BioReliance®
Contract Testing Services

MERCK

Leave No Gap in Your AAT Strategy

De-risk IND filings with a complete adventitious agent testing (AAT) package

Regulatory guidance

"Testing for adventitious viruses should include both broad and specific virus detection assays"
ICH Q5A(R2) Viral Safety Evaluation of Biotechnology Products Derived from Cell Lines of Human or Animal Origin provides harmonized guidance.

Virus safety testing checklist

Broad Specificity Methods
- *In Vitro* adventitious agent assay
- ~~*In Vivo* adventitious agent assay~~

Retroviruses
- PCR enhanced Reverse Transcriptase

NGS AAT Method

- Transmission Electron Microscopy
- Infectivity Assays

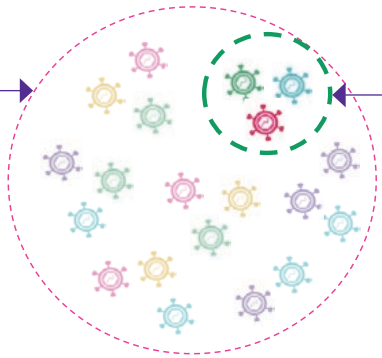
Species Specific Viruses
- ~~MAP/HAP/RAP invivo assays~~

Porcine/Bovine Viruses
- Culture-based Methods (9CFR)
- Virus Specific PCR Methods

Blazar® tNGS Rodent Virus Panel

Ensure viral safety with complementary NGS-based methods

NGS AAT Method
- Wide breadth of coverage to aid in the detection of replicating viruses



Blazar® tNGS Rodent Virus Panel
- Species-specific testing with rapid results
- Industry leading sensitivity on the rodent viruses named in ICH Q5A(R2)
- Can detect even when replication is limited*

Delivering a complete adventitious agent testing package

- A complete AAT strategy combines NGS AAT for broad, unbiased detection of replicating viruses with Blazar® tNGS Rodent Virus Panel for species specific, sequence confirmed sensitivity on the ICH Q5A(R2) rodent viruses
- Remove the use of live animals and minimized risk — 3Rs aligned assays with automation reduces false positives and deviations, which in turn de-risk IND pathway and lower risk to patients

*Within the assay's validated performance

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