



## Rapid Mycoplasma Testing

Mycoplasma contamination of cell lines used to produce biopharmaceutical products can disrupt cellular growth and metabolism and lead to changes in gene expression, which results in decreased product quantity and quality. For these reasons, worldwide regulatory agencies require that biotechnological products produced in cell substrates be tested to ensure the absence of mycoplasma contamination.

The challenge with mycoplasma testing is that current procedures are time consuming, requiring a 28-day duration. However, this time requirement is not amenable for obtaining the rapid lot release testing results needed for biopharmaceutical products that have short half-lives or those that are in high market demand. The lengthy assay period is also not conducive to the rapid screening of raw materials intended for use in future production, nor to the rapid in-process screening of intermediates for the purpose of detecting and containing contamination events.

Eurofins BioPharma Product Testing now offers a rapid mycoplasma test comparable in sensitivity to the 28-day compendial method.

### Instrumentation

To execute this rapid technology, Eurofins BioPharma Product Testing uses ABI's MycoSEQ Real Time Detection System for Mycoplasma. This SYBR Green based system, which utilizes magnetic beads to purify mycoplasma DNA, has the capability of processing a volume of material comparable to that tested in the compendial method, making it preferable to rapid mycoplasma detection methods that have volume limitations. The system incorporates features that allow it to preferentially detect over 90 different viable mycoplasma DNAs.

### Applications

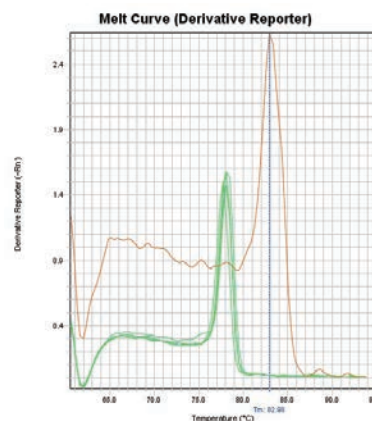
- Products with short half-lives (i.e., cell therapies).
- Unprocess Bulk Cell Culture Harvest.
- Cell Banks.
- Raw Materials.
- Process Evaluation/Clearance Studies.

### Why Choose Eurofins BioPharma Product Testing?

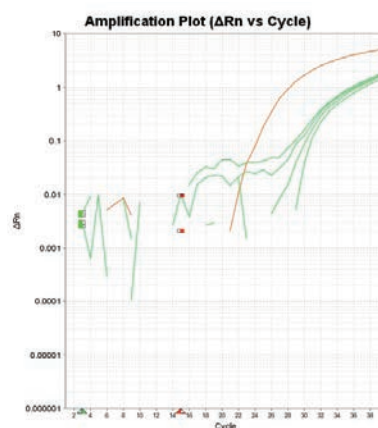
- We can support all mycoplasma needs, including USP, EP, Points to Consider and harmonized methodologies.
- We offer GMP and non-GMP Assays.

### Advantages of Using our Validated Assay

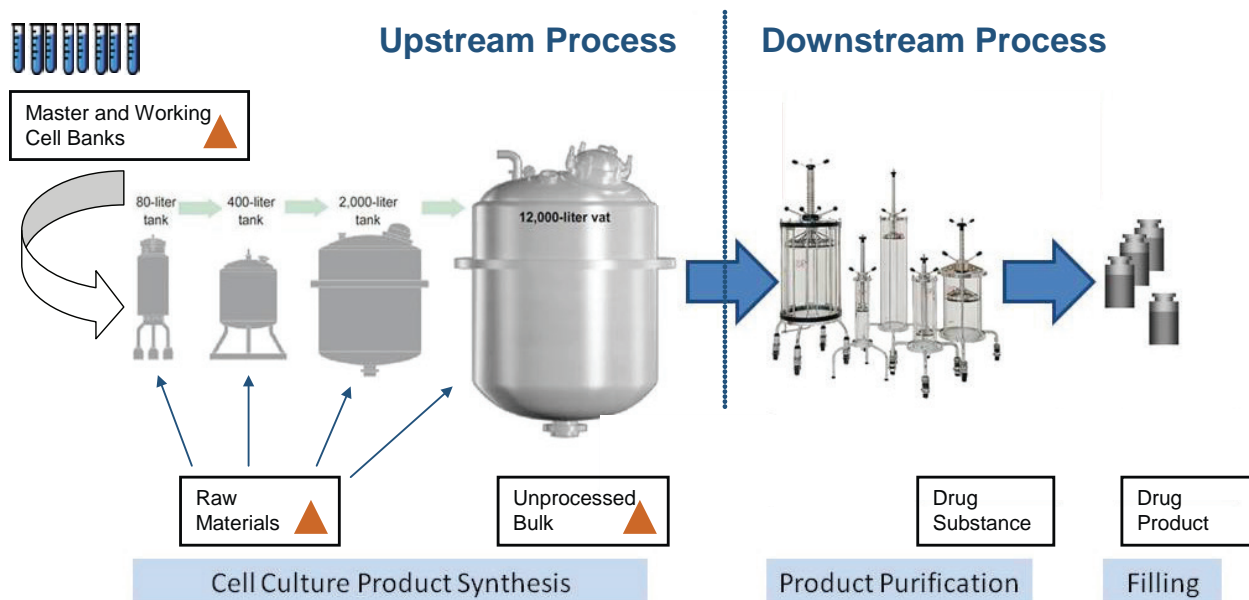
- Ensures **rapid, robust and reliable** culture-free mycoplasma detection.
- Delivers results with a full CoA release within 5 days.
- Achieves sensitivity comparable to culture-based compendial testing.
- Meets European Pharmacopeia 2.6.7 guidelines.



Melt curves of Applied Biosystems' discriminatory positive control (tan curve) and a CHO-S aliquot spiked with live mycoplasma (*M. pneumoniae* at  $\leq 10$  CFU/mL; green curves)



Amplification plots and melt curves of Applied Biosystems' discriminatory positive control (tan curve) and a CHO-S aliquot spiked with live mycoplasma (*M. pneumoniae* at  $\leq 10$  CFU/mL; green curves). The discriminatory positive control has a  $T_m$  range of 82-86°C which is distinctly different than the  $T_m$  range for mycoplasma (76-81°C). The different profile allows for the differentiation between a true positive mycoplasma contamination and a potential false positive result.



**▲ Rapid Mycoplasma Testing Point**

**Species for which Eurofins Biopharma Product Testing performed a user verification of limit of detection:**

*M. orale*  
*M. hyorhinis* -  $\alpha$   
*M. pneumoniae*  
*S. Melleiferum*

**Species Detected by ABI MycoSEQ System**

*A. laidlawii*  
*M. pneumoniae*  
*M. orale*  
*M. hyorhinis*  
*M. synoviae*  
*M. fermentans*  
*M. arginini*  
*S. citri*  
*M. salivarium*  
*M. hominis*

**Bold** = EP listed strains

Note: As stated above, MycoSEQ can detect over 90 mycoplasma species according to the vendor. The species listed above were used in the original vendor validation.

### 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	