CERTIFICATE OF ANALYSIS

MolliScience® ts-11 DIVA qPCR Kit

1. Document Identification

Document Title: Certificate of Analysis
Product Name: MolliScience® ts-11 DIVA qPCR Kit
Product Type: Probe-based quantitative PCR assay kit
Lot / Batch Number: G12604/01
Manufacturing Date: April 2026
Expiration Date: December 2029
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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 ts-11 vaccine strain (Vaxsafe® MG, Strain TS-11; Bioproperties Pty. Ltd.) 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
ts-11 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
ts-11 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
ts-11 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)
ts-11 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. All analyses were performed on Bio-Rad CFX Opus 96 Dx (Bio-Rad Laboratories, Inc., CA, USA) real-time system.

5. Positive Control Performance

Fluorescence Channel	HEX (ts-11 control)		FAM (wild-type MG control)	
Parameter	**Cycle threshold (Ct) value**	**Maximum fluorescence threshold (RFU)**	**Cycle threshold (Ct) value**	**Maximum fluorescence threshold (RFU)**
Specification	9 – 17	200 – 2500	9 – 17	200 – 1400
Result	11.08 – 12.12	1500 – 2500	12.08 – 14.06	400 – 900
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 (ts-11 control)		FAM (wild-type MG control)	
	Cycle threshold (Ct)	**Detection rate (%)**	**Cycle threshold (Ct)**	**Detection rate (%)**
10^7	11.08 – 12.12	100	12.08 – 14.06	100
10^6	14.83 – 15.41	100	15.86 – 17.02	100
10^5	18.23 – 19.07	100	19.36 – 20.20	100
10^4	21.66 – 24.11	100	22.68 – 25.34	100
10^3	25.18 – 25.47	100	26.49 – 26.85	100
10^{2*}	28.20 – 29.11	100	29.36 – 30.34	100
10^1	31.85 – 33.55	100	33.07 – 35.29	100
10^0	34.68 – 35.87	87.5	36.06 – 37.33	87.5
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	9 – 17	Controls worked.
HEX	N/A	9 – 17	
FAM	N/A	≤40	Problem with Amplification. Repeat run after Troubleshooting.
HEX	N/A	N/A	
FAM	N/A	N/A	
HEX	N/A	≤40	
FAM	≤40	9 – 17	Possible contamination. Repeat run after Troubleshooting.
HEX	≤40 or N/A	9 – 17	
FAM	≤40 or N/A	9 – 17	
HEX	≤40	9 – 17	

N/A: no amplification detected

9. Quality Assurance Approval

Role	Name	Signature	Date
QA Manager	Zsuzsa Kreizinger, DVM, PhD		24/04/2026

10. Symbols glossary

Protect from light