

# Mycoplasma testing for LOT release of biopharmaceuticals and ATMPs

## Venor®GeM Classic, qEP, SP Kit - Beads, Sample Preparation, 10CFU™ and 100CFU™ Sensitivity Standards

### Flexible

- ✓ PCR-based assays compatible with almost any commercially available cycler
- ✓ Product variants for conventional or real-time PCR

### Powerful

- ✓ Highest robustness, sensitivity and specificity (>100 species detectable)
- ✓ Meets EP 2.6.7 / USP <1071>/ JP G3 criteria
- ✓ Incl. separate internal amplification control for optional process monitoring
- ✓ Available product validation

### Convenient

- ✓ Pre-aliquoted PCR mix ensures long-term stability
- ✓ Lyophilized kit components simplify logistics and storage



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# PCR-based assays for EP 2.6.7, USP<1071> and JPG3 compliant release testing: Venor®GeM Classic & qEP

## Recommended use:

Applicable in research and industry.

For direct screening of cell cultures and biologicals. For EP 2.6.7/JP G3/USP<1071> compliant release testing.

Not applicable for clinical diagnostics.

## Sample volume per PCR:

2 µl for screening (research); 10 µl for EP 2.6.7/USP <1071>/JP G3 compliant testing

**Validation:** Validation report available on request.

## For process validation and testing according to EP 2.6.7/USP<1071>/JP G3:

- 10CFU™ Sensitivity Standards available for all EP / JP - listed mycoplasma species
- 100CFU™ Sensitivity Standards
- Venor®GeM Sample Preparation Kit

## Shelf life and storage:

Components can be stored at +2 to +8 °C for at least 12 months. After rehydration the reagents must be stored at ≤-18 °C until the expiry of the labelled shelf life.

## Venor®GeM Classic

### Description

Venor®GeM Classic is a basic PCR kit for fast, reliable and time-saving routine monitoring of mycoplasma contamination. After DNA extraction, the assay can be applied for testing of cell culture derived biologicals and biopharmaceuticals. The kit is designed to detect more than 100 Mollicutes species and was extensively tested on several common culture contaminants.

### Order Information

#### Catalog number

Cat. No. 11-1025	25 Reactions
Cat. No. 11-1050	2 x 25 Reactions
Cat. No. 11-1100	4 x 25 Reactions
Cat. No. 11-1250	10 x 25 Reactions

### Additional information

**Type of PCR:** Conventional, endpoint PCR

**Kit components:** Lyophilized Master Mix; 10 x Reaction Buffer; Internal Amplification Control; Positive Control DNA; PCR-grade Water

**Required lab devices:** PCR cycler; agarose gel electrophoresis and DNA staining system; pipetting equipment; microcentrifuge

#### Required consumables:

Taq DNA Polymerase (suitable Taq polymerase is available from us); PCR reaction tubes; gel loading buffer and dye

#### Optional consumables for process monitoring and EP/JP/USP testing:

Internal Control DNA extra (Cat. No. 11-1905)

## Venor®GeM qEP

### Description

Venor®GeM qEP utilizes quantitative, real-time PCR for high quality and reliable detection of mycoplasma contaminations. After DNA extraction, the assay can be applied for EP/JP/USP compliant testing of cell culture derived biologicals, like autologous transplants (ATMPs), sera, cell culture media and therapeutic antibody formulations. The kit is designed to detect more than 100 Mollicutes species and was extensively tested on several common culture contaminants.

### Order information

#### Catalog number

Cat. No. 11-9025	25 Reactions
Cat. No. 11-9100	4 x 25 Reactions
Cat. No. 11-9250	10 x 25 Reactions

### Additional information

**Type of PCR:** Taq polymerase based quantitative real-time PCR (qPCR)

#### Kit components:

Lyophilized Master Mix; Rehydration Buffer; Internal Amplification Control; Positive Control DNA; PCR-grade Water

#### Required lab devices:

qPCR cycler with FAM™ and HEX™ filters; pipetting equipment; microcentrifuge

#### Required consumables:

PCR reaction tubes

#### Optional consumables for process monitoring and EP/JP/USP testing:

Internal Control DNA extra (Cat. No. 11-1905)



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## Additional products

# Venor®GeM Sample Preparation

## Description

Venor®GeM Sample Preparation is an extraction kit, intended for the isolation of mycoplasma DNA from cell culture or biopharmaceutical material.

This DNA extraction kit provides excellent results and can be reliably used in combination with our PCR kits for mycoplasma detection.

## Features

**Recommended use:** Sample preparation and purification of cell culture supernatants incl. cells and cell debris, ATMPs, samples with polymers, DMSO and glycerin (e.g. cryoconservation media), cell culture media, and protein solutions, incl. antibodies and enzymes.

**Required lab devices:**

Pipetting equipment; heat block; microcentrifuge

**Required consumables:**

PCR reaction tubes; ethanol; Proteinase K (Opt. Cat. No. 56-0002)

**Kit components:** Spin columns; Collection tubes; Conditioner; binding buffer; wash buffers; elution buffer

**Storage:**

Storage and shipment at ambient temperature

**Sample volume per extraction:** 200 µl

## Ordering information

**Catalog number**

Cat. No. 56-1010	10 Reactions
Cat. No. 56-1050	50 Reactions
Cat. No. 56-1200	200 Reactions

# Venor®GeM SP Kit - Beads

## Description

The Venor®GeM SP Kit - Beads is a DNA/RNA extraction kit designed to separate nucleic acids from mycoplasma. The Venor®GeM SP Kit - Beads is based on the extraction of nucleic acid using

magnetic beads. The kit is also compatible with extraction robots such as the KingFisher™ Flex. Its automated nucleic acid extraction significantly improves the reproducibility of individual extractions.

## Features

**Recommended use:** Sample preparation and purification of cell culture supernatants incl. cells and cell debris, cell suspensions, samples with polymers, DMSO and glycerin (e.g. cryoconservation media), biopharmaceuticals, ATMPs, and protein solutions, incl. antibodies and enzymes.

**Required lab devices:**

Manual extraction: Magnetic rack; thermoshaker; pipetting equipment

Automatic extraction: Automatic extractor (e.g. KingFisher™ Flex); plastic material for extractor

**Required consumables:** 1-propanol ≥99,5%; PCR reaction tubes

**Kit components:** Binding-, Elution-, Lysis-, Rehydration-Buffer, Wash Buffers 1-3; Magnetic Bead Suspension; Proteinase K

**Storage:** Storage and shipment at ambient temperature, exception Proteinase K storage at +2 to +8 °C

**Sample volume per extraction:** 250 µl

## Order information

**Catalog number**

Cat. No. 56-3010	10 Reactions
Cat. No. 56-3100	100 Reactions

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# 10CFU™ Sensitivity Standards

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

## Background & description

The *European Pharmacopoeia* (EP 2.6.7), the *Japanese Pharmacopoeia* (JP G3) and the *US Pharmacopoeia* (USP <1071>) define the required sensitivity for nucleic acid-based assays (e.g. PCR) as valid detection methods for microbiological testing of biopharmaceuticals. According to these guidelines, a test sensitivity of 10 colony-forming units (CFU) per ml of sample volume (or min. 100 CFU/ml for USP) must be reached 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 and production facilities, where a microbiology lab is not available. Once resuspended in the sample matrix of interest, 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. The genome units (GU) to CFU ratio is provided in The Certificate of Analysis for each lot.

### Content:

Unit package: 3 vials with 10 CFU of the corresponding mycoplasma species; 2 vials with negative controls; Set package (Mycoplasma set Cat. No. 102-0002): 2 vials with 10 CFU of each mycoplasma species listed in the EP 2.6.7 (18 vials in total; *M. salivarium* is not included in the set). 2 vials with negative controls

## Ordering information

### Catalog Number

Cat. No. 102-8003	<i>Acholeplasma laidlawii</i>	Cat. No. 102-2003	<i>Mycoplasma orale</i>
Cat. No. 102-1003	<i>Mycoplasma arginini</i>	Cat. No. 102-4003	<i>Mycoplasma pneumoniae</i>
Cat. No. 102-6003	<i>Mycoplasma fermentans</i>	Cat. No. 102-5003	<i>Mycoplasma synoviae</i>
Cat. No. 102-3003	<i>Mycoplasma gallisepticum</i>	Cat. No. 102-1103	<i>Mycoplasma salivarium</i>
Cat. No. 102-7003	<i>Mycoplasma hyorhinis</i>	Cat. No. 102-9003	<i>Spiroplasma citri</i>
		Cat. No. 102-0002	Mycoplasma Set

# 100CFU™ Sensitivity Standards

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

## Background & description

100CFU™ Sensitivity Standards are designed to support the validation of nucleic acid amplification technology (NAT)-based tests for mycoplasma detection, according to USP <1071>. More generally, including this supplementary concentration in the matrix validation procedure significantly improves the confidence of the test method.

- Irreversibly inactivated mycoplasma in an amount corresponding to 100 CFU.

- Additional test concentration to the 10CFU™ Sensitivity Standards for the validation of PCR-based detection tests.
- The genome units (GU) to CFU ratio is provided in The Certificate of Analysis for each lot.

**Content:** Unit package: 3 vials with 100 CFU of the corresponding mycoplasma species; 2 vials with negative controls

## Ordering information

### Catalog Number

Cat. No. 103-8003	<i>Acholeplasma laidlawii</i>	Cat. No. 103-2003	<i>Mycoplasma orale</i>
Cat. No. 103-1003	<i>Mycoplasma arginini</i>	Cat. No. 103-4003	<i>Mycoplasma pneumoniae</i>
Cat. No. 103-6003	<i>Mycoplasma fermentans</i>	Cat. No. 103-1103	<i>Mycoplasma salivarium</i>
Cat. No. 103-3003	<i>Mycoplasma gallisepticum</i>	Cat. No. 103-5003	<i>Mycoplasma synoviae</i>
Cat. No. 103-7003	<i>Mycoplasma hyorhinis</i>	Cat. No. 103-9003	<i>Spiroplasma citri</i>

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