PathoQuest

iDTECT® VIROME

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

GMP GOOD MANUFACTURING PRACTICE CERTIFIED

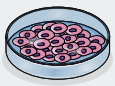
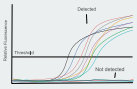
MODALITIES

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

WHY CHOOSE IDTECT® VIROME?

- ✓ GMP validated
- ✓ Fast turnaround time
- ✓ Minimal test article volume
- ✓ Reduced sample compatibility issues (no viral vector neutralization)
- ✓ Broader detection than traditional methods
- ✓ Immediate identification of contamination
- ✓ Replacement of animal-based methods (3Rs) including MAP/HAP/RAP

SUPERIORITY OF NGS VERSUS TRADITIONAL BIOTESTING


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

DESIGNED FOR GMP APPLICATIONS

- **Regulatory compliance:** Meets ICH Q5A(R2), EU Pharmacopeia, and global guidelines, providing reliable and validated viral safety data.
- **Risk mitigation:** Early detection of viral contaminants ensures consistent product quality and safety throughout development and lot release.
- **Easy workflow integration:** Offering faster and more sensitive detection than the panel of conventional tests without viral vector neutralization, supporting efficient product release.

Next Generation Sequencing (NGS) combines the benefits of PCR with the agnostic capabilities of traditional culture or animal models, especially for challenging samples that contain high concentrations of therapeutic virus. Regulatory guidelines now specifically include NGS for viral detection in these cases.

For example, the ICH guideline Q5A has been revised to state "NGS is encouraged as a replacement for *in vivo* assays". ICHQ5A(R2)[1] also mentions that "because of the assay sensitivity and breadth of virus detection, NGS may also be used to replace cell-based infectivity assays, to overcome potential assay limitations".
iDTECT® Virome GMP validated assay addresses the challenges of detecting adventitious viral contamination including samples such as viral seed stocks, oncolytic viruses, biologics bulk harvest, and ATMPs. A validated ultracentrifugation step concentrates the viral particles, allowing for more sensitive and robust detection of viral sequences. Also, an assessment of both DNA and RNA sequences gives for certain viruses a higher degree of confidence that identified sequences come from adventitious agents, rather than innocuous endogenous cellular sequences.

SAMPLE REQUIREMENTS*	SHIPMENT & STORAGE	STANDARD TURNAROUND TIME	FASTTRACK TURNAROUND TIME	OUTPUT
2 x 5ml Backup sample required BSL1 or 2*	Dry Ice / -80°C	6 weeks	5 weeks	GMP CoA Any viral sequences are identified in 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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