bionique Testing Laboratories

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 raw materials, cell banks, virus seed stocks, unprocessed bulk harvest and final products. 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!

www.bionique.com/about/contact.html | 518.891.2356 | info@bionique.com

GMP PCR TESTING SERVICES *ORDER NOW:*

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 > 10e6/mL CHO cells).

Excellent Service
Having 30 years of experience, we offer unparalleled knowledge, focus and expertise in QC and Biosafety testing for mycoplasma.

OUR PORTFOLIO ALSO INCLUDES

Custom method development & validation of rapid molecular-based technologies.