Laragen SEQUENCING & GENOTYPING

GLP-compliant qPCR mycoplasma detection assay: class-leading in accuracy and reliability

Laragen's MycoDetective™ Mycoplasma Detection Assay is an **in-house** assay specifically formulated to reliably meet USP chapter <63> and EP Section 2.6.7 guidelines, so that you can expedite the certification process and have confidence that your cell-lines and cell products are mycoplasma-free.

MycoDetective™ employs **probe-based qPCR** to detect a wide variety of mycoplasma contaminates in cell culture, cell therapy products, and biologics. Equipped with optimized master mix reagents, buffers, and proprietary primers and probes, this GLP compliant protocol guarantees maximized quantification accuracy while minimizing cost, time, and test inhibitors.

MycoDetective™ Mycoplasma Detection Assay — rapid & reliable results at an affordable price

With a turnaround time (TAT) of **24-48 hours**, and a **price tag well-below leading mycoplasma detection services**, MycoDetective™ promises to deliver affordable and expeditious results without compromised test quality.

We take pride in the integrity of our test. We ensure that each step of the workflow is confound-free by using *synthetic* recovery control DNA in each aliquot. This way, you can have trust that a negative result truly means your culture is in the clear.

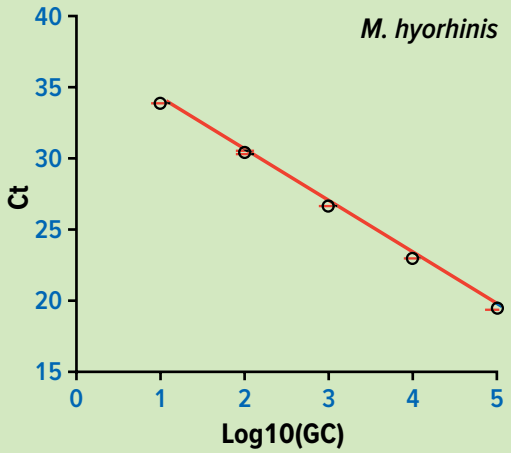
A qPCR assay with validated specificity, robustness, & sensitivity

SPECIFICITY: Our highly specific primers and probes target the **16S rRNA region** and can detect over **110 mycoplasma species** while avoiding reactions with closely related gram positive bacteria.

ROBUSTNESS: Validation studies show that our mycoplasma DNA extraction yields exceedingly high recovery rates of Mycoplasma DNA, with qPCR **amplification efficiencies above 90%** for both mycoplasma DNA and recovery control DNA and across all assay replicates.

SENSITIVITY: We offer a **broad dynamic range of detection**, with amplification curves found in serial dilutions with as **low as 10 genomic copies** of mycoplasma DNA.

LINEARITY: All ten mycoplasma species in the validation study exhibit similarly strong linear patterns and amplification efficiencies of **over 90%**, with **coefficient determination R^2 > 0.99**.



This standard curve represents the qPCR amplification of five 10-fold serial dilutions of *M. hyorhinis* DNA, one of the ten mycoplasma species assessed. The standard curve was made by plotting the log of the known starting template copy numbers against the ct values obtained during amplification.

The linearity of these standard curves, with slopes nearing the optimal -3.3 mark, indicate that our qPCR protocol efficiently duplicates target DNA each amplification cycle, and does so consistently across all five ten-fold serial dilutions and assay replicates.

LIMIT OF DETECTION (LoD): As confirmed by our validation studies — the MycoDetective™ assay effectively extracts, amplifies and detects even trace amounts of mycoplasma DNA present in cell culture samples, allowing you to be confident that our services will deliver the reliable results you need for accurate cell-line authentication.

Mycoplasma species	GC/ml	GC/CFU ratio	CFU/ml	LOD ≤ 10 CFU/ml
M. arginini	10	25.4	0.39	Yes
M. hominis	10	8.1	1.23	Yes
M. fermentans	10	36.2	0.28	Yes
M. gallisepticum	20	4.0	5.00	Yes
M. hyorhinis	20	8.1	2.47	Yes
A. laidlawii	20	30.3	0.66	Yes
M. orale	50	74.2	0.67	Yes
M. pneumoniae	50	11.6	4.31	Yes
M. salivarium	10	7.3	1.37	Yes
M. synoviae	10	65	0.15	Yes

This table lists the Limit of Detection (LoD), i.e. the lowest spike-level of target DNA with detectable amplification curves, for all ten mycoplasma species assessed in our validation study. All ten species show comparable results.

Laragen's assay consistently detects mycoplasma DNA in colony-forming units (CFU) well-below the USP Chapter <63> and EP section 2.6.7 acceptance criteria of **<10 CFU/mL**, evidencing the ability of our assay to detect accurate signals in samples with low template concentrations. All controls correspond with these results, confirming that our test is genuinely sensitive.

Call Laragen today to get a quote or talk more about your mycoplasma detection needs.

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