Bionique's Mycoplasma Real-Time PCR Assay: An Alternative to Cell Culture-Based Methods for Mycoplasma Detection.

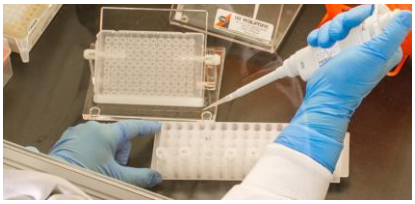
As an industry leader, Bionique is actively engaged in the development and evaluation of emerging methods that meet the unique challenges of cell and gene therapies while simultaneously offering faster time to results for testing of cell cultures and raw materials. Bionique has validated a rapid mycoplasma detection method for in-process testing. Samples are briefly enriched in our proprietary media which offers the key advantages of enhanced sensitivity, the neutralization of potential inhibitory matrix components, and the ability to differentiate between viable and nonviable contaminations if necessary. This same platform, or a variation thereof, can be used to support a rapid lot release test after the successful completion of a product-specific validation.

Contact Bionique to see how our GMP-compliant PCR testing can benefit you!

Call 518-891-2356 or e-mail PCR@bionique.com

Now Available

- **M-1500 Real-Time PCR with Broth Enrichment**
- **M-1500Q Real-Time PCR Matrix Qualification**



GMP PCR Testing Services

M-1500 Real-Time PCR with Broth Enrichment

A specific and sensitive method for the detection of mycoplasma using Real-time PCR coupled with a pre-enrichment procedure. Each assay includes a comprehensive control panel to ensure accurate results.

- Total Testing Time: 3 - 6 days
- Minimum Test Volume is 1.2 mL

M-1500Q Real-Time PCR Matrix Qualification

Samples should be qualified prior to testing in order to evaluate potential influence of the sample matrix on the culture enrichment component and PCR efficiency for any given sample type. This qualification only needs to be conducted once unless there are any changes in the matrix of the test article.

- Total Testing Time: 3 - 6 days
- Minimum Test Volume is 1.2 mL

Discover Bionique for your PCR mycoplasma testing needs

Faster Results

Accurate results generated with a turnaround time (TAT) of 3 -6 days versus the standard 28 days for culture-based testing.

Outstanding Quality

A comprehensive control panel ensures the outstanding performance of assays and results you can trust.

High Sensitivity

LLOD of 10 CFU/mL in the presence of low (< 10 GC/CFU) genomic copy ratio (80 CFU/mL for *M. pneumoniae* in the presence of > $10e^6$/mL CHO).

Excellent Service

With over 27 years of experience, we offer unparalleled knowledge, focus and expertise in QC and Biosafety testing for mycoplasma.

Our portfolio also includes custom assay validation services to support the development of molecular-based rapid methods.

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