eurofins | BioPharma Product Testing

Unprocessed Bulk Testing

Unprocessed bulk (UPB) is the material collected directly from the bioreactor in which genetically engineered cells grow and produce product. Low levels of adventitious agents such as bacteria, yeast, fungi, molds, mycoplasma and viruses that bypass detection during raw materials testing, may grow to detectable levels under the highly enriching conditions of the bioreactor. At this point in the manufacturing process, it is optimal to test for these adventitious agents and testing of each lot of UPB is a regulatory requirement.

Eurofins BioPharma Product Testing's experienced team offers a streamlined, cGMP approach to unprocessed bulk testing to ensure product purity in order to move into downstream purification faster and with less risk of contamination.

While we can fully customize our approach to meet any testing needs, our recommended approach consists of a package of testing including, bioburden, mycoplasma testing, in vitro viral screening, and virus specific qPCR assays, all performed in 21 or 35 calendar days.

Why Choose Eurofins BioPharma Product Testing?

Our specialized sample delivery and receipt process ensures seamless communication between our lab and yours and expedites your samples into our laboratory within a few days of receipt.

We provide an individual or summary Certificate of Analysis within 21 or 35 calendar days.

Our secure, 24/7 online data portal, LabAccess.com provides timely access to your test results.

Our experienced project management and technical teams serve as your single-source solution for all of your cell line and production needs.

Our Recommended Testing

- Bioburden testing
- Mycoplasma Testing (Harmonized Compendial or PCR)
- *In vitro* viral screening
- Virus specific qPCR

Cell Lines Available for *in vitro* Viral Screening

- Vero
- MRC-5
- CHO K1
- A9
- NIH 3T3
- HeLa
- 324K
- HT1080
- MDCK
- A549
- BHK-21
- MDBK
- Sf9
- HEK-293
- RK-13
- LLC-MK2
- Other cell lines upon request

Testing Sample Requirements

The 21-day release testing program utilizes the shorter in vitro adventitious agent test method (14-day), as well as using the molecular-based PCR approach to mycoplasma testing. The table below includes information on the test methods, test codes, turnaround times, and sample requirements. Consult with your regulatory reviewer if the shorter UPB test approach is preferred.

21 Calendar Day Turnaround Time			
Method	**US Test Codes**	**US TAT**	**US Sample Requirements**
Bioburden Suitability	GPM33, GPM39	16 Days	20mL
Bioburden Routine	GPM02, GPM05	21 Days	25mL
Mycoplasma PCR Interference	QL0EG	5 Days	11mL
Mycoplasma PCR	QL0EC	21 Days	11mL
14 Day *in vitro* Adventitious Agent CHO Detector Line	QL09B		7mL Bulk Harvest
14 Day *in vitro* Adventitious Agent MRC-5 Detector Line	QL098		7mL Bulk Harvest
14 Day *in vitro* Adventitious Agent Vero Detector Line	QL09C		7mL Bulk Harvest
Optional 4th indicator cell line - 324K or other	Varies		7mL Bulk Harvest
MMV PCR Routine	QL0EB	21 Days	2x2mL
TEM*	QL116	Varies	10mL Harvest

The 35-day release testing program is the traditional approach utilizing the longer test methods. The table below includes information on the test methods, test codes, turn around times, and sample requirements.

35 Calendar Day Turnaround Time			
Method	**US Test Codes**	**US TAT**	**US Sample Requirements**
Bioburden Suitability	GPM33, GPM39	16 Days	20mL
Bioburden Routine	GPM02, GPM05	21 Days	25mL
Mycoplasmastasis	GPMYK, GPMYL	35 Days	2x25mL, 4x1.5mL > $1x10e^6$
Mycoplasma GMP Analysis	GPMYM, GPMYN		2x12mL, 2x1.5mL > $1x10e^6$
28 Day *in vitro* Adventitious Agent CHO Detector Line	QL07X	35 Days	7mL Bulk Harvest
28 Day *in vitro* Adventitious Agent MRC-5 Detector Line	QL07V		7mL Bulk Harvest
28 Day *in vitro* Adventitious Agent Vero Detector Line	QL07W		7mL Bulk Harvest
MMV PCR Routine	QL0EB	21 Days	2x2mL
TEM*	QL116	Varies	10mL Harvest

*If possible, TEM testing should be performed on 3 lots of UPB to assess retroviral load to help design the IND or BLA viral clearance study. After 3 lots have been tested, the TEM assay is no longer required.

The MMV interference and mycoplasmastasis test methods only need to be performed once for early stage clinical trials. For late stage/commercialization, product specific qualifications (multiple lots, multiple spike controls) should be considered.