IDENTITY TESTING AT PATHOQUEST

PathoQuest

PathoQuest is a leading expert in the provision of NGS testing services for biopharmaceuticals. We offer GMP service for the identity testing of viral vectors such as AAV and lentivirus including manufacturing plasmids. Identity testing is also offered for non-viral vector applications such as CRISPR as well as vaccine applications.

GMP GOOD MANUFACTURING PRACTICE CERTIFIED

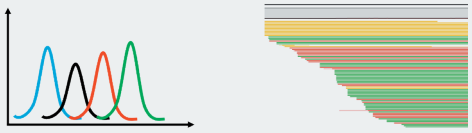
MODALITIES TESTED

- Plasmids
- Vaccines (Viral & RNA)
- Gene Therapy Vectors
- Oncolytic Virus
- Bacteria

BENEFITS OF NGS FOR IDENTITY TESTING

- ✓ GMP Validated Assay
- ✓ Subpopulation Identification
- ✓ Can handle sequence motifs that are challenging to PCR/sequence – e.g. AAV ITR, lentivirus LTR, or certain promoters

SANGER VS NGS FOR IDENTITY TESTING



	SANGER SEQUENCING	NGS
Speed	★★☆☆☆	★★★★☆
Cost	★★☆☆☆	★★★☆☆
Variant detection	★★★☆☆	★★★★★
Challenging sequences	★★☆☆☆	★★★★☆

Identity testing is a critical testing component to release vector products, including viral and non-viral cell and gene therapies; as well as vaccine and oncolytic applications. Determination of the nucleic acid sequence of the vector and gene of interest is a regulatory requirement. Therefore, direct sequencing is a standard and well accepted approach. Traditionally, this has been carried out using a Sanger sequencing assay. However, the use of Next Generation Sequencing (NGS) provides several advantages: NGS can identify ultra-rare genetic variants below 5%, compared to at least a 20% variant detection limit for Sanger. NGS can also be more cost and time efficient over a sequential Sanger sequencing approach. Other identity testing methods such as PCR and restriction enzyme analysis can provide only very limited information when compared to the deep insights NGS provides. An aligned testing strategy should also be employed for plasmid input materials, as non-clonal variation within the manufacturing plasmids can be carried through to affect the quality of the final product.

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PathoQuest use a short-read NGS approach for identity testing, which provides excellent detection capabilities for very low occurrence variance detection of typically <1%. The full workflow is GMP validated from sample preparation, through to sequencing and bioinformatics.

SAMPLE REQUIREMENTS	SHIPMENT & STORAGE	STANDARD TURNAROUND TIME	FASTTRACK TURNAROUND TIME	SENSITIVITY**	OUTPUT
Min sample vol of 200µl at titres of $1x10^{13}$ for AAV, $1x10^{10}$ for lentivirus, $1x10^{8}$ for adenovirus. Minimum 1ng at 0.5ng/µl for plasmids. Backup sample required BSL1 or 2*	Dry Ice / -80°C	28 days	14 days	Detection of variants validated at 5% abundance (Lower occurrence variants can be reported if required)	GMP CofA Consensus sequence Variant sequences at > 5% abundance

*Biosafety level classifications can vary between regulatory authorities – contact PathoQuest to discuss.
**NGS should be considered as semi-quantitative in this application. Abundance figures are provided at the occurrence rate of the variant as it appears within the read data. Detection of variants is possible below the validated 5% level. Please discuss with our experts if this is required.

Find out more: **www.pathoquest.com/index.php/ID**
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