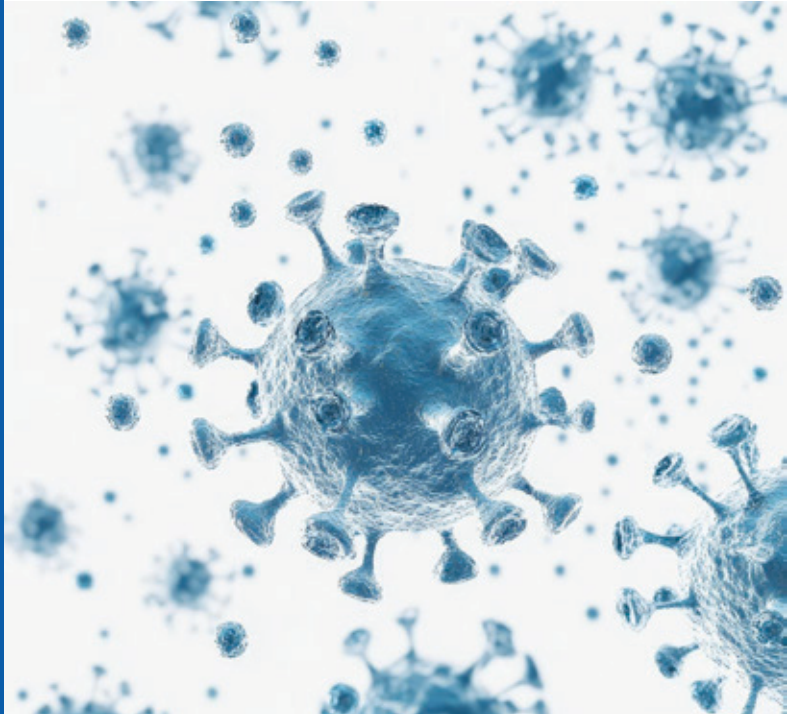


GLP-Certified Viral Testing and Clearance Services



Ensure Viral Safety for Your Biologics

Prioritize the biosafety of your product with Syngene's expertise, flexibility, and rapid turn around times meeting global regulatory compliance.



India's only **GLP-certified facility** for viral safety studies.



Regulatory-accepted submissions:
FDA, EMA, WHO & more.



Proven success in
100+ global clinical programs.



Phase appropriate
viral safety studies.



Fast turnaround:
**Phase I in 11 weeks,
Phase III in 15 weeks.**



Flexible scheduling with
**lead times as short as
2 months.**

We Support

- Monoclonal antibodies
- Fusion proteins
- Recombinant proteins
- Plasma products
- Medical devices

Our Services

- Viral clearance studies
- Cell bank testing
- In-process / batch testing



For more information, contact bdc@syngeneintl.com
www.syngeneintl.com

Delivering Safe and High-Quality Drugs to Patients



Our comprehensive viral testing services are designed to ensure the safety of biotechnology products derived from cell lines of human or animal origin. Our assays are rigorously validated and comply with ICH, USP, and EP guidelines.

Our Assays for Research Cell Bank and Unprocessed Bulk Harvest Testing

Assay	Research Cell Bank Testing	Unprocessed Bulk Testing	Test Duration
<i>In vitro</i> adventitious virus detection	Y	Y	6 - 7 weeks
Retrovirus detection	Y	Y	6 weeks
MVM detection	Y	Y	1 week
Mycoplasma detection	Y	Y	1 week
TEM analysis	-	Y	~10 weeks

Our List of Assays for Viral Clearance Studies

Virus	Characteristics	Phase I	Phase III & BLA
MVM	Non-env / ssDNA	√	√
MuLV	Env / ssRNA	√	√
Reo 3	Non-env / dsRNA	NA	√
HSV-1	Env / dsDNA	NA	√

Viruses recommended in ICH Q5A are used for comprehensive clearance evaluation.

We offer molecular assays (qPCR) tailored to your specific study design, providing accurate and reliable results for your viral clearance needs.

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