

## DISCOVER CELL LINE NGS AAT ENHANCED

Keep regulatory confidence, gain modern objectivity for your cell line characterization

Our next-generation sequencing for cell line characterization delivers a modern, objective assay aligned with the latest regulatory guidelines

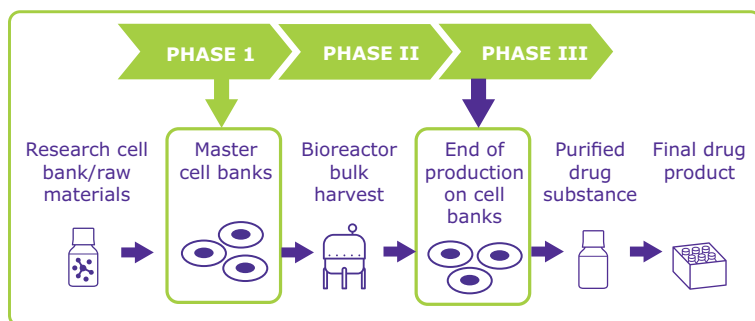
and a proven record of regulatory acceptance, backed by 4R principles and NGS leadership since 2009 to de-risk submissions and accelerate safety decisions.

Featured attributes	<i>in vivo</i> assay	Cell Line NGS AAT Enhanced
<b>Reduce risk to IND:</b>		
<b>TAT</b>	49 days	<b>28 days</b>
<b>Method</b>	Animal-based test	<b>Non-targeted NGS (Transcriptomic)</b>
<b>Industry leading sensitivity:</b>		
<b>LOD</b>	Not validated	<b>Minimum 1E4 Viral Genome Copies (VGC) per 1E6 cells</b>
<b>More objective results:</b>		
	Symptom-driven detection infers contamination	<b>Sequence specific virus detection</b>
<b>Better compliance:</b>		
	Qualitative test	<b>GMP compliant qualitative limit test validated according to ICH Q2 (R2) and Ph. Eur. 2.6.41 regulatory guidelines</b>

Transparent performance and integrated package design

- ✓ Robust validation package
- ✓ Consulting and regulatory support
- ✓ Package turnaround time (TAT)
- ✓ Low regulatory risk approach where possible

### Primary Applications



- ✓ De-risk the path to IND submission with an objective assay that do not rely on animal testing
- ✓ Validated limit of detection (LOD) in commonly used cell lines
- ✓ Hedge risk with a 28-day TAT

Learn more at: [SigmaAldrich.com/NGS](https://SigmaAldrich.com/NGS)



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