e-Myco™ VALiD-Q Real-time PCR Kit (v3.0 PRO)

Cat. 25247 100 tests

DESCRIPTION

Mycoplasma is a common contaminant in cell culture processes; therefore, rapid and accurate detection is essential.The e-Myco™ VALiD-Q Real-time PCR Kit (v3.0 PRO) is designed to target highly conserved regions of the Mollicutes 16S rRNA gene and detects a total of 10 major Mycoplasma and related species, including representative strains required for pharmacopeial NAT suitability evaluation.The assay demonstrates an analytical sensitivity of 10 CFU/mL and provides stable detection performance across various biological matrices, as well as under different extraction methods and instrument conditions.In addition, a dual-channel External Control (EC) and Internal Control (IC) system is incorporated to enhance test reliability and to ensure the validity of the entire testing process.

CONTENTS

- 2X qPCR Mix : 520 µl x 2 tubes
- Detection solution : 260 µl x 2 tubes
- Internal Control: 500 µl x 2 tubes
- External Control : 25 µl x 3 tubes
- DNase/RNase free water : 1 ml x 1 tube

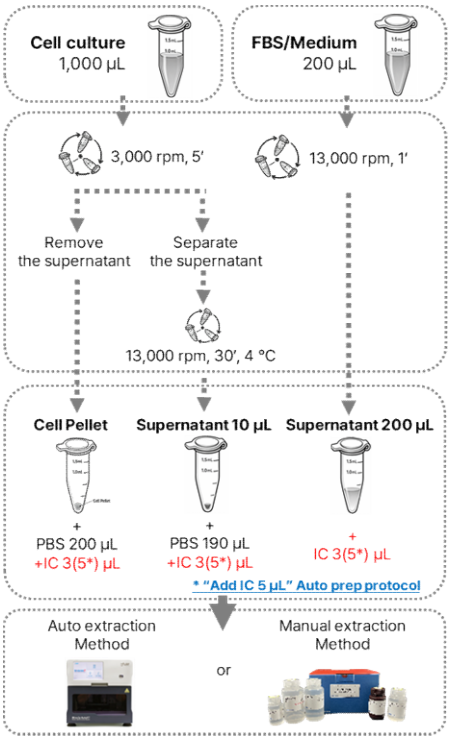
STORAGE CONDITION

- Storage Conditions : Store at -20 °C or below.
- Shelf Life : 12 months from the date of manufacture ; use within 6 months after opening.

SAMPLE PREPARATION

EP/USP/JP Compliant Testing Samples

- This procedure outlines the automated and manual extraction methods and qPCR reaction setup.

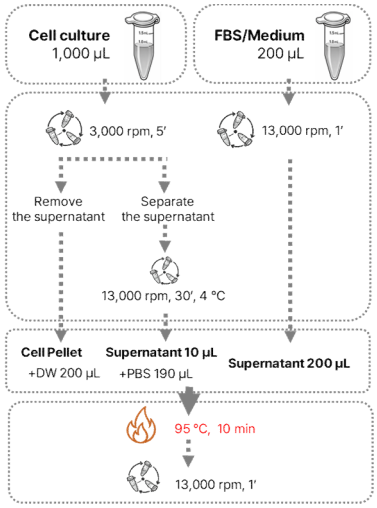


Note : If the IC was added during extraction, do not add it to the reaction mixture.

Note : Add 5 µL of IC only when using the automated extraction method.

General Cell Culture Samples

- This method provides a rapid preparation of template DNA from cultured cells.



Note : Close the tube cap tightly during heating. Sensitivity may be reduced compared to standard extraction methods.

TESTING PREPARATION

Please refer to the following composition for the qPCR reaction mixture.

Components	1 test	10 tests	20 tests
2X qPCR Mix	10 µL	100 µL	200 µL
Detection solution	5 µL	50 µL	100 µL
Internal Control	1 µL	10 µL	20 µL
(qPCR Reaction Mix) Total volume	16 µL	160 µL	320 µL

Note : If the IC is added during extraction, do not add it to the qPCR Reaction Mix.

Prepare the qPCR reaction mixture according to the composition described below.

Components	Sample (Auto/Manual)	Sample (Boiling)	Positive control	Negative control
qPCR Reaction Mix	15 µL	15 µL	15 µL	15 µL
External Control	-	-	5 µL	-
Sample	5 µL	2 µL	-	-
DNase/RNase free water	-	3 µL	-	5 µL
Total volume	20 µL	20 µL	20 µL	20 µL

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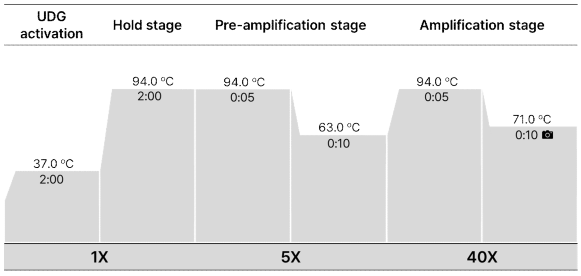
PROTOCOL

The PCR conditions for this product are as follows.



The fluorescence signals for each target are listed below.

Channel	FAM	HEX	Cy5
Target	Mycoplasma	Internal control	External control

Note : The External control (EC) is detected simultaneously in the FAM and Cy5 channels.

PROGRAM SETTING

The recommended instruments and their setup procedures are listed below. Instrument Setup files are provided. For details, contact the manufacturer.

[FaSTARamp 96 Real-time PCR system]

- Launch the FaSTARamp96 PCR System software → Select "New Expt. From Item" → Choose the setup file → Assign the wells to be used → Click "Start".

[CFX96 Touch Real-time PCR Detection system]

- Launch the Bio-Rad CFX Maestro software → Select the setup file under "Protocol" and "Plate" tabs → Click "Start Run" to begin the run.

[QuantStudio5 Real-time PCR Instrument]

- Launch the QuantStudio 5 Dx Development software → Select "Created from Existing Template" → Choose the setup file → Start the run under the "Run" tab.

[ABI7500 Real-time PCR System]

- Launch the 7500 software → Select the setup file under the "Template" tab → Start the run.

ANALYSIS

Mycoplasma detection is determined based on the FAM channel fluorescence signal. The interpretation criteria are as follows.

Target	Baseline	Threshold	Positive	Negative
Mycoplasma (FAM)	Auto	Auto	≤38	>38

Note : Baseline and threshold settings follow the instrument default (Auto); Ct values may vary. Contact the manufacturer if abnormal amplification is observed.

INTERPRETATION

The criteria for determining positive and negative results are as follows.

Case	FAM	HEX	Cy5
Mycoplasma	≤38	>23	NoCt
Non-Mycoplasma	No.Ct of >38	>23	NoCt
External Control	30 ± 2	25 ± 2	30 ± 2

Mycoplasma detection is determined based on the FAM channel fluorescence signal. The interpretation criteria are as follows.

Case	FAM	HEX	Cy5	Interpretation
Sample1	+	+	-	Positive
Sample2	-	+	-	Negative
Sample3	+	-	-	Positive (IC check required*)
Sample4	-	-	-	Invalid (Retest required*)
Sample5	+	+	-	Carry-over contamination su spected
EC	+	+	+	Valid
	+	-	+	Valid (IC check required*)
	-	-	-	Test failure*
NC	-	+	-	Valid
	-	-	-	Test failure*

Note : Interpretation should be made only when the Internal Control (HEX) and/or External Control (Cy5) meet the acceptance criteria.

FULL INSTRUCTION FOR USE

For the complete Instructions for Use (IFU), scan the QR code below.

ORDERING INFORMATION

Product	Cat No.	Q'ty
e-Myco™ VALiD-Q Real-time PCR Kit (v3.0 PRO)	25247	100 tests
e-Myco™ VALiD-Q Real-time PCR Kit (ver.2.0)	25246	50 tests
e-Myco™ VALiD-Q Mycoplasma qPCR Detection Kit	25245	50 tests
e-Myco™ VALiD Mycoplasma PCR Detection Kit	25239	48 tests
e-Myco™ plus Mycoplasma PCR Detection Kit	25237	48 tests
e-Myco™ Mycoplasma PCR Detection Kit (ver.2.0)	25235	48 tests
MycoClean™ plus Mycoplasma Prevention Spray	21084	200 mL
G-spin™ Total DNA Extraction Mini Kit	17045	50 col.
	17046	100 col.
AutoXT Total gDNA Kit	17188-48	48 tests
	17188-96	96 tests
Miracle-AutoXT Automated Nucleic Acid Extraction System	IMC-NC15 PLUS	-

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