PathoQuest

iDTECT® IDENTITY

ADVANCED GMP-VALIDATED IDENTITY TESTING FOR THE RELEASE OF VIRAL AND PLASMIDS PRODUCTS

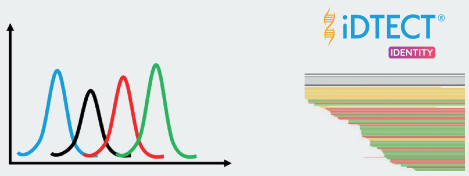
MODALITIES

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

WHY CHOSE iDTECT® IDENTITY NGS ASSAY?

- ✓ GMP validated
- ✓ Faster turnaround time
- ✓ Cost-effective
- ✓ Deep insights with comprehensive subpopulation identification
- ✓ Ability to work with limited material

SUPERIORITY OF NGS TESTING VERSUS SANGER



SANGER SEQUENCING | NGS

	SANGER SEQUENCING	NGS
Faster turnaround time	★★☆☆☆	★★★★☆
Variant detection	★★★☆☆	★★★★★
Challenging sequences	★★☆☆☆	★★★★☆

DESIGNED FOR GMP APPLICATIONS

- **Regulatory compliance:** Meet global agencies requirements with robust, validated data
- **Risk mitigation:** Early detection of subpopulations and sequence variants to ensure product quality and consistency
- **Easy workflow integration:** Ensure a reliable and consistent product release

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 viruses. 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 time efficient over a sequential Sanger sequencing approach.

PathoQuest uses a short-read NGS approach for identity testing, providing excellent detection of rare and ultra-rare sequence variants down to 5% representation within a population. The entire workflow is GMP validated from sample preparation, through to sequencing and bioinformatics.

SAMPLE REQUIREMENTS*	SHIPMENT & STORAGE	STANDARD TURNAROUND TIME	FASTTRACK TURNAROUND TIME	SENSITIVITY***	OUTPUT
Purified plasmid: min. 50µl @ 0.5ng/µl or 25ng AAV: $1x10^{13}$ VG/ml (40ng min.) Lentivirus: $1x10^{10}$ PFU/ml (10ng min.) Adenovirus: $10x10^{8}$ IU/ml (1ng min.) Backup sample required BSL1 or 2**	Dry Ice / -80°C	3 weeks	2 weeks	Detection of variants validated at 5% abundance (Lower occurrence variants can be reported if required)	GMP CoA Consensus sequence Variant sequences at > 5% abundance

* Please discuss with PathoQuest if you have limited material as we can often work with much less input.
** 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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