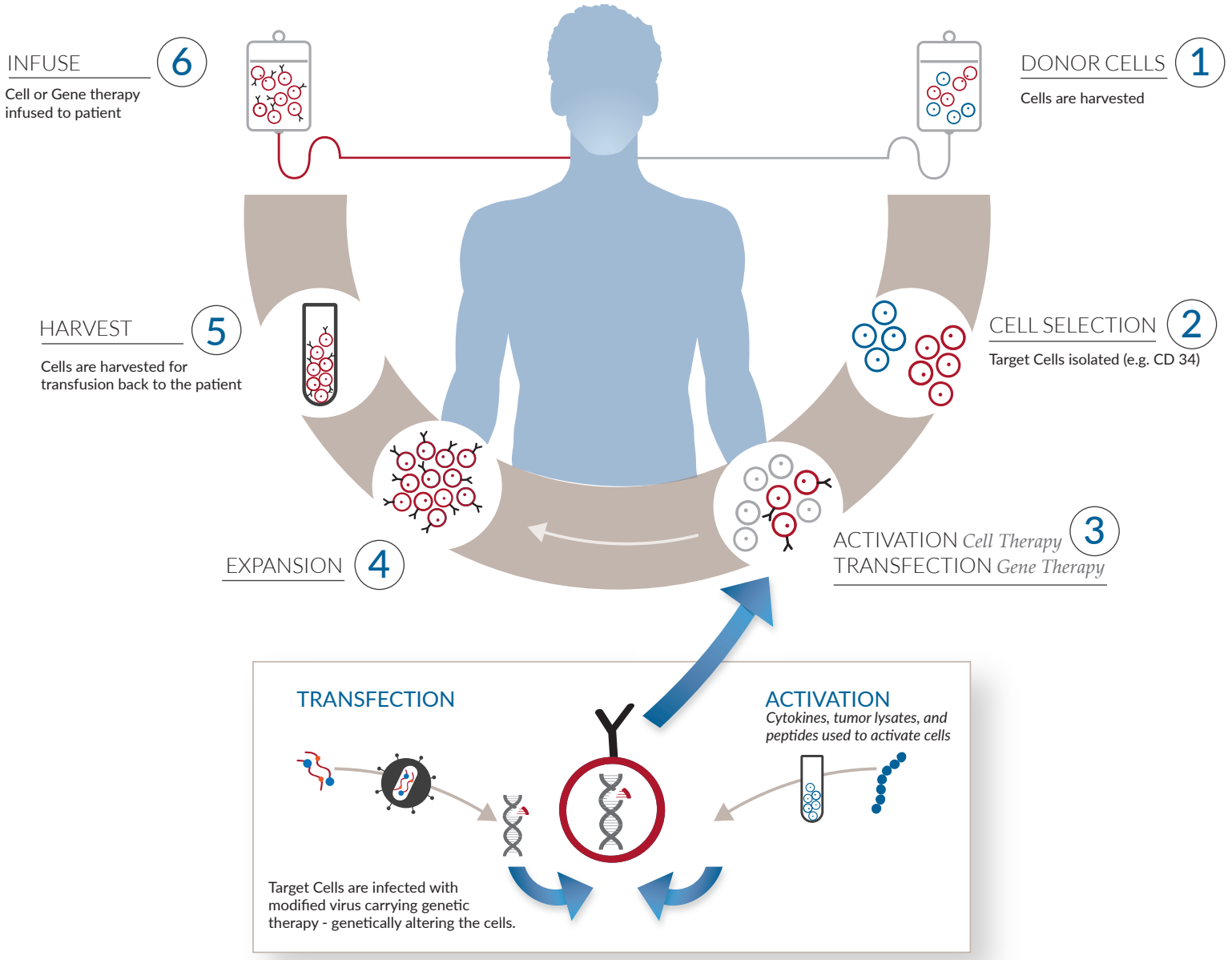
bionique Testing Laboratories

BIONIQUE'S MYCOPLASMA TESTING SOLUTION

to ensuring the integrity and safety of Cell and Gene Therapies



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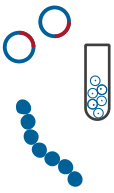
The unique nature of cell and gene therapy products, including limited production volume, high cell densities, limited shelf life, and other factors demand new approaches to mycoplasma testing. Bionique has evolved the tools needed to address the unique product characteristics and requirements inclusive of rapid, reliable, and small volume testing assays. Bionique has developed a routine rapid, reliable and robust molecular method for testing of cell and gene therapy products with sensitivity comparable to the 28-day compendial methods. In addition, Bionique offers custom assay development and consultancy to support an alternative rapid lot release assay after successful completion of a product-specific validation.

OUR RECOMMENDATIONS FOR MYCOPLASMA ANALYTICAL TESTING TO SUPPORT THE CELL AND GENE THERAPY PROCESSES

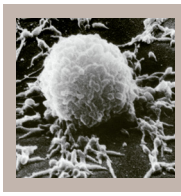
Cell Selection: Antibodies and magnetic separation reagents used to select donor cells of interest can be contaminated with mycoplasma.

Plasmids, viral vectors, transfection reagents, and activation agents like peptides, cytokines, and tumor lysates used in the production of cell and gene therapy manufacturing can introduce unwanted contamination such as mycoplasma. Manufacturers of these components, as well as, cell and gene therapy developers should ensure their products are tested by a well validated and sensitive assay capable of detecting 10 CFU/mL of mycoplasma. Plasmids used for gene insertion should be tested for purity before use.



Likewise, its 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 and Final Drug Product: Final harvest material where volume of material available for analytical testing may be limited, consider Bionique Cat. No. M-1500—Real-Time PCR with Broth Enrichment Assay which requires only 1.2 mL for test analysis.



FROM RESEARCH TO VALIDATION...
Providing unparalleled Mycoplasma testing expertise to move your products forward.

RAPID MICROBIAL METHODS (RMM) FOR LOT RELEASE OF CELL AND GENE THERAPIES

Bionique® is fully engaged in the advancement and support of emerging Rapid Microbial Methods (RMM) for mycoplasma detection. Our comprehensive knowledge and experience with these technologies allows us to offer a full spectrum of validation and consultancy services to expedite the implementation of a rapid method for the detection of mycoplasma. Contact us today for free consultation of how we can help validate a rapid method for mycoplasma lot release testing for your program.

BIONIQUE'S HYBRID REAL-TIME PCR ASSAY:
An Alternative to Cell Culture-Based Methods for Mycoplasma Detection

Bionique's validated, Real-Time PCR assay (Cat. No. M-1500) incorporates a brief broth enrichment of a sample with our proprietary media which 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. Bionique performs a matrix qualification assay on initial submission of a sample or matrix type, (Cat. No. M-1500Q). Results and delivery of Certificate of Analysis available within four to six days from sample set up.

Cell Culture Testing

- Real-Time Polymerase Chain Reaction (PCR) Mycoplasma Tests
- Multi- Media Direct Culture Method with DNA Fluorochrome Staining Assay (Cat. No. M-250)

Lot Release Testing

- Quality control mycoplasma testing for final lot release of biologics in accordance with USP <63> and harmonized with E.P. chapter 2.6.7 Mycoplasma, Japanese Pharmacopoeia (JP) Edition 17, and the FDA's 1993 *Points to Consider* (Cat. No. M-1400/M-1450).
- USP<63> Qualification assays upon initial submission of test articles as required by the USP <63> method.

Raw Materials Testing

- Large Volume Barile Test (Cat. No. M-300)
- USP <63> Harmonized Mycoplasma Assay (Cat. No. M-1400/M-1450)