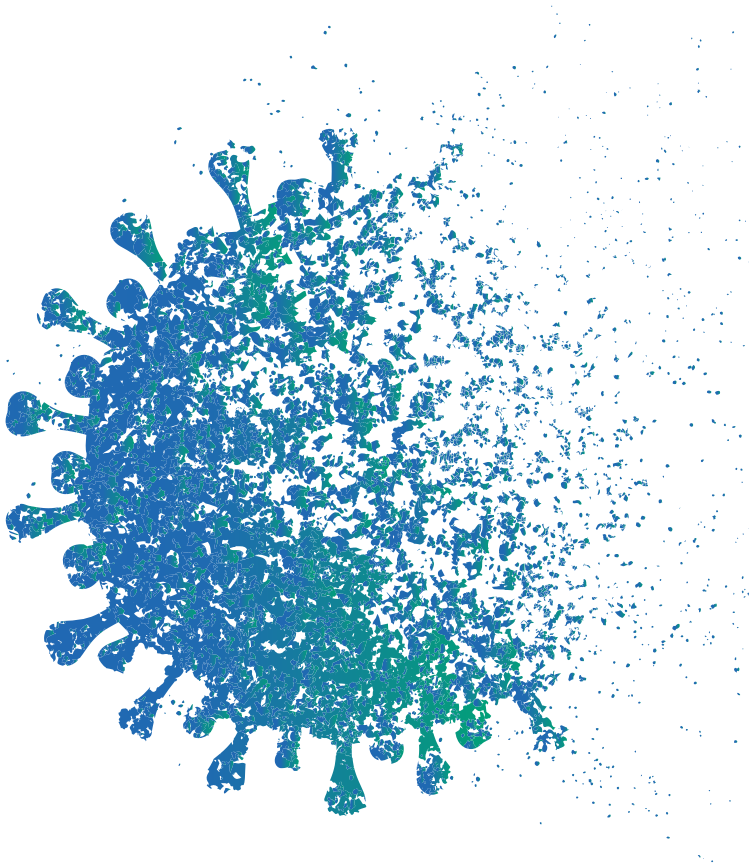
Syngene

Putting Science to Work

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 turnaround 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 as little as **2 months' lead time.**

WE SUPPORT

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

SERVICES

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

Scan the QR code to know more about our viral testing and clearance services.

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

Stay Connected

Syngene
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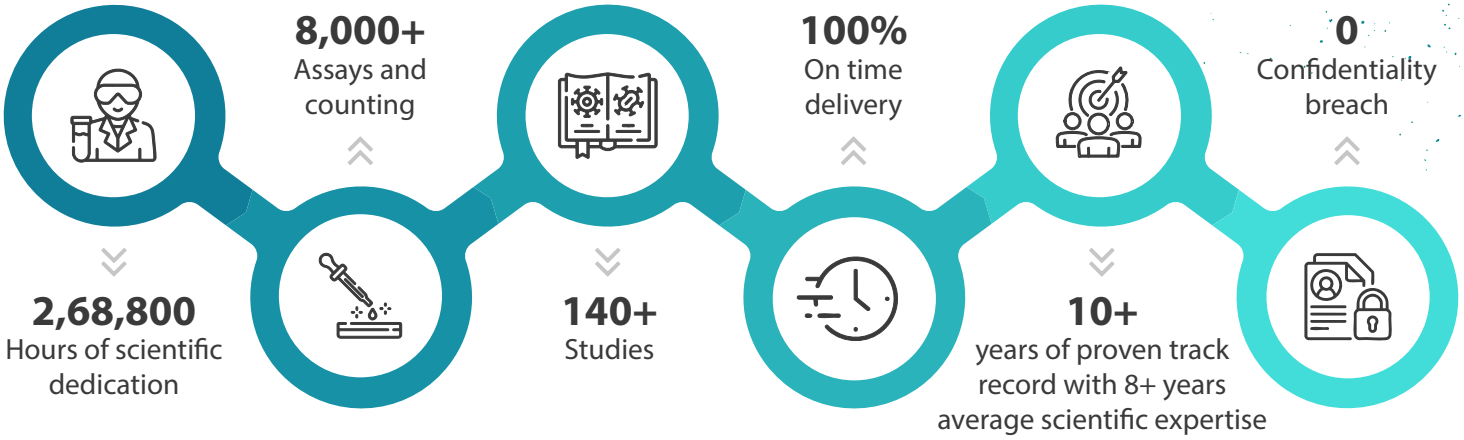
Delivering safe and high-quality drugs to patients



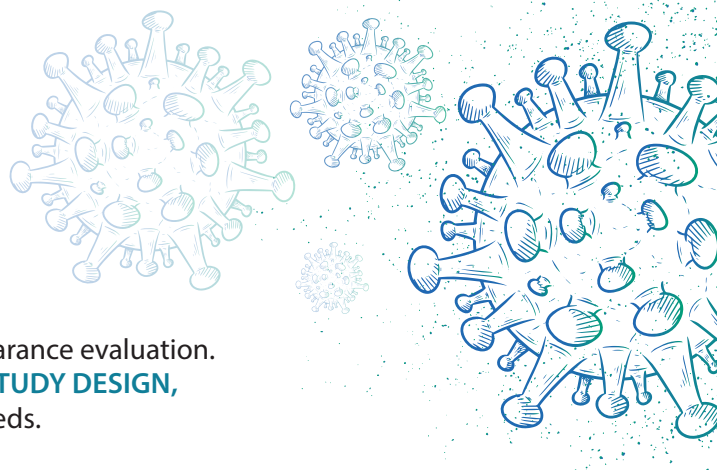
Our comprehensive viral testing services are designed to ensure the safety of biotechnology products derived from cell lines of human or animal origin. Our assays are rigorously validated and comply with **ICH, USP AND EP GUIDELINES.**

Our assays for Research cell bank and Unprocessed bulk harvest testing

Assay	Research Cell Bank Testing	Unprocessed bulk testing	Test Duration
In vitro 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	
		CT- I	CT-III & MAA
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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