# CERTIFICATE OF ANALYSIS

## MolliScience® MG F DIVA qPCR Kit

# 1. Document Identification

**Document Title:** Certificate of Analysis
**Product Name:** MolliScience® MG F DIVA qPCR Kit
**Product Type:** Probe-based quantitative PCR assay kit
**Lot / Batch Number:** GF261001
**Manufacturing Date:** October 2026
**Expiration Date:** December 2029
**Document Number:** GF261001-COA-MG_F-DIVA-QPCR-100-REV01
**Revision:** 1.0
**Prepared by:** MolliScience Kft.
**Quality Review:** MolliScience Kft.

# 2. Description

This kit is an *in vitro* molecular assay for the detection and differentiation of wild-type *Mycoplasma gallisepticum* (MG) and the MG F vaccine strain DNA. The kit distinguishes wild-type strains from vaccine strains using specific genetic markers, and is applicable directly on DNA samples of clinical samples (e.g. tissue, swabs, secretions, cell cultures, FTA card) and isolates. The test is for veterinary use only and should be performed by qualified laboratory personnel.

# 3. Kit Components

| Component | Cap Colour | Description | Quantity (per kit) | Storage |
|---|---|---|---|---|
| **MG F DIVA qPCR Reaction Mix 1** | white | Liquid ready-to-use PCR mix containing buffer, dNTPs and polymerase. | 2 × [600 µL] (100 rx kit) | –20 °C |
| **MG F DIVA qPCR Reaction Mix 2** | yellow | Liquid ready-to-use PCR mix containing primers and probes (FAM, HEX). | 1 × [500 µL] (100 rx kit) | –20 °C |
| **MG F DIVA qPCR Reaction Mix 3** | blue | Nuclease-free water. Used as a negative control (no-template control) also. | 1 × 1 mL (100 rx kit) | –20 °C (or 2–8 °C) |
| **MG F DIVA qPCR Positive Control** | red | Ready-to-use DNA control (wild-type and vaccine target). | 1 × [50 µL] (100 rx kit) | –20 °C |

# 4. Manufacturing and Quality System

This product was manufactured in accordance with molecular diagnostic reagent manufacturing standards and internal SOPs for nucleic acid reagent production. All raw materials and reagents undergo qualification and incoming quality control prior to manufacturing.

## 5. Positive Control Performance

| Fluorescence Channel | HEX (MG F control) | | FAM (wild-type MG control) | |
|---|---|---|---|---|
| **Parameter** | **Cycle threshold (Ct) value** | **Maximum fluorescence threshold (RFU)** | **Cycle threshold (Ct) value** | **Maximum fluorescence threshold (RFU)** |
| **Specification** | 10 – 16 | 2000 – 3500 | 10 – 16 | 1500 – 2000 |
| **Result** | 11.39 – 11.77 | 3000 – 3500 | 10.72 – 11.98 | 1500 – 1600 |
| **Status** | validation passed | | validation passed | |

## 6. Contamination Test

| Parameter | Cycle threshold (Ct) value | |
|---|---|---|
| **Fluorescence Channel** | **HEX** | **FAM** |
| **Specification** | N/A | N/A |
| **Result** | N/A | N/A |
| **Status** | validation passed | validation passed |

N/A: no amplification detected

## 7. Sensitivity Check

| Positive Control template number | HEX (MG F control) | | FAM (wild-type MG control) | |
|---|---|---|---|---|
| | **Cycle threshold (Ct)** | **Detection rate (%)** | **Cycle threshold (Ct)** | **Detection rate (%)** |
| **$10^7$** | 11.39 – 11.77 | 100 | 10.72 – 11.98 | 100 |
| **$10^6$** | 15.65 – 16.40 | 100 | 15.54 – 16.60 | 100 |
| **$10^5$** | 18.74 – 20.19 | 100 | 18.58 – 20.35 | 100 |
| **$10^4$** | 22.82 – 23.63 | 100 | 22.64 – 23.90 | 100 |
| **$10^3$** | 26.36 – 27.58 | 100 | 26.30 – 27.80 | 100 |
| **$10^{2*}$** | 29.74 – 31.18 | 100 | 29.74 – 31.22 | 100 |
| **$10^1$** | 32.93 – 34.66 | 100 | 33.13 – 34.84 | 100 |
| **$10^0$** | 36.53 – 37.59 | 37.5 | 36.98 – 38.47 | 37.5 |
| **Status**** | validation passed | | validation passed | |

*Limit of detection (LOD).

**The assay passed validation, if at 10× LOD concentration detection is 100%.

## 8. Validation and Interpretation

| Channel | Negative Control (Ct) | Positive Control (Ct) | Interpretation |
|---|---|---|---|
| FAM | N/A | 10 – 16 | Controls worked. |
| HEX | N/A | 10 – 16 | |
| FAM | N/A | 10 – 16 | Problem with Amplification. Repeat run after Troubleshooting. |
| HEX | N/A | N/A | |
| FAM | N/A | N/A | |
| HEX | N/A | 10 – 16 | |
| FAM | N/A | N/A | |
| HEX | N/A | N/A | |
| FAM | ≤40 | 10 – 16 | Possible contamination. Repeat run after Troubleshooting. |
| HEX | ≤40 or N/A | 10 – 16 | |
| FAM | ≤40 or N/A | 10 – 16 | |
| HEX | ≤40 | 10 – 16 | |

N/A: no amplification detected



## 9. Quality Assurance Approval

| Role | Name | Signature | Date |
|---|---|---|---|
| QA Manager | Zsuzsa Kreizinger, DVM, PhD |  | 17/11/2026 |

## 10. Symbols glossary



Protect from light