



Viral Clearance Studies

For all stages throughout the development, manufacturing and release of your biological product, Lancaster Laboratories offers comprehensive, fully cGMP-compliant Viral Clearance Services.

Why Choose Lancaster Laboratories?

- All of our assays are fully validated to meet ICH Q2 requirements.
- We have multiple dedicated clearance suites for extensive capacity and timely execution and reporting of your study results.
- With more than 50 years of collective viral clearance experience, our technical team has vast industry knowledge and experience performing viral clearance studies.

Viral Clearance Services

Our scientists design and run viral clearance studies to meet regulatory requirements. Our viral clearance offerings include:

- A variety of validated and well characterized viral stocks to support animal- and human-derived products
- Purified virus stocks
- Viral stocks with titers of 10^7 pfu/ml or greater
- Validated qPCR assays
- Infectivity assays performed real-time
- Large volume assays
- Ongoing regulatory support upon study completion

Facilities and Equipment

- Multiple HEPA-filtered virus clearance labs
- Multiple AKTA chromatography systems
- Manual chromatography equipment available
- Capacity to accommodate studies with minimal delay

Discover our solutions at: LancasterLabsPharm.com

Global Services:

Biochemistry
Cell Bank Manufacturing
Facility & Process Validation
Method Development & Validation
Microbiology
Molecular & Cell Biology

Mycoplasma Services
Raw Materials Testing
Release Testing
Residuals & Impurities Testing
Stability Testing & Storage
Viral Clearance & Viral Safety

Facilities:

USA
Lancaster, PA | 717-656-2300
Portage, MI | 269-323-3366

Ireland

Dungarvan Co. Waterford | 00 353 (0) 58 48300



Four Viral Clearance Models

Lancaster Laboratories offers several service models for the performance of viral clearance studies:

- **Level 1 – Basic Service:** The client provides all materials and down-scale procedures and performs the study in Lancaster Laboratories' viral clearance suites.
- **Level 2 – Enhanced Service:** The client provides all materials and down-scale procedures and performs all column chromatography steps. Lancaster Laboratories personnel perform inactivation and virus removal filtration steps.
- **Level 3 – Full Service:** The client provides all materials and down-scale procedures for transfer to Lancaster Laboratories personnel, who perform all clearance steps.
- **Level 4 – Turnkey Service:** The client provides a description of the full-scale manufacturing process. Lancaster Laboratories personnel develop and validate the down-scale procedures and perform all clearance steps.