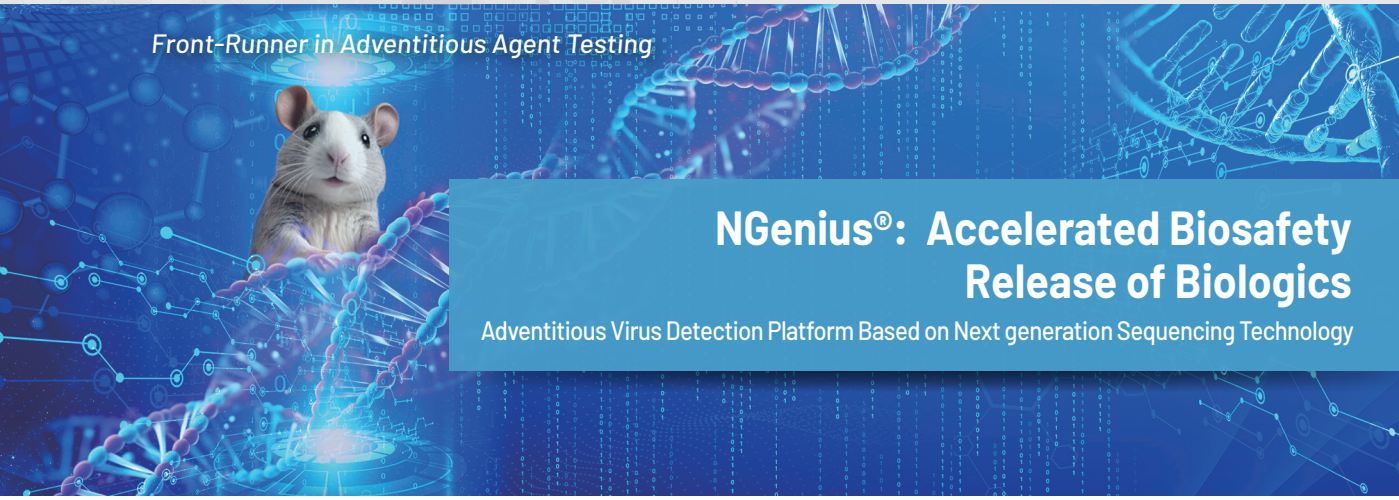
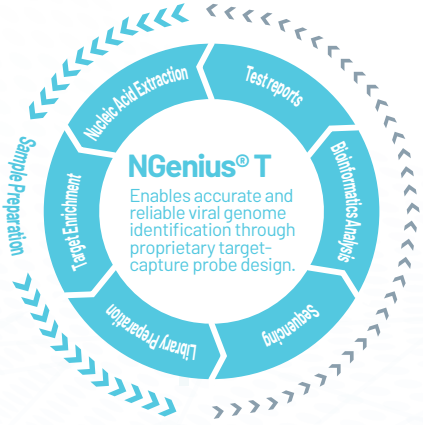


NGenius®: Accelerated Biosafety Release of Biologics

Adventitious Virus Detection Platform Based on Next generation Sequencing Technology

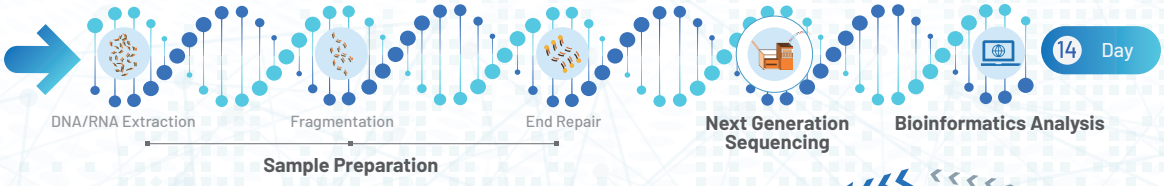
ICH Q5A(R2), WHO, EMA, FDA, and NMPA encourage the adoption of Next Generation Sequencing (NGS) as a supplement or alternative to traditional viral detection methods. Because of the sensitivity and scope of virus detection, NGS has been increasingly applied in viral safety evaluation of biologics products .

NGenius® Testing Platform leverages NGS technology to deliver compliant, efficient, sensitive, and accurate adventitious virus detection services, ensuring biologics safety and accelerating time-to-market.



- Replacement of *in vivo/in vitro* virus-specific assays (e.g., MAP/HAP/RAP) for murine virus testing in cell bank & cell harvest
- Application for species-specific virus screening of animal-derived materials, including 9CFR-mandated porcine/bovine virus testing
- Rapid and accurate detection of high-risk human viruses to ensure safety of cell therapy products

- Compliant with the 3Rs principles
- Comprehensive detection of viral subtypes
- 14-day turnaround time
- Highly consistent limit of detection (20 copies)
- Minimized requirements of sample volume with consistency
- Rigorous validation with excellent data reproducibility



- Replacement of *in vivo/in vitro* adventitious virus testing
- Viral safety evaluation of recombinant protein, viral vaccines, oncolytic viruses and gene therapy products

- Compliant with the 3Rs Principles
- Comprehensively screening of virus risks, covering comprehensive virus species
- Rigorous validation with excellent data reproducibility

Comparison between NGenius® T and other methods

	MAP/HAP/RAP	qPCR	NGenius® T
Short Turnaround Time	★☆☆☆☆	★★★★★	★★★★★
High Sensitivity	★★★☆☆	★★★★★	★★★★★
Low Sample Volume	★☆☆☆☆	★★★★☆	★★★★★
High Resolution	★☆☆☆☆	★★☆☆☆	★★★★★
Specificity	☆☆☆☆☆	★★☆☆☆	★★★★★
Compliance	ICH	ICH + 3Rs	ICH+3Rs+2025 ChP

Regulatory guidelines support NGS as a replacement for traditional viral testing methods

ICH
- ICHQ5A (R2) Quality of Biotechnological Products: Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin

WHO
- 2013,Recommendations for the evaluation of animal cell cultures as substrates for the manufacture of biological medicinal products and for the characterization of cell banks (TRS 978)

EP
- EP 5.2.14 Substitution of in vivo method (s) by in virto method (s) for the quality control of vaccines
- EP 5.2.3 Cell Substrates for the production of vaccines for human use
- EP 2.6.16 Tests for extraneous agents in viral vaccines for human use
- EP 5.2.4 Cell cultures for the production of vaccines for veterinary use
- EP 5.2.5 Management of extraneous agents in immunological veterinary medicinal products
- EP 2.6.37 Principles for the detection of extraneous viruses in immunological veterinary medicinal products using culture methods

USP
- 2010 Guidance for Industry: Characterization and qualification of cell substrates and other biological materials used in the production of viral vaccines for infectious disease indications.
- 2024 ICHQ5A (R2) Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Original

CHP
- 2024 Q5A (R2) Viral Safety Evaluation of Biotechnology Products Derived From Cell Lines of Human or Animal Origin Guidance for Industry
- 2023 Guidance on CMC Study and Evaluation Techniques of Oncolytic Virus Products (Trial)
- 2025 Preparation and Quality Control of Animal Cell Substrates for Production of Biological Products

GMP-compliant Laboratory
Fast Turnaround Time
Flexibly Designed Solution
Premium Standard Service
Experienced Technical Team
Scientifically Rigorous Validation

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