GENETIC CHARACTERIZATION

Identity:

- High-resolution sequence verification
- Broad genomic coverage
- Detection of complex mixed populations

2 GMP MIRROR FACILITIES

REGULATORY GUIDELINES

- ICH Q5A(R2) – Viral safety (2023 revision)
- ICH Q5B – Expression construct analysis for production of r-DNA derived protein products
- ICH Q5D – Derivation and characterization of cell substrates
- EMA Guideline: EMA/CHMP/BWP/457920/2012 Rev.1
- FDA Guidance for the Industry: Points to consider in the characterization of cell lines (1993)
- FDA GUIDANCE for industry - Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications - 2010
- USP <1050> – Viral safety from cell lines of human and animal origin
- Ph Eur 2.6.16 – Tests for extraneous agents in viral vaccines for human use
- Ph. Eur. 5.2.14 – Substitution of in vivo method(s) by in vitro method(s) for the quality control of vaccines
- Ph. Eur. 5.2.3/5.1.7 – Cell substrates for the production of vaccines and biologicals and viral safety
- Ph. Eur. 2.6.41 – High-throughput sequencing for the detection of viral extraneous agents: New chapter adopted in March 2025
- WHO TRS No. 978, Annex 3 (2010) – Recommendations for the evaluation of animal cell cultures as substrates for the manufacture of biological medicinal products and for the characterization of cell banks
- WHO Expert Committee on Biological Standardization_80th report (2025)

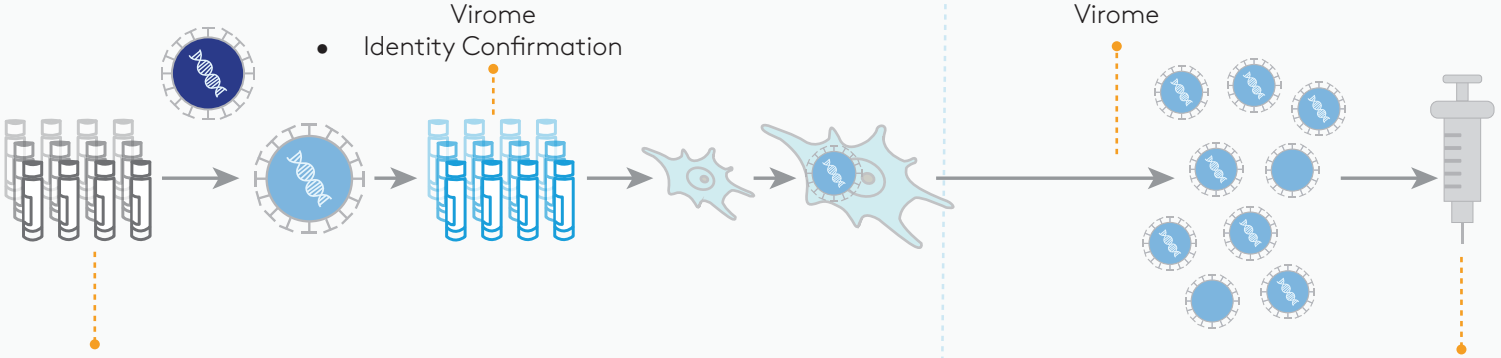
PathoQuest
Your GMP Next-Gen Biosafety Partner

UPSTREAM PROCESSING (USP)

DOWNSTREAM PROCESSING (DSP)

Master/Working Virus Bank
GMP NGS
- Adventitious Agent Testing: Virome
- Identity Confirmation

Bulk Harvest
GMP NGS
Adventitious Agent Testing: Virome



Master/Working Cell Bank
GMP NGS
Adventitious Agent Testing: Transcriptome

Drug Substance
Drug Product
GMP NGS
Identity Confirmation

ASSAY SPECIFICATIONS

	Assay	GMP	Sample Requirements	Turnaround Time (Calendar Days)	Deliverables to Client
VIRAL SAFETY	**iDTECT® Transcriptome** For cell-based material	✓	Min. 3×10⁵ cells	28 days (Standard) 21 days (Fast Track)	• Certificate of Analysis • Expert virologist report • Raw data
VIRAL SAFETY	**iDTECT® Virome** For cell-free material	✓	2×5 mL	42 days (Standard) 35 days (Fast Track)	• Certificate of Analysis • Expert virologist report • Raw data
GENETIC CHARACTERIZATION	**iDTECT® Identity**	✓	Varies by sample type	21 days (Standard) 14 days (Fast Track)	• Certificate of Analysis (% identity match to reference, presence and nature of variants)

Back up samples required. BSL1 and BSL2 samples accepted. | Shipment & storage: - 80°C / Dry Ice

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iDTECT® by PathoQuest