Mycoplasma Testing Solutions for Advanced Therapies

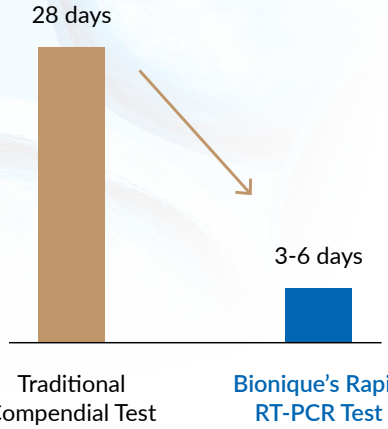
Rapid

Mycoplasma testing is a required release test for cell and gene therapy products as specified in the major pharmacopeias. Legacy compendial methods require ≥28 days to generate results. However, many advanced therapies have a total production time of 9-14 days – making a 28-day compendial culture-based test unsuitable as it extends the lot release time beyond the actual production time. Other advanced therapies have a short shelf-life that rule out a 28-day lot release test.

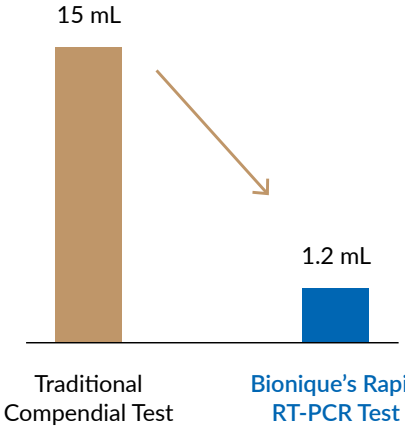
Still others are personalized therapeutics of such low batch volume that traditional test sample volumes consume much of the patient batch.

Bionique has resolved these issues by offering a validated alternative nucleic acid-based test method that reduces the time for mycoplasma testing of cell and gene therapies to days instead of weeks with lower sample volumes and high sensitivity.

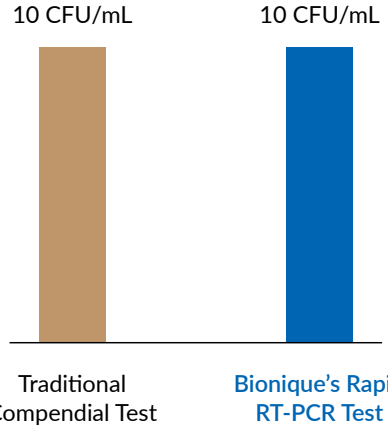
Up to 89% time reduction



92% reduction in sample volume



Equivalent Sensitivity



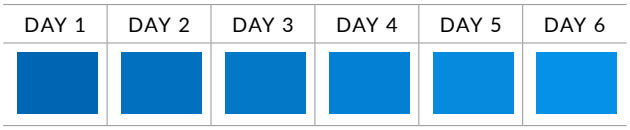
Reliable

Bionique understands that your cell or gene therapy has unique requirements that may not fit an off-the-shelf mycoplasma testing solution. To ensure the most reliable test for your product, we offer custom assay development and consultancy to establish an alternative rapid lot release test after successful completion of a phase-appropriate validation.

Robust

Bionique's validated, Hybrid Real-Time PCR assay (Cat. No. M-1500) incorporates a brief enrichment period using our proprietary mycoplasma culture medium followed by RT-PCR analysis. This method offers the key advantages of enhanced sensitivity, neutralization of potential inhibitory matrix components, and the ability to differentiate between viable and nonviable contaminations (if necessary).

<1 Week Rapid Testing
Ideal for Cell & Gene Therapies



Bionique's M-1500 PCR Assay can be used to support a rapid lot release test after the successful completion of a phase-appropriate validation.

Real-Time PCR with Broth Enrichment Assay Catalog No. M-1500

Technology	Total Testing Time	Sample Requirements	Target Detection Limit	Validation
Brief Broth Enrichment + Real-Time PCR	3-6 days	Minimum Test Volume: 1.2 mL*	10 CFU/mL	GMP Testing for in-process or lot release testing

* For first time submission of a new sample type, a minimum volume of 2.4 mL is required to perform the matrix qualification and sample analysis.

RT-PCR Qualification

Bionique performs a matrix qualification for initial submission of sample or matrix type to ensure the absence of interfering substances could impact assay performance (Cat. No. M-1500Q).

Testing Points for Cell and Gene Therapies

Raw Materials

- Transfection reagents
- Activation agents
- Magnetic separation agents
- Cell culture media and supplements

Antibodies and magnetic separation reagents used to select donor cells of interest can be contaminated with mycoplasma.

Transfection reagents, and activation agents like peptides, cytokines, and tumor can introduce unwanted contamination such as mycoplasma.

Starting Materials

- Plasmids
- Viral vectors

Plasmids and viral vectors used in cell and gene therapy manufacturing can introduce unwanted contamination such as mycoplasma.

Manufacturers of these components, as well as cell & gene therapy developers should ensure their products are tested by a well validated and sensitive assay.

Cell & Virus Banks

It is recommended that master cell banks, working cell banks, master viral banks, working viral banks, and bulk viral harvest material be tested.

Cell lines sourced from external providers should be quarantined and tested for mycoplasma prior to use.

Bulk Harvest & Final Drug Product

Final harvest material and final drug product should be tested for mycoplasma as a lot release test.

An important CMC consideration for CGT development is a phase-appropriate method qualification or validation to not only ensure the method's suitability towards the specific product tested, but to also fulfill the key performance parameters required by the regulatory authorities.

NOTE: Raw materials with less time dependency can also be tested for mycoplasma using our compendial 28-day culture test such as Bionique's Harmonized USP <63> Mycoplasma Test.

Scan the QR code to learn more about our PCR Sample Submission Instructions ⟶