GMP lab

Virus-specific qPCR panel for targeted viral nucleic acid testing

PPD Laboratory Services' GMP Biosafety Lab offers targeted virus-specific nucleic acid testing using singleplex qPCR and RT-qPCR. The platform involves qualified TaqMan™ assays for defined DNA and RNA viral targets and is designed to support cell banks and other cell-containing or cell-associated materials. Built on Thermo Fisher Scientific technologies, the service provides qualitative DETECTED / NOT DETECTED results within a controlled GMP laboratory workflow.

A culture of quality and service for **30+** years

Extensive regulatory experience in the U.S., U.K., Ireland and the EU

Flexible, customized solutions to meet customer needs

Why targeted virus-specific qPCR?

- **Faster, focused answers**—qPCR can provide more focused results than broader viral-safety approaches when the viral risk is already defined
- **Risk-based testing**—Customers can select viral targets based on cell substrate, raw materials, manufacturing process and product-specific viral-risk assessment rather than relying on a generic panel
- **Sample efficient molecular testing**—Targeted molecular methods may be particularly useful where sample volume is limited or where extensive broad testing is not scientifically warranted
- **Clear results**—Defined method criteria support DETECTED / NOT DETECTED reporting for specified targets
- **Part of broader viral strategy**—Virus-specific qPCR complements adventitious-virus assays, retrovirus testing, TEM, NGS/HTS and other viral-safety methods where appropriate

TaqMan™ qPCR/ RT-qPCR assay panel

- Up to 21 virus-specific singleplex assays tested on one PCR plate
- Detection of both DNA and RNA viral targets
- Qualitative limit test reported as DETECTED/ NOT DETECTED
- 30-day routine testing turnaround time
- Use of Thermo Fisher Scientific owned products and workflows from trusted brands like Applied Biosystems™, Thermo Scientific™, and Invitrogen™
- Additional viral targets can be incorporated following appropriate qualification

Intended for master cell banks (MCB), working cell banks (WCB) and other cell-containing or cell-associated materials. Other matrices or cell lines may require appropriate matrix verification.

PPD Laboratory services GMP lab met or exceeded expectations for quality of analytical testing for 98% of our customers

Based on customer survey data

Viral target menu

Viral Target ID	Virus Name*	Viral Family	Genome Type
HSV-1	Herpes simplex virus 1	*Herpesviridae*	DNA Virus
HSV-2	Herpes simplex virus 2	*Herpesviridae*	
HHV4	Human herpesvirus 4 / Epstein–Barr virus	*Herpesviridae*	
HHV5	Human herpesvirus 5 / Human Cytomegalovirus	*Herpesviridae*	
HHV6	Human herpesvirus 6 (subtypes 6A and 6B)	*Herpesviridae*	
HHV7	Human herpesvirus 7	*Herpesviridae*	
HHV8	Human herpesvirus 8	*Herpesviridae*	
HBV	Hepatitis B virus	*Hepadnaviridae*	
B19	Human Parvovirus B19	*Parvoviridae*	
HADV-C	Human Adenovirus - Species C	*Adenoviridae*	
HPV-16	Human Papillomavirus type 16	*Papillomaviridae*	
HPV-18	Human Papillomavirus type 18	*Papillomaviridae*	
BKV	BK Polyomavirus	*Polyomaviridae*	
JCV	JC Polyomavirus	*Polyomaviridae*	
SV40	Simian Virus 40	*Polyomaviridae*	
HAV	Hepatitis A virus	*Picornaviridae*	RNA Virus
HCV	Hepatitis C virus	*Flaviviridae*	
HIV-1	Human Immunodeficiency virus type 1	*Retroviridae*	
HIV-2	Human Immunodeficiency virus type 2	*Retroviridae*	
HTLV-1	Human T-lymphotropic virus type 1	*Retroviridae*	
HTLV-2	Human T-lymphotropic virus type 2	*Retroviridae*	

* Virus names stated in the table represent the common name and/or species name as appropriate, based on coverage of Thermo Fisher TaqMan™ assays, and may not indicate full subtype coverage of the target-specific assay. Assay coverage data is available upon request; however, specific gene and sequence data of TaqMan™ assays are proprietary.

Integrated Thermo Fisher Scientific workflow

Reagents, automation, assays and instrumentation in an integrated, end-to-end GMP viral-testing workflow:

Combine automated nucleic acid extraction and highly specific TaqMan™ qPCR/ RT-qPCR detection to provide targeted viral-safety results while offering the flexibility to expand to additional viral targets as customer needs evolve.

Powered by Thermo Fisher Scientific Technologies

- Applied Biosystems™ extraction kits, gene expression assays, qPCR reagents, instrumentation, and software
- Thermo Scientific™ KingFisher™ Purification Systems
- Invitrogen™ Services

One lab, multiple locations

Athlone, Ireland

More than **82,000 sq. ft** and **450+** staff

Middleton, Wisconsin, USA

More than **550,000 sq. ft.** and **2,400+** staff

Scientific Resourcing

700+ employees embedded at customer sites across and Europe

Learn more at **thermofisher.com/ppd**

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