

# NEXT GENERATION SEQUENCING, THE NEW ALTERNATIVE TO IN VIVO TESTING

Method Comparison: Quality Control Testing of Biologics



**TARGET** >

Professionals in  
Pharma and Biotech  
developing cell therapy,  
cell banks, virus seeds...

## WHAT ARE THE BIOLOGICAL MATERIALS CONCERNED?

A large number of applications and products :

vaccines

recombinant  
proteins

cell and gene  
therapies



**1**

**NGS**  
(RNA sequencing  
method)



VS

**In vivo**  
(conventional  
test for the viral  
safety of cells)



**2**



Collaboration

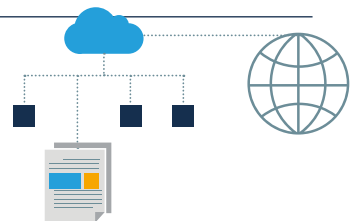
 PathoQuest

X

 charles river

**3**

Goal of study: Generate data to support the replacement of in vivo testing w/NGS approach on cells

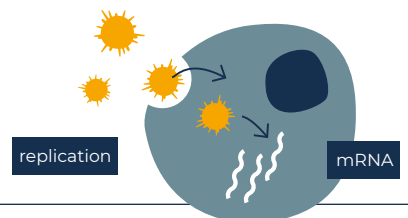


**4**

**In vivo** = Suckling mice, adult mice, embryonated eggs, guinea pigs\* and hamsters\*

**5**

NGS transcriptomic approach



**6**

Viruses chosen for this study

### CATEGORY A

Vesicular Stomatitis Virus, Influenza A

NGS < In Vivo

### CATEGORY B

Herpes Simplex Virus type 1, Coxsackie viruses A and B, Mumps

NGS < or similar In Vivo


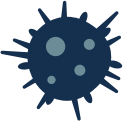





### CATEGORY C

Echovirus 11, Measles, Bovine Viral Diarrhea Virus

Undetectable in in vivo assay

\* Guinea pigs and hamsters are used in some tests that are not shown here

In anticipation of  
upcoming ICHQ5A revision

		Animal Testing	NGS	Comments
	<b>Detection range</b>	✗	✓	NGS has a broader range of detection as <i>in vivo</i> testing. Entire families of viruses cannot be detected with animal testing.
	<b>Specificity for virus identification</b>	✗	✓	NGS detection is based on sequencing, which ensures virus detection and identification. Detection using animal models is based on clinical signs which are not specific to viruses and need further investigation for identification.
	<b>Sensitivity</b>	✗	✓	As shown in this study, NGS has greater or equal sensitivity compared to most animal testing.
	<b>Turnaround time</b>	✗	✓	Suckling mice assay takes 28 days for observation period alone. Animal testing failures are common (increased TAT)
	<b>3Rs compliance</b>	✗	✓	Directive 2010/63/EU requires Replacement, Reduction, and Refinement of animal testing whenever possible
	<b>Validation</b>	✗	✓	Animal testing is not validated (due to ethical concerns), NGS is available at a GMP grade. <b>Revised ICHQ5A to be released in 2022.</b> EP 5.2.14 clearly states the use of NGS as an alternative
	<b>Regulatory acceptance</b>	✓	✓	EP 2.6.16 requires justification for the use of animal testing whereas NGS is considered an acceptable alternative method.

**IF YOU WANT TO SWITCH TO A SAFER, FASTER,  
AND MORE ETHICAL METHOD, CONTACT US HERE :**

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