eurofins | BioPharma Product Testing



Mycoplasma Testing

Mycoplasma contamination events can lead to altered physio-chemical properties of cells, potentially resulting in reduced or altered cellular products and perhaps unsafe biopharmaceuticals. Thus, testing for the presence of mycoplasma contamination in development and manufacturing is a requirement by worldwide regulatory agencies. Guidance for this testing is provided in the United States Pharmacopeia (USP) Chapter <63> Mycoplasma Tests, European Pharmacopoeia (EP) Chapter 2.6.7 Mycoplasmas, Japanese Pharmacopoeia, Chinese Pharmacopoeia, FDA 1993 Points to Consider (PTC), and the Code of Federal Regulations 21 CFR 610.30 test for mycoplasma.

In October 2010, the U.S. and European mycoplasma methods were brought into alignment, enabling the creation of harmonized direct culture and indirect cell culture assays. A single assay of each type will now be able to meet or exceed regulatory requirements. Viral vaccines, however, require testing in accordance with 21 CFR 610.30. The 21 CFR 610.30 is a more extensive direct culture method with multiple incubation conditions and growth media requirements that can not be harmonized with the USP/EP/JP/PTC assays. For the Chinese market, Eurofins BioPharma Product Testing also offers the CP test.

Eurofins BioPharma Product Testing offers harmonized mycoplasma assays, which comply with the USP <63> monograph, FDA 1993, PTC, JP, CP and the EP 2.6.7 Guidelines, as well as a fully validated 21 CFR 610.30 method.

Why Choose Eurofins BioPharma Product Testing?

- We provide fully characterized and qualified positive control strains.
- We have a formalized analyst training program, including required proficiency assessments using blind samples.
- We perform mycoplasmastasis testing to qualify each assay for each test article.
- With over 20 years of experience, we offer support for mycoplasma clearance studies, including consultation and study design.
- We utilize an optimized proprietary media.

Mycoplasma Assays

Eurofins BioPharma Product Testing offers comprehensive mycoplasma services that are available for:

- Testing of master, working and end-of-production cell banks
- Unprocessed bulk harvest
- Cell culture raw materials (e.g., serum, trypsin)
- Final product release
- AT MPS

Facilities & Instrumentation

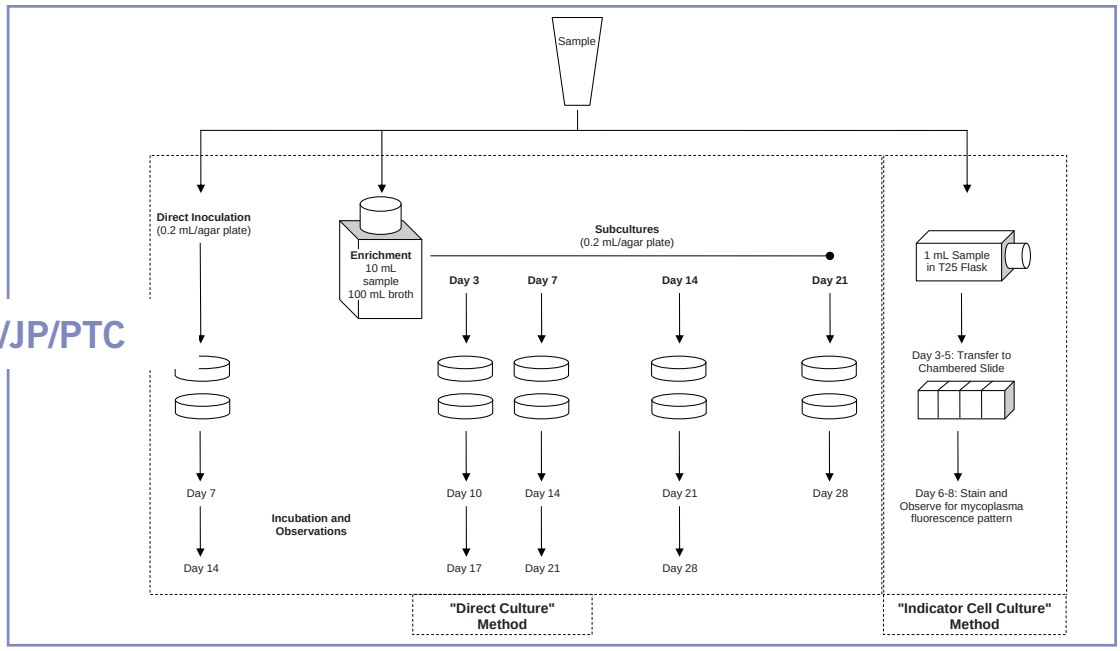
- Limited-access laboratories that are pressure-controlled, HEPA-filtered and operate on independent air handling systems to prevent cross-contamination.
- Separate areas for testing of client test articles and handling of positive control strains, including a unidirectional workflow that ensures handling of test articles prior to manipulating positive controls on each working day.
- Validated cleaning disinfection and environmental monitoring programs.
- Access to our proprietary LabAccess.com system, allowing 24/7 easy access to study information, final reports and actual raw study data.

eurofins

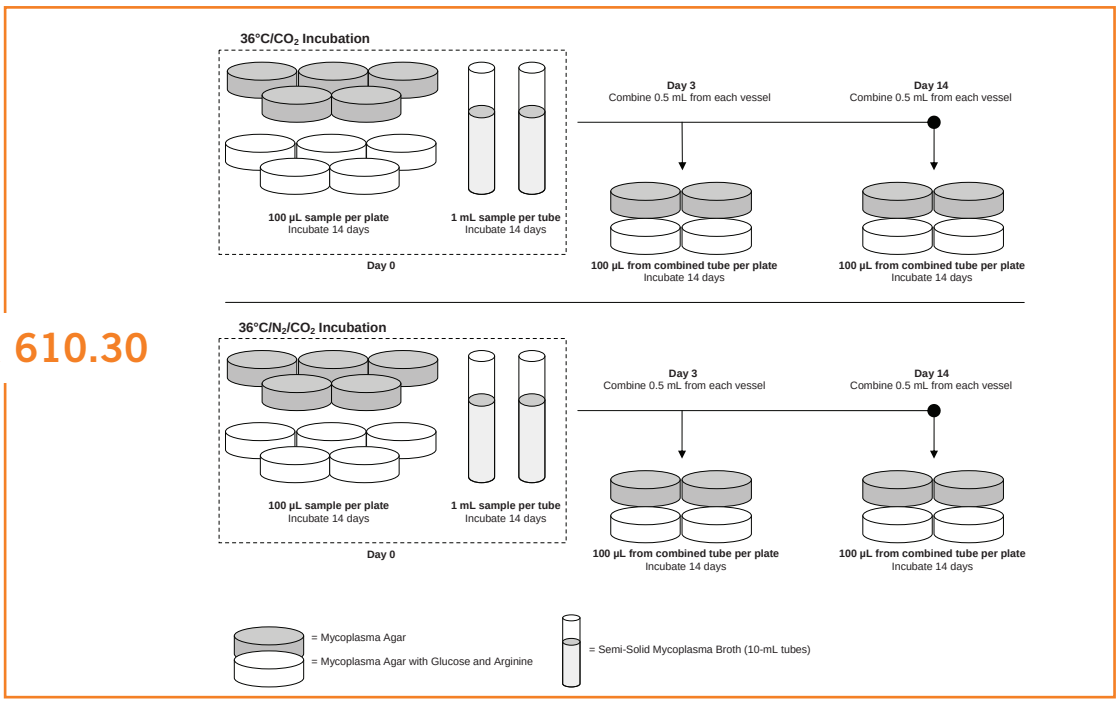
BioPharma Product Testing



USP/EP/JP/PTC



21 CFR 610.30



Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Raw Materials Testing
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Stability Testing & Storage • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
Professional Scientific Services® (PSS)

Global Facilities

Australia	Denmark	India	Japan	Spain	UK
Belgium	France	Ireland	Netherlands	Sweden	US
Canada	Germany	Italy	New Zealand	Switzerland	

www.eurofins.com/BPT