Mycoplasma Detection Kits

Minerva takes advantage of long standing experience and extended research in molecular testing. Combined with high quality manufacturing standards, this knowledge guarantees excellent test kits for detection of mycoplasma contaminations in cell cultures and biopharmaceutical products.

Economic

- Select from 5 product variants with different validation levels and technical configurations.
- Pre-aliquoted PCR mix, 25 reactions each, for highest convenience and long-term stability for sporadic users.
- Critical kit components are provided freeze-dried for easy logistics, storage and best reagent stability.

Flexible

- For fast and reliable screening of cell cultures in research, *European* and *Japanese Pharmacopoeia* (EP/JP)-compliant lot release testing of ATMPs, in-process testing, raw material testing, etc.
- Compatible with almost any commercially available PCR/qPCR device.

High Performance

- Highest robustness, sensitivity and specificity with easy-to-use protocols.
- Venor®GeM Classic and Venor®GeM qEP are extensively validated according to the EP 2.6.7/JP G3. The separate Internal Amplification Control allows for optional process monitoring.
- Superior results in proficiency studies and detailed robustness testing.

MB minerva biolabs®

Venor®GeM Classic

Description
Venor®GeM Classic is a basic PCR kit for fast, reliable and time-saving routine monitoring of mycoplasma contamination.

Recommended Use
Applicable in research and industry:
For direct screening of cell cultures and biologicals.
For EP 2.6.7/JP G3 compliant release testing. Not applicable for clinical diagnostics.

Type of PCR
Conventional, endpoint PCR

Required Lab Devices
PCR cycler / Agarose gel electrophoresis and DNA staining system / Pipetting equipment / Tube- and Microcentrifuge

Required Consumables
PCR reaction tubes / Gel loading buffer and dye

Kit Components
Primers, nucleotides / 10x Reaction Buffer / Positive Control DNA / Internal Amplification Control / PCR Grade Water

Sample Volume per PCR
2 µl for screening / 10 µl for EP 2.6.7/JP G3 compliant testing

Result Evaluation
Gel analysis

Validation
Validation report available on request

EP 2.6.7/JP G3 compliance
Yes, after appropriate sample preparation and matrix validation

Optional Consumables
For process monitoring and EP/JP testing:
Internal Control DNA extra (Cat. No. 11-1905)

For process validation and testing according to EP 2.6.7/JP G3:
10CFU™ Sensitivity Standards available for all EP/JP-listed mycoplasma species (e.g. *M. orale*, Cat. No. 102-2003)

Venor®GeM Sample Preparation Kit (Cat. No. 56-1010, 56-1050, 56-1200 or Cat. No. 56-2096)

Venor®GeM Advance

Description
Venor®GeM Advance contains PCR strips predispensed with all PCR reagents, including polymerase, to reduce pipetting steps and total assay time. For additional convenience, the gel loading buffer and dye are already included in the reaction buffer. After PCR, the products can be loaded directly on the agarose gel.

Recommended Use
Applicable in research for direct testing of cell cultures and cell culture-derived biologicals. Not applicable for clinical diagnostics.

Type of PCR
Conventional, endpoint PCR

Required Lab Devices
PCR cycler / Agarose gel electrophoresis and DNA staining system / Pipetting equipment / Tube- and Microcentrifuge

Required Consumables
None

Kit Components
Primers, nucleotides, Taq polymerase, Internal Amplification Control, dispensed in 0.2 ml PCR reaction tubes / Rehydration buffer including gel loading buffer and running dye / Positive controls dispensed in 0.2 ml PCR reaction tubes / PCR Grade Water / Caps

Sample Volume per PCR
2 µl

Result Evaluation
Gel analysis

Validation
Not provided

EP 2.6.7/JP G3 compliance
No

Venor®GeM OneStep

Description
Venor®GeM OneStep is a complete kit, which includes all reagents required for PCR. Primers, nucleotides, polymerase and the internal amplification control are provided in a ready-to-use, freeze-dried reaction mix. Once rehydrated, the OneStep Mix can be dispensed to the PCR reaction tubes where then samples or Positive Control DNA are added prior to PCR.

Recommended Use
Applicable in research for direct testing of cell cultures and cell culture-derived biologicals. Not applicable for clinical diagnostics.

Type of PCR
Conventional, endpoint PCR

Required Lab Devices
PCR cycler / Agarose gel electrophoresis and DNA staining system / Pipetting equipment / Tube- and Microcentrifuge

Required Consumables
PCR reaction tubes / Gel loading buffer and dye

Kit Components
Primers, nucleotides, Taq polymerase, and Internal Amplification Control / Rehydration Buffer / Positive Control DNA / PCR Grade Water

Sample Volume per PCR
2 µl

Result Evaluation
Gel analysis

Validation
Not provided

EP 2.6.7/JP G3 compliance
No

Venor®GeM qOneStep

Description
Venor®GeM qOneStep is a qPCR kit for mycoplasma detection, which includes all reagents required for the qPCR reaction. Primers, nucleotides, polymerase, and the internal amplification control are provided ready-to-use in a lyophilized reaction mix. The protocol is optimized for fast and reliable screening of cell culture supernatants. Eukaryotic DNA is not amplified by this primer/probe system.

Recommended Use
Applicable in research for direct testing of cell cultures and cell culture derived biologicals. Not applicable for clinical diagnostics.

Type of PCR
TaqMan®-based quantitative real-time PCR

Required Lab Devices
qPCR cycler with FAM™ and HEX™ filters / Pipetting equipment / Tube- and Microcentrifuge

Required Consumables
PCR reaction tubes

Kit Components
Primers, nucleotides, Taq polymerase and Internal Amplification Control / Rehydration Buffer / Positive Control DNA / PCR Grade Water

Sample Volume per PCR
2 µl

Result Evaluation
Cycler-based, real-time PCR

Validation
Not provided

EP 2.6.7/JP G3 compliance
No

Venor®GeM qEP

Description
Venor®GeM qEP utilizes quantitative, real-time PCR for high quality and reliable detection of mycoplasma contaminations. It can be used in combination with cell culture enrichment, for direct screening of cell cultures or after DNA extraction for EP/JP compliant testing of cell culture derived biologicals, like autologous transplants (ATMPs), sera, cell culture media and therapeutic antibody formulations.
Not applicable for clinical diagnostics.

Recommended Use
Applicable in research and industry:
For direct screening of cell cultures and biologicals.
For EP 2.6.7/JP G3 compliant release testing. Not applicable for clinical diagnostics.

Type of PCR
Probe assay for qPCR

Required Lab Devices
qPCR cycler with FAM™ and HEX™ filters / Pipetting equipment / microcentrifuge

Required Consumables
PCR reaction tubes

Kit Components
Primers, nucleotides and Taq polymerase / Internal Amplification Control / Rehydration Buffer / Positive Control DNA / PCR Grade Water

Sample Volume per PCR
2 µl for screening / 10 µl for EP 2.6.7/JP G3 compliant testing

Result Evaluation
Cycler based, real-time PCR

Validation
Validation report available on request

EP 2.6.7/JP G3 compliance
Yes, after appropriate sample preparation and process validation

Optional consumables
For process monitoring and EP/JP testing:
Internal Control DNA extra (Cat. No. 11-9905)

For process validation and testing according to EP 2.6.7/JP G3:
10CFU™ Sensitivity Standards available for all EP-/JP-listed mycoplasma species (e.g. *M. orale*, Cat. No. 102-2003)

Venor®GeM Sample Preparation Kit (Cat. No. 56-1010, 56-1050, 56-1200 or Cat. No. 56-2096)

Storage (applies to all kits)
Components can be stored at +2 to +8 °C for at least 12 months. After rehydration the reagents must be stored at ≤ -18 °C.

Ordering information / package sizes

Venor®GeM Classic		Venor®GeM Advance		Venor®GeM OneStep		Venor®GeM qOneStep		Venor®GeM qEP	
Cat. No. 11-1025	25 Reactions	Cat. No. 11-7024	24 Reactions	Cat. No. 11-8025	25 Reactions	Cat. No. 11-91025	25 Reactions	Cat. No. 11-9025	25 Reactions
Cat. No. 11-1050	50 Reactions	Cat. No. 11-7048	48 Reactions	Cat. No. 11-8050	50 Reactions	Cat. No. 11-91100	100 Reactions	Cat. No. 11-9100	100 Reactions
Cat. No. 11-1100	100 Reactions	Cat. No. 11-7096	96 Reactions	Cat. No. 11-8100	100 Reactions	Cat. No. 11-91250	250 Reactions	Cat. No. 11-9250	250 Reactions
Cat. No. 11-1250	250 Reactions	Cat. No. 11-7240	240 Reactions	Cat. No. 11-8250	250 Reactions				

	Conventional PCR	qPCR	Extraction Control	Polymerase included	Recommended for research	Recommended for industry / pharma	EP 2.6.7/JP G3 conformity	Description
Venor®GeM Classic	y	n	y	n	n	y	y	The classical version for gel evaluation. 20 years of experience, EP 2.6.7 and JP G3 compliant, always improved and at the state-of-the-art of DNA-based mycoplasma detection – the optimal choice for money-savers!
Venor®GeM Advance	y	n	n	y	y	n	n	The ready-to-use version of Venor®GeM is pre-aliquoted and freeze-dried in reaction tubes, ready for gel electrophoresis. Just add the rehydration buffer and the sample into the pre-dispensed PCR tubes. After PCR, the amplication products can be loaded directly onto a gel, as marker and loading buffer are already included. The best version for time-savers!
Venor®GeM OneStep	y	n	n	y	y	n	n	Venor®GeM OneStep is all-in-one! Do you need a robust and reliable work-horse? The Venor®GeM OneStep is the best choice. All PCR reagents including the polymerase are freeze-dried and only need to be resuspended in rehydration buffer and mixed to your sample. Best value for money!
Venor®GeM qEP	n	y	y	y	n	y	y	qEP stands for qPCR-based, EP 2.6.7 and JP G3 compliant mycoplasma testing. Venor®GEM qEP can be performed with any type of real-time PCR cycler able to detect the fluorescence dyes FAM™ and HEX™. Two protocols allow the fast screening of research samples or highly sensitive and robust testing of regulated biopharmaceutical samples.
Venor®GeM qOneStep	n	y	n	y	y	n	n	TaqMan®-based qPCR assay with FAM™ and HEX™ labeled probes. Recommended for fast and reliable direct screening of cell culture supernatants. Highly sensitive and robust assay. Ready-to-use kit. Best offer!!

10CFU™ Sensitivity Standards

For validating robustness and detection limit of molecular mycoplasma test methods in presence of a specific sample matrix.

Background & Description

The chapters of *European Pharmacopoeia* 2.6.7 / *Japanese Pharmacopoeia G3* about mycoplasma testing define the required sensitivity for nucleic acid-based methods like PCR as alternatives to the traditional culture method. Such test sensitivity of 10 colony-forming units or CFU pro ml of sample volume must be shown by the performing lab as part of the robustness testing in presence of the sample matrix. Each vial of 10CFU™ Sensitivity Standards contains 10 CFU of inactivated mycoplasma, which can be safely and reliably used in cell culture labs and production facilities where a microbiology lab is not available.

Once resuspended in the sample matrix of interest (as in EP 2.6.7/JP G3), these samples must be tested positive by the applied method. Please note that due to the mycoplasma inactivation, the 10CFU™ Sensitivity Standards are not suitable for the culture method. Extensive proficiency tests indicated that mycoplasma DNA extraction is indispensable to achieve highest sensitivity by PCR-based methods. After extraction, the 10CFU™ extract can directly be used for PCR.

Note: This standard material is not titrated for genome copies (GU) as EP 2.6.7/JP G3 do not provide sensitivity specifications on DNA level. The GU:CFU ratio may vary from lot to lot.

Content

• Unit package: 3 vials with 10 CFU of the corresponding mycoplasma species; 2 vials with negative controls

• Set package (mycoplasma set): 2 vials with 10 CFU of each species listed in the EP (*M. arginini, M. orale, M. gallisepticum, M. pneumoniae, M. synoviae, M. fermentas, M. hyorhinis, A. laidlawii, S. citri*). *M. salivarium* is not included in the set; 2 with vials negative controls

Ordering Information

102-8003	*Acholeplasma laidlawii*
102-1003	*Mycoplasma arginini*
102-6003	*Mycoplasma fermentans*
102-3003	*Mycoplasma gallisepticum*
102-7003	*Mycoplasma hyorhinis*
102-2003	*Mycoplasma orale*
102-4003	*Mycoplasma pneumoniae*
102-5003	*Mycoplasma synoviae*
102-1103	*Mycoplasma salivarium*
102-9003	*Spiroplasma citri*
102-0002	Mycoplasma Set

PCR Quantification Standards

Background & Description

• Performance controls for conventional and real-time PCR
• Standard curves for quantification

The PCR Quantification Standards contain genomic DNA, extracted from defined microorganisms at low passage by subsequent column absorption methods. The identity of the species is confirmed by sequencing.

Ordering information

52-0116	*Acholeplasma laidlawii*
52-5571	*Bordetella pertussis*
52-0083	*Escherichia coli*
52-0101	*Legionella pneumophila*
52-0129	*Mycoplasma arginini*
52-0117	*Mycoplasma fermentans*
52-0115	*Mycoplasma gallisepticum*
52-0130	*Mycoplasma hyorhinis*
52-0112	*Mycoplasma orale*
52-0119	*Mycoplasma pneumoniae*
52-0103	*Mycoplasma salivarium*
52-0124	*Mycoplasma synoviae*
52-0071	*Pseudomonas aeruginosa*
52-0164	*Spiroplasma citri*

Content

1 vial with DNA, $1x10^8$ genome copies, freeze-dried
3 vials with 2 ml of Tris-HCl buffer (10 mM, pH 8.5) for rehydration and preparation of serial dilutions

How to order

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