PathoQuest
Your GMP Next-Gen Biosafety Partner

iDTECT® VIROME

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REPLACE TRADITIONAL VIRUS TESTING WITH NEXT GENERATION SEQUENCING (NGS): COMPLIANT, FASTER, AND ANIMAL-FREE.

GMP GOOD MANUFACTURING PRACTICE CERTIFIED

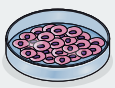
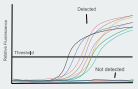
MODALITIES

- **Vaccines**
  - Bulk Harvests
  - Viral Seed Stocks
- **ATMPs**
  - Gene Therapy Bulk Harvest
  - Oncolytic Viral Vectors Bulk Harvests

WHY CHOOSE IDTECT® VIROME

- ✓ Replaces traditional adventitious virus testing
- ✓ Faster than traditional methods
- ✓ Simplified testing (no viral vector neutralization and no control cells testing needed)
- ✓ Safer (broad sprectrum detection of known and distant viruses across complex matrices)
- ✓ GMP validated assay integrated into our Type V Biologics Master File (FDA) available for reference

SUPERIORITY OF NGS VERSUS TRADITIONAL BIOTESTING METHODS


	In vivo	*In vitro*	PCR	NGS
Fast turnaround time	★☆☆☆☆	★★☆☆☆	★★★★★	★★★★☆
Validated methods	★☆☆☆☆	★★★☆☆	★★★★★	★★★★★
Identification of unknowns	☆☆☆☆☆	☆☆☆☆☆	☆☆☆☆☆	★★★★★
Low volume of sample	★★★★★	★★☆☆☆	★★★☆☆	★★★★☆

iDTECT® Virome is a GMP-validated NGS assay designed to meet ICH Q5A(R2), EU Pharmacopeia and global viral safety expectations for cell-free materials. It provides reliable and comprehensive detection of adventitious viral sequences within complex viral products such as bulk harvests, viral seed stocks, oncolytic viruses, gene therapy vectors and biologics. By enabling early identification of viral contaminants, the assay strengthens risk mitigation strategies and supports consistent product quality throughout development and lot release.

Compared to other methods that may simply assess free nucleic acids within a sample, iDTECT® Virome assay workflow integrates a critical ultracentrifugation step to first collect intact viral particles that may be present in the test sample. By focusing on the nucleic acid content contained within these particles, this method increases the confidence that any detected viral sequences originate from true adventitious agent contaminants rather than residual or endogenous nucleic acid background. By default, this process enhances the sensitivity and specificity of detection, independent of the nature of the viral contaminant.

iDTECT® Virome seamlessly fits into GMP workflows by offering broader and more sensitive detection than conventional panels, without the need for viral vector neutralization, which often limits the performance of classical methods. Regulatory guidelines now explicitly recognize the value of NGS in these contexts: ICH Q5A(R2) encourages the use of NGS as a replacement for in vivo assays, noting that its sensitivity and breadth of detection can overcome limitations associated with cell-based infectivity tests. With its validated workflow and regulatory alignment, iDTECT® Virome provides a robust, efficient and animal-free approach for viral safety evaluation of vaccines and ATMPs.

SAMPLE REQUIREMENTS*	SHIPMENT & STORAGE	TURNAROUND TIME (CALENDAR DAYS)	OUTPUT
2 x 5ml Backup sample required BSL1 or 2*	Dry Ice / -80°C	· Standard: 42 days · Fast Track: 35 days	· Certificate of Analysis · Expert virologist report · Raw data · Study final report

*Biosafety level classifications can vary between regulatory authorities – contact PathoQuest to discuss.

REFERENCE
1) ICH Guideline Q5A(R2) on viral safety evaluation of biotechnology products derived from cell lines of human or animal origin.

To find out how PathoQuest can help you meet your 3Rs objectives visit **www.pathoquest.com/3Rs**

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