AgentSCREEN™ GMP Adventitious Virus Detection by NGS

Minaris Advanced Testing

Flyer

Minaris **AgentSCREEN™** is a GMP-qualified Next Generation Sequencing (NGS) platform that simplifies adventitious agent testing with a predictable 28-day turn-around time, regulatory aligned workflow, and U.S. based end-to-end support.

NGS has been proven to provide the breadth, sensitivity and confidence needed for adventitious agent screening and is recognized as a key technology for biologic and advanced therapy providers striving to modernize their viral safety strategies and reduce their dependency on animal testing.

AgentSCREEN™ Benefits

Unbiased Detection
Identifies expected and unexpected viral agents

Enhanced Safety
Greater confidence in product viral safety

Broad Coverage
Screens for multiple viral species in one assay

Lifecycle Flexibility
Applicable from master to end of production cell bank

High Sensitivity
Detects low-level viral contaminants

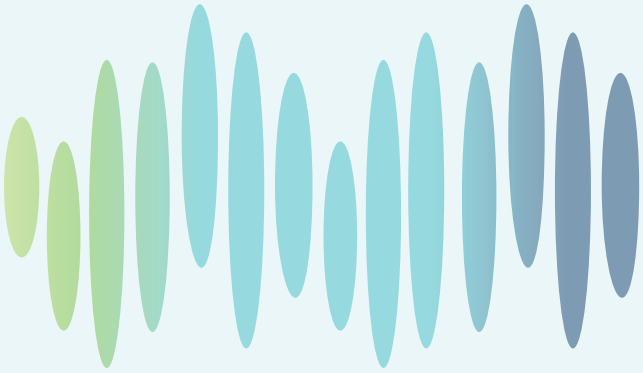
Regulatory Alignment
Supports regulatory direction of reducing animal testing

Faster Results
Shorter turn-around timelines than traditional virology assays

Rich Data
Enables retrospective analysis and investigations

About AgentSCREEN™

ICH Q5A(R2) guidelines encourage the use of Next Generation Sequencing (NGS) as a replacement for *in-vivo* tests for adventitious virus detection, recognizing its higher sensitivity and reduced testing time. AgentSCREEN™ is a transcriptomic approach with a 28-day turn-around time. The assay examines all the messenger RNA (mRNA) in a cell bank sample for the presence of viral RNA transcripts. The method is designed to detect any active viral infection from both RNA and DNA viruses.



The Minaris next generation sequencing system utilizes 21 CRF part 11 compliant software that provides an audit trail, data integrity and security to ensure adherence to FDA regulations. A custom GAMP5 validated bioinformatics pipeline compares AgentSCREEN sequencing data to the Reference Viral Database (RVDB) curated by CBER/FDA to accurately identify viral contaminants.

The method provides broad virus detection for unexpected viral contaminations to replace in-vivo tests and can complement in-vitro cell culture assays. If an unanticipated positive signal occurs, Minaris has the ability to perform a full investigation including expert virology review and orthogonal assays.

AgentSCREEN™ NGS Transcriptome

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FL-T-261041-1

CONTACT US

Get in Touch With Our Team Today

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