PathoQuest
Your GMP Next-Gen Biosafety Partner

iDTECT® TRANSCRIPTOME

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

GMP GOOD MANUFACTURING PRACTICE CERTIFIED

MODALITIES

- **Manufacturing cell banks & bulk harvest:**
  - Monoclonal antibodies
  - Gene therapy
  - Oncolytic virus
  - Vaccines
- **CAR-T and cell therapy lots**

WHY CHOOSE iDTECT® TRANSCRIPTOME

- ✓ Replacing traditional Adventitious Virus Testing, Species-Specific Virus Testing (MAP/HAP/RAP, Human Virus PCR panel), 9CFR (Bovine and Porcine viruses) testing with one single assay
- ✓ Detection of cells infected by live viruses
- ✓ Broader detection capabilities than traditional methods
- ✓ Low volume of sample
- ✓ GMP validated

SUPERIORITY OF NGS VERSUS TRADITIONAL BIOTESTING

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

Traditionally, cell culture and animal models have been used for the detection of adventitious viral contaminants. The advantage of these systems is that both known and emerging viral risks could potentially be identified. However, the detection capability of these systems is limited because of low sensitivity and virus may not propagate. These assays are also very slow. Molecular methods such as PCR overcome many of the issues with speed, sensitivity and sample compatibility. However, PCR cannot discriminate between live virus and inactivated virus or viral fragments.
Next Generation Sequencing (NGS) combines the benefits of PCR with the agnostic capabilities of traditional culture or animal models. Regulatory guidelines now specifically include NGS for viral detection. For example, the ICH guideline Q5A [1] has been revised to state “NGS is encouraged as a replacement for in vivo assays”. Q5A also states 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® Transcriptome GMP assay can help with 3Rs objectives by replacing in vivo assays in cell characterization packages, including mouse, hamster and rat antibody production assays. Our approach is shown to have superior performance over in vivo methods [2], detects only live replicating viruses and helps discriminate true viral contaminations from non-significant signals. With equivalent or better sensitivity across a broad range of viruses as well as manufacturing cell lines; including CHO, HEK293, Sf9 and Vero.
iDTECT® Transcriptome assay can also detect all viruses listed under adventitious virus, MAP, HAP, RAP, human/simian PCR panels, and 9CFR guidelines at a detection limit of 0.1 RNA copies per cell. This included both homolog and distant viral strains, proving its superior performance and reliability.
iDTECT® Transcriptome offers an advanced solution for viral detection by consolidating multiple traditional tests into a single comprehensive assay.

SAMPLE REQUIREMENTS*	SHIPMENT & STORAGE	STANDARD TURNAROUND TIME	FASTTRACK TURNAROUND TIME	SENSITIVITY OF DETECTION - ONE INFECTED CELL IN BACKGROUND OF UNINFECTED CELLS**	DELIVERABLES TO CLIENT
Minimum $3x10^5$ cells Backup sample required BSL1 or 2*	Dry Ice / -80°C	5 weeks	4 weeks	$1x10^3$ (Cox A16 and Mumps) to $1x10^7$ (Influenza A)	· Certificate of Analysis · Expert virologist report · Raw data

* Biosafety level classifications can vary between regulatory authorities – contact PathoQuest to discuss. Contact PathoQuest for patient or tissue samples.
** NGS sensitivity determined by dilution of infected cell extracts into non-infected cell extracts. Note, all tested viruses detected by NGS; Cox A16 was not detectable in *in vivo assays*, Echo 11, Measles and BVDV1 were not tested *in vivo* for ethical reasons.

REFERENCES

1. ICH Guideline Q5A(R2) on viral safety evaluation of biotechnology products derived from cell lines of human or animal origin.
2. Beurdeley-Fehlbaum, P., et al (2023) Vaccine, https://doi.org/10.1016/j.vaccine.2023.07.019 (Aug 2023)

To read our NGS vs in vivo comparison publication scan here:

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

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