

Cell Culture Testing

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 to enhance method sensitivity. Each assay includes a comprehensive control panel to assure accurate results.

GMP service

Total Testing Time: 3-6 days

Sample Requirements: Minimum Test Volume = 1.2 mL

M-1500Q Real-Time PCR Matrix Qualification

Any sample submitted for Real-Time PCR analysis should be qualified within the context of the assay to evaluate the effect of the sample matrix on the enrichment procedure and Real-Time PCR performance. This analysis would only need to be conducted once for any given sample unless there are changes in the test article components.

GMP service

Total Testing Time: 3-6 days

Sample Requirements: Minimum Test Volume = 1.2 mL

M-100 CELLshipper® Mycoplasma Detection Kit

Our exclusive CELLshipper® DNA fluorochrome staining kit is a fast and convenient qualitative assay for the detection of mycoplasma contamination in cell cultures. Purchase the slides and store in your lab for use at your convenience. Simply add your cell culture sample, fix and dry. Return the (hazard-free) slides to our laboratory for diagnosis.

Total Testing Time: Results within 48 hours of receipt.

M-150 DNA Fluorochrome Staining Assay with Indicator Cell Line

DNA fluorochrome staining assay with sample inoculation on an indicator cell line. This approach enhances the assay sensitivity by reducing background from genetically unstable cell lines (e.g. hybridomas, etc.) and amplifies the titer of mycoplasma contaminants. Developed for the detection of mycoplasma contamination in cell cultures and related samples, this test provides reliable and timely results.

GMP service

Total Testing Time: 4-5 days

Sample Requirements: Minimum Test Volume = 2 mL

M-175 CELLshipper Mycoplasma Detection Kit (In-house sample preparation and slide fixation)

This test includes the use of our exclusive CELLshipper® DNA fluorochrome staining kit. However, all the steps including the preliminary sample collection, slide preparation and fixation are performed by our expert Technical Staff. This test is designed to screen for mycoplasma contamination in a variety of cell culture samples (i.e. adherent and non-adherent cell lines.)

Total Testing Time: 1-2 days

Sample Requirements: Minimum Test Volume = 2 mL

Cell Culture Testing (Continued)

M-250 Multi-Media Direct Culture Method with DNA Fluorochrome Staining Assay

Multi-media direct culture procedure using three (3) mycoplasma media preparations combined with the indicator cell culture procedure. The DNA fluorochrome assay with indicator cell line enhances the detection of non-cultivable mycoplasma species. This is the optimum screening procedure for detecting mycoplasma contamination in cell cultures.

Total testing time: 28 days

Sample Requirements: Minimum Test Volume = 5 mL

GMP service

Raw Materials Testing

M-155 DNA Fluorochrome Staining Assay with Indicator Cell Line for Sera Products

Mycoplasma screening of serum products by DNA fluorochrome staining assay with indicator cell line. The enrichment component of this method enhances detection of non-cultivable mycoplasma species.

Total Testing Time: 3-5 days

Sample Requirements: Minimum test volume = 35 mL

M-300 Large Volume Barile Method

Mycoplasma testing of sera, media and bioproducts by direct culture method described in the Large Volume Barile Method. Bionique enhances the test by utilizing three (3) mycoplasma media formulations to maximize detection of potentially fastidious cultivable mycoplasma species.

Total Testing Time: 28 days

Sample Requirements:
Minimum test volume = 55 mL; 100 mL aliquot preferred

GMP Service

M-350 Large Volume Barile Method with DNA Fluorochrome Staining Assay

This test consists of the Large Volume Barile Method (M-300 testing service) with the addition of the Indicator Cell Culture procedure and DNA fluorochrome staining assay (M-155 testing service). Advantages of this combined approach include detection of both the cultivable and non-cultivable mycoplasma species.

Total Testing Time: 28 days

Sample Requirements:
Minimum test volume = 90 mL; 100 mL aliquot preferred

GMP service

Lot Release Testing

M-700 FDA Points to Consider Method (1993)

Mycoplasma screening of biologicals and cell cultures used to produce biologicals by direct culture method and indicator cell culture procedure. This test is recommended for each lot of product harvest concentrate and the master cell banks, working cell stocks and cell substrates used for the manufacturing of biopharmaceutical products.

GMP Service

Total Testing Time: 28 days

Sample Requirements: Minimum Test Volume = 15 mL

M-800 Mycoplasma Test for Human Vaccines and Biologicals Compliance with 21 CFR 610.30

Mycoplasma screening of vaccines and biologicals for human use in compliance with 21 CFR 610.30 Subpart D - Test for Mycoplasmas. Bionique enhances the regulatory required direct-culture based method by incorporating the DNA fluorochrome staining assay with indicator cell line to detect potentially non-cultivable mycoplasma species.

GMP service

Total Testing Time: 28 days

Sample Requirements:
Minimum Test Volume = 12 mL Test Article and
12 mL of Control Fluid

M-1000 Mycoplasma Validation Study

Bionique offers Mycoplasma validation studies to validate our M-700 or M-800 Assay for an individual test article. The qualification study is designed to determine the presence or absence of product-specific inhibition of mycoplasma growth within our assays. This test is recommended only once for any given final product unless changes within the test article matrix or manufacturing processes occur.

M-1400 Harmonized USP <63> Mycoplasma Test

Bionique offers mycoplasma testing in full accordance with USP <63> and harmonized with the U.S. FDA Points to Consider and European Pharmacopoeia methods. This test can detect both agar cultivable and non-cultivable mycoplasmas. The M-1400 USP <63> test may be applied for testing tissues and/or cell cultures used to produce test articles, digest broth, or any material in which mycoplasma contamination is suspected.

GMP service

Total Testing Time: 28 days

Sample Requirements: Minimum Test Volume = 15 mL

M-1450 Inhibition Testing for the Harmonized USP <63> Mycoplasma Test

The M-1450 Test is designed to determine the presence or absence of product-specific inhibition of mycoplasma growth within Bionique's Harmonized USP <63> assay. USP <63> and EP 2.6.7 both require the testing for inhibitory substances in the test article. This qualification study is recommended only once for any given final product unless changes within the test article matrix or manufacturing processes occur.

GMP service

Mycoplasma Clean Up and Elimination

M-500 Antibiotic Sensitivity Testing

This test determines the susceptibility of a mycoplasma isolate to a range of antibiotics. Resistance to antibiotics, whether inherent or acquired, is a well known characteristic of mycoplasma. Therefore, the antibiotic sensitivity profile developed in this assay provides information regarding potential therapeutic agents targeted for an individual mycoplasma species and strain. Sample must currently be on test by a direct culture method at Bionique.

M-900 Mycoplasma Elimination

Elimination of mycoplasmas from contaminated cell cultures. Cells are treated with an antibiotic cocktail specifically formulated for the isolated mycoplasma(s). Requires M-250 and M-500, preliminary testing. R&D Non-GMP service.

Consultation with Technical Services required prior to sample submission.

Other Products and Services

M-100 CELLshipper® Mycoplasma Detection Kit

Our exclusive CELLshipper® DNA fluorochrome staining kit is a fast and convenient qualitative assay for the detection of mycoplasma contamination in cell cultures. Purchase the slides and store in your lab for use at your convenience. Simply add your cell culture sample, fix and dry. Return the (hazard-free) slides to our laboratory for diagnosis.

Total Testing Time: Results within 48 hours of receipt.

M-600 Mycoplasma Control Slides

Five (5) control slides are provided per order for in-house DNA fluorochrome staining. Each slide contains two negative and two positive mycoplasma controls, fixed and ready for staining. These Mycoplasma Quality Control slides are designed to verify the quality of reagents and staining methods used for the detection of mycoplasma contamination via DNA fluorochrome staining. For use as quality controls in your laboratory.

Mycoplasma Antigen Preparations

Custom service providing high quality, purified antigen for use as positive controls in bioassays.

Mycoplasma Reference Standards

M-1200 Non-viable Mycoplasma Lysate Preparations

Quantitated non-viable mycoplasma defined in GC/mL

- Avoids the introduction of viable microorganisms into the laboratory and facility
- Developed to optimize the mycoplasma DNA isolation process of PCR-based rapid microbial methods for mycoplasma detection
- May be used to evaluate all processes downstream of centrifugation
- Risk-free proficiency testing and personnel training on your isolation method and PCR assay

M-1250 Genomic Mycoplasma DNA Preparations

Quantitated mycoplasma DNA defined in GC/uL

- Avoids the introduction of viable microorganisms into the laboratory and facility
- Proof-of-Concept (POC) evaluations for your PCR assay
- Post-centrifugation spiking studies to evaluate analytical sensitivity and specificity
- Risk-free proficiency testing and personnel training on your PCR assay

Validation and Consultancy Services

Bionique Testing Laboratories also offers validation and consultancy services related to the evaluation and implementation of **Rapid Microbial Methods** for the detection of mycoplasma. Our vast in-depth knowledge and experience with these technologies allows us to provide a wide range of services to include phase appropriate method development to validation studies for regulatory submission. Our technical experts are able to customize the projects to ensure we are meeting the individual scientific needs and regulatory expectations of our clients.

Contact Us:

For further information or inquiries please contact us at info@bionique.com or call us directly at +1 518-891-2356.

Bionique requests that you contact us 48 hours in advance of shipping your samples. Information can be forwarded either by contacting us directly by phone at (518) 891-2356, faxing your sample submission form to (518) 891-5753, or e-mailing your sample submission form to reporting@bionique.com. Please provide details on the number of samples shipped and the mycoplasma testing service requested by catalog #. This will assist us in meeting your needs for quality and timely service.

Effective Date: Sept 2016