Venor® GeM Classic, Venor® GeM qEP, Venor® GeM Sample Preparation, 10CFU™ and 100CFU™ Sensitivity Standards

LOT Release Testing of Bio-pharmaceuticals and ATMPs

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
- ✓ Probe assays for clear interpretation of results

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.

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

Sample Volume per PCR
2 µl for screening (research), 10 µl for EP 2.6.7 / USP <1071> / JP G3 compliant testing

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.

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

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	50 Reactions
Cat. No. 11-1100	100 Reactions
Cat. No. 11-1250	250 Reactions

Additional Information

Type of PCR: Conventional, endpoint PCR

Kit Components: Primers, nucleotides, Taq polymerase, 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, Tube- and Microcentrifuge

Required Consumables:
PCR reaction tubes, Gel loading buffer and dye

Optional Consumables for process monitoring and 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	100 Reactions
Cat. No. 11-9250	250 Reactions

Additional Information

Type of PCR:
Quantitative real-time PCR (qPCR)

Kit Components:
Primers, probes, nucleotides and Taq polymerase; 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 and EP/JP/USP testing:
Internal Control DNA extra (Cat. No. 11-1905)

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

Kit Components:
Spin columns; Collection tubes; Conditioner, binding, wash and elution buffers

Sample Volume per Extraction: 200 µl

Required Lab Devices: Pipetting equipment, Heat block, Microcentrifuge

Required Consumables:
Tubes, Ethanol, Proteinase K (Opt. Cat. No. 56-0002)

Recommended Use:
For DNA extraction from:

- Cell culture supernatants incl. cells and cell debris
- ATMPs
- Samples with polymers, DMSO and glycerin (e.g. cryoconservation media)
- Cell culture media
- Protein solutions, incl. antibodies and enzymes

Storage:
Storage and shipment at ambient temperature

Ordering Information

Catalog Number

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

Additionally available products for cell culture screening

	Conventional PCR	qPCR	Extraction Control	Polymerase included	Recommended for research	Recommended for industry / pharma	EP 2.6.7/JP G3 conformity	Description
Venor® GeM Advance Cat. No. 11-7024 / 11-7048 / 11-7096 / 11-7240	y	n	n	y	y	n	n	The ready-to-use version of Venor®GeM is pre-aliquoted and lyophilized in reaction tubes, ready for gel electrophoresis. Just add the rehydration buffer and the sample into the pre-dispensed PCR tubes. After PCR, the amplification 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 Cat. No. 11-8025 / 11-8100 / 11-8250	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 qOneStep Cat. No. 11-91025 / 11-91100 / 11-91250	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!
Venor® GeM Classic	y	n	y	n	n	y	y	
Venor® GeM qEP	n	y	y	y	n	y	y	

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	*Acholeplasma laidlawii*
Cat. No. 102-1003	*Mycoplasma arginini*
Cat. No. 102-6003	*Mycoplasma fermentans*
Cat. No. 102-3003	*Mycoplasma gallisepticum*
Cat. No. 102-7003	*Mycoplasma hyorhinis*
Cat. No. 102-2003	*Mycoplasma orale*
Cat. No. 102-4003	*Mycoplasma pneumoniae*
Cat. No. 102-5003	*Mycoplasma synoviae*
Cat. No. 102-1103	*Mycoplasma salivarium*
Cat. No. 102-9003	*Spiroplasma citri*
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	*Acholeplasma laidlawii*
Cat. No. 103-1003	*Mycoplasma arginini*
Cat. No. 103-6003	*Mycoplasma fermentans*
Cat. No. 103-3003	*Mycoplasma gallisepticum*
Cat. No. 103-7003	*Mycoplasma hyorhinis*
Cat. No. 103-2003	*Mycoplasma orale*
Cat. No. 103-4003	*Mycoplasma pneumoniae*
Cat. No. 103-1103	*Mycoplasma salivarium*
Cat. No. 103-5003	*Mycoplasma synoviae*
Cat. No. 103-9003	*Spiroplasma citri*

How to order
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