



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, 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/PTC assays.

Lancaster Laboratories offers harmonized mycoplasma assays, which comply with the USP <63> monograph, FDA 1993, PTC and the EP 2.6.7 Guidelines, as well as a fully validated 21 CFR 610.30 method.

Why Choose Lancaster Laboratories?

- 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 mycoplasma testing to qualify each assay for each test article.
- We offer support for mycoplasma clearance studies, including consultation and study design.



Mycoplasma Assays

Lancaster Laboratories offers comprehensive mycoplasma services that are available for:

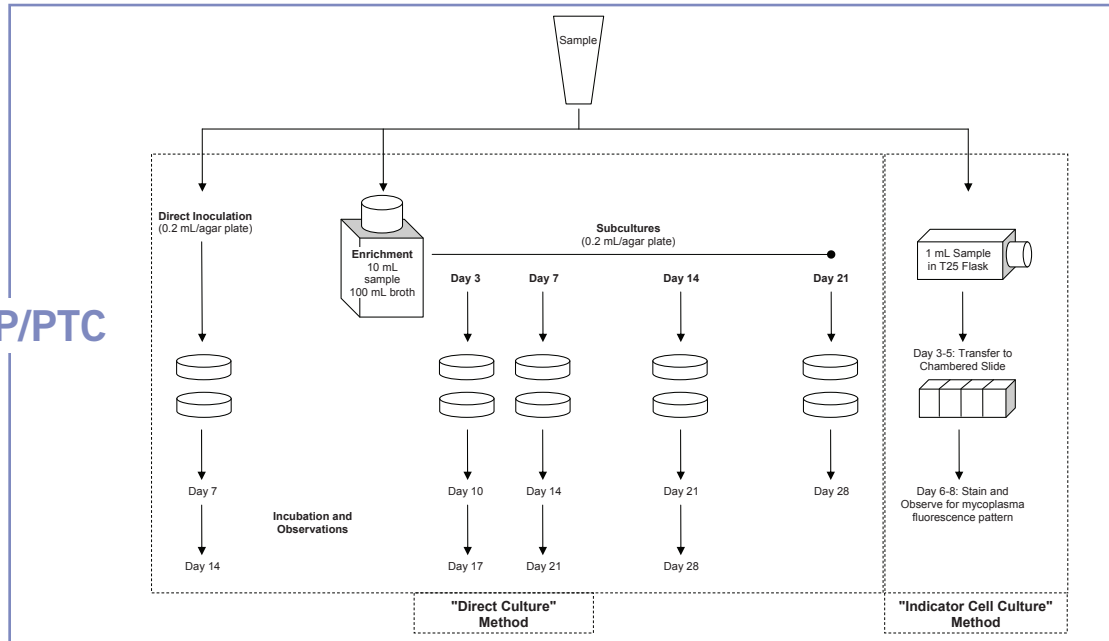
- Testing of master, working and end-of-production cell banks
- Unprocessed bulk harvest
- Cell culture raw materials (e.g., serum, trypsin)
- Final product release

Facilities & Equipment

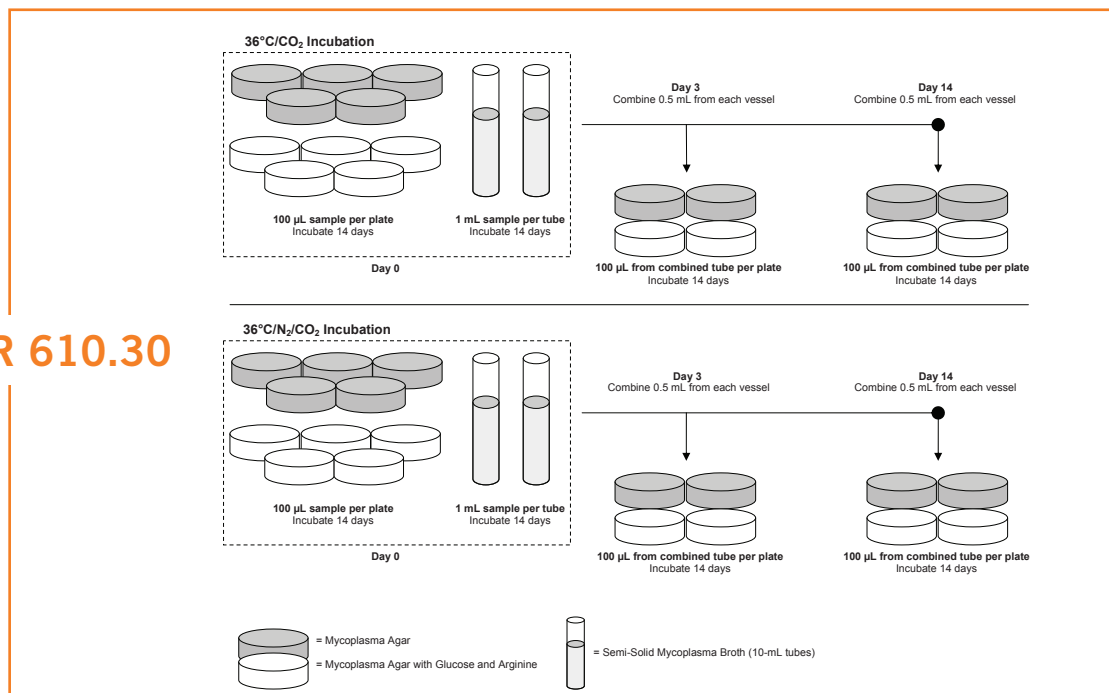
- Limited-access laboratories that are pressure-controlled, HEPA-filtered and operate on independent air handling systems to prevent cross-contamination.
- Separate laboratories for testing of client test articles and handling of positive control strains, including a unidirectional workflow that ensures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



USP/EP/PTC



21 CFR 610.30



Discover our solutions at: LancasterLabsPharm.com

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 Method Development & Validation
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