

Detection of Human Infectious Agents in Research Biologics

To help maintain the validity of your *in vivo* research, it is important to perform precautionary screening on your research biologics to confirm that they are free of infectious agents. Charles River provides TaqMan® PCR testing to identify human infectious agents in any of your research biologics. TaqMan® technology is ten to one hundred times more sensitive than traditional gel-based qualitative PCR, and the use of an internal probe provides incomparable specificity. This technology allows samples to be analyzed without opening reaction tubes, which prevents the release of potentially contaminating PCR products, a common downfall associated with gel-based PCR assays.

Human Agent PCR Panels

Agent	Human Essential	Human Comprehensive
Polyomavirus (John Cunningham virus)	■	■
Polyomavirus (BK virus)	■	■
Herpesvirus type 6	■	■
Herpesvirus type 7	■	■
Herpesvirus type 8	■	■
Parvovirus B19	■	■
Epstein-Barr virus	■	■
Hepatitis A virus	■	■
Hepatitis B virus	■	■
Hepatitis C virus	■	■
Papillomavirus type 16	■	■
Papillomavirus type 18	■	■
Human T-lymphotropic virus	■	■
Human cytomegalovirus	■	■
Human immunodeficiency virus type 1	■	■
Human immunodeficiency virus type 2	■	■
Adeno-associated virus	■	■
Human foamy virus	■	■
<i>Mycoplasma</i> (genus) (including <i>Acholeplasma</i>)	■	■
Lymphocytic choriomeningitis virus		■
Hantavirus hantaan		■
Hantavirus seoul		■
Spike inhibition control	■	■
Nucleic Acid Recovery Control (NARC)	■	■
Positive template control	■	■
Negative template control	■	■

Commonly Screened Research Biologics

- Cell lines – primary and continuous (including tumors and tumor cell lines)
- Cell line products, such as basement membrane matrix proteins
- Feeder cells (e.g., splenocytes and thymocytes)
- Acites
- Purified antibodies

Measures to Verify Results Accuracy

- TaqMan® PCR assays
- Sample-suitability controls – Spike and Nucleic Acid Recovery Controls
- System-suitability controls – positive and negative template
- Assays and controls performed in duplicate
- Extraction by sample set
- Confirmation testing by real-time TaqMan® PCR performed free of charge

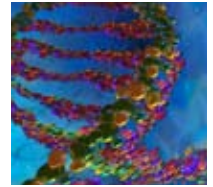
Sample Preparation and Submission

- Two frozen, undiluted aliquots of at least 200µl each
- Complimentary sample shipping materials

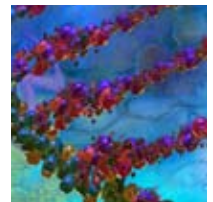


Measures to Verify Results Accuracy

Unique to Charles River's viral panel testing, we have taken extra measures to prevent false-negative results by incorporating Spike and Nucleic Acid Recovery Controls, which help to determine sample suitability; positive and negative template controls are also included to help verify system suitability. A negative result for the Spike Control, in which a known amount of exogenous template is added to the sample and tested, indicates the presence of PCR inhibitors, requiring dilution or re-extraction of the sample prior to retesting. The Nucleic Acid Recovery Control (NARC) is included to monitor the nucleic acid extraction procedure and reverse-transcription.



To limit the potential for cross contamination, each research biologics sample set is extracted as a group independent from any other institution. To ensure well-to-well assay consistency, individual assays and controls are performed in duplicate for each sample. If we find that initial testing produced a positive result, the sample is evaluated, free of charge, using real-time TaqMan® PCR testing to estimate target copy number. This method allows us to interpret results and potentially categorize samples as equivocal, therefore reducing the rate false-positive results.



Sample Preparation and Submission

When submitting research biologics for PCR testing, please provide two frozen, undiluted aliquots of at least 200µl each (to allow for confirmatory testing), shipped in vials on dry ice. Although cell number is not critical, please note on the submission form if there are more than 5 x 10⁷ cells/mL. All samples must be accompanied by a completed Infectious Disease PCR Sample Submission Form (found online at www.criver.com/info/diagnostic_sample_submission).

To submit samples, please follow the instructions found on the Infectious Disease PCR Sample Submission Form. To ensure that your samples arrive safely at our laboratory, we provide International Air Transport Association (IATA)-compliant shipping materials (sample submission vials, submission forms, shipping labels, containers, etc.) free of charge to all Charles River Research Animal Diagnostic Services customers. To request materials, simply complete our Diagnostic Services Shipping Materials Request Form (www.criver.com/info/quotes) prior to sample submission.

Please note that this service is available for research purposes only.