Mycoplasma Testing Assays

The integrity and biosafety of your biopharmaceutical product is of utmost importance. At Bionique Testing Laboratories, we've spent over 30 years honing our skills in the critical but nuanced world of mycoplasma testing.

	M-150	M-250	M-300	M-350	M-700	M-1400/M-1450	M-1500/M-1500Q	ASSAY VALIDATION
CELL LINES	⊙	⊙			⊙	⊙	⊙	
RAW MATERIALS			⊙	⊙		⊙	⊙	
CLINICAL TRIAL MATERIALS					⊙	⊙	⊙	⊙
COMMERCIAL PRODUCTS					⊙	⊙	⊙	⊙

● May require product specific phase-appropriate validation.

● Requires product specific validation.

TEST

- **M-150** DNA Fluorochrome Staining Assay with Indicator Cell Line
- **M-250** Multi-Media Direct Culture Method with DNA Fluorochrome Staining Assay
- **M-300** Large Volume Barile Method
- **M-350** Large Volume Barile Method with DNA Fluorochrome Staining Assay
- **M-700** FDA Points to Consider Method
- **M-1400/ M-1450** Harmonized USP <63> Mycoplasma Test
- **M-1500/M-1500Q** Real-Time PCR with Broth Enrichment
- **Assay Development & Validation Services: Rapid Microbiological Methods**

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TEST	DESCRIPTION (ALL INCLUDE GMP SERVICES)	TESTING TIME	MINIMUM TEST VOLUME
M-150 DNA Fluorochrome Staining Assay with Indicator Cell Line	This DNA fluorochrome staining assay consists of sample inoculation onto an indicator cell line (Vero cells). After 3-5 days of co-culture, samples are fixed and stained using the fluorescent dye (Hoechst 33258), then examined under UV epi fluorescence. This assay is suitable for the screening of cell lines used for research purposes only.	3-5 days	2 mL
M-250 Multi-Media Direct Culture Method with DNA Fluorochrome Staining Assay	The multi-media direct culture procedure uses three custom mycoplasma media formulations combined with the indicator cell culture procedure. The DNA fluorochrome assay with indicator cell line enhances the detection of non-cultivable mycoplasma species, making this a highly sensitive test for the detection of mycoplasma contamination in cell cultures.	28 days	5 mL
M-300 Large Volume Barile Method	This test is a direct culture technique described in the Large Volume Barile Method. The test is enhanced by employing three custom mycoplasma media formulations, maximizing the detection of fastidious cultivable mycoplasma species in sera, media, and bioproducts.	28 days	55 mL; 100 mL aliquot preferred
M-350 Large Volume Barile Method with DNA Fluorochrome Staining Assay	This test consists of the Large Volume Barile Method, with the addition of the indicator cell culture procedure. This combined method detects both the cultivable and non-cultivable mycoplasma species.	28 days	90 mL; 100 mL aliquot preferred
M-700 FDA Points to Consider Method	This is the compendial method prescribed in the FDA Points to Consider to ensure the safety of biologics. The combined method (direct culture assay and indicator cell culture procedure) is required for the testing of bulk harvest, master and working cell banks, and cell substrates used in the manufacturing of biologics.	28 days	15 mL
M-1400 Harmonized USP <63> Mycoplasma Test	Bionique offers mycoplasma testing in full accordance with USP <63>, harmonized with the US FDA's 1993 Points to Consider, Ph. Eur. ch. 2.6.7, and the JP 18th Edition. This test can detect both agar cultivable and non-cultivable mycoplasmas. This compendial test may be applied to testing tissues, cell cultures, digest broth, or any material suspected of mycoplasma contamination.	28 days	15 mL
M-1450 Inhibition Testing for the Harmonized USP <63> Mycoplasma Test	This test checks for product-specific inhibition of mycoplasma growth within Bionique's Harmonized USP <63> assay. USP <63> and EP 2.6.7 require testing for inhibitory substances in the test article. This qualification study is recommended once for final product, unless there are changes within the test article matrix or manufacturing processes.	28 days	45 mL
M-1500 Real-Time PCR with Broth Enrichment	This test uses Real-Time PCR paired with a pre-enrichment procedure to enhance method sensitivity and discriminate between viable and non-viable cells in the event of a positive PCR test result. Each assay includes a comprehensive control panel to ensure accurate results.	3-6 days	1.2 mL
M-1500Q Real-Time PCR Matrix Qualification	Samples 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 only needs to be conducted once, unless there are changes in the test article components.	3-6 days	1.2 mL
Assay Development, Validation and Transfer Services	Our GMP-registered site offers custom assay development services with a focus on validation of novel rapid molecular-based technologies for mycoplasma detection. With over 30 years of experience, you can rely on our experts to develop an alternative method and validation strategy using a phase-appropriate approach that suits the CMC needs of your unique biologic.		