

iDTECT® IDENTITY

UNMATCHED PRECISION FOR GMP IDENTITY CONFIRMATION AND SEQUENCE VARIANT DETECTION USING NEXT GENERATION SEQUENCING (NGS)



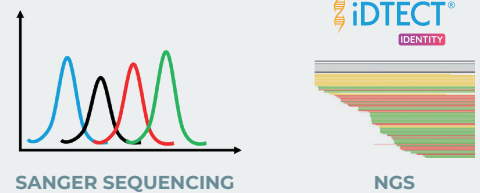
MODALITIES

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

WHY CHOOSE iDTECT® IDENTITY

- ✓ Faster turnaround time
- ✓ Deeper genetic insights over Sanger, detects minor variants and mixed populations with confidence
- ✓ GMP validated assay integrated into our Type V Biologics Master File (FDA) available for reference

SUPERIORITY OF NGS ASSAY VERSUS SANGER



Faster turnaround time	★ ★ ☆ ☆ ☆	★ ★ ★ ★ ☆
Variant detection	★ ★ ★ ☆ ☆	★ ★ ★ ★ ★
Challenging sequences	★ ★ ☆ ☆ ☆	★ ★ ★ ★ ☆

DESIGNED FOR GMP APPLICATIONS

iDTECT® Identity is a fully GMP-compliant NGS assay designed to meet global regulatory expectations for sequence identity confirmation of plasmids, vaccines, and viral vectors. It provides robust, high-resolution sequence data essential for confirming the integrity of the vector or gene of interest.

By detecting both common and rare sequence variants across the full construct, the assay enhances risk mitigation and supports consistent product quality throughout development and manufacturing.

In contrast to traditional Sanger sequencing, which has long been considered the standard for identity testing,

iDTECT® Identity assay provides significantly deeper and more comprehensive sequence coverage in a single reaction. This results in exquisite sequence resolution, with the ability to identify rare to ultra-rare sequence variants with unmatched confidence in sequence accuracy, something that is simply not possible with Sanger sequencing.

Combined with a streamlined workflow eliminating the need for multiple sequencing reactions, the iDTECT® Identity assay is your go-to solution for rapid, accurate sequence identity confirmation.

SAMPLE REQUIREMENTS	SHIPMENT & STORAGE	TURNAROUND TIME (CALENDAR DAYS)	SENSITIVITY*	OUTPUT
Varies by sample type	Dry Ice / -80°C	<ul style="list-style-type: none"> • Standard: 21 days • Fast Track: 14 days 	Detection of variants validated at 5% abundance (Lower occurrence variants can be reported if required)	Certificate of Analysis (% identity match to reference, presence and nature of variants)

*NGS is considered semi-quantitative. Variant frequencies are based on detection of the variant within the individual data set population



Find out more: www.pathoquest.com/index.php/ID or contact us via contact@pathoquest.com

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