

Mycoplasma PCR Assays The New Gold Standard

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

Economic

- Select from 4 product variants with different validation levels and technical configurations according to your requirements.
- PCR mix is provided in aliquots of 25 reactions for highest convenience and long term stability even for low frequent tester.
- Critical kit components are provided freeze-dried for easy logistics, storage and best reagent stability.

Flexible

- Applicable for fast and reliable screening of cell cultures in research, EP-compliant lot release testing of ATMPs, in-process testing, raw material testing, etc.
- Kits work on almost any commercially available PCR/qPCR machine.

High Performance

- Highest robustness, sensitivity and specificity with a protocol easy to apply.
- Venor®GeM Classic and Venor®GeM qEP are validated comprehensively according to the European Pharmacopoeia 2.6.7. The separate Internal Amplification Control allows for optional process monitoring.
- Superior results in proficiency tests and in depth robustness studies.



Kit Selection	Venor [®] GeM Classic	Venor [®] GeM One Step	Venor [®] GeM Advance	Venor®GeM qEP
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Description	Venor®GeM Classic is a basic PCR kit for fast, reliable and time-saving routine monitoring of mycoplasma contamination.	Venor®GeM OneStep is a complete kit which includes all reagents required for PCR. Primer, nucleotides, polyme- rase and the internal amplification control are provided ready-to-use in a freeze-dried reaction mix. The included rehydration buffer is added to the mix, aliquots made according to the sample number, sample or Positive Control DNA added and the setup is ready for PCR.	Venor®GeM Advance contains PCR reaction tubes pre-coated with all PCR reagents to reduce the total assay time without need to prepare aliquots of a master mix. For additional convenience the gel loading buffer and dye are already included in the reaction buffer. After thermal cycling the PCR can be loaded directly on the agarose gel.	Venor®GeM qEP utilizes quantitative, real-time PCR for high quality and reliable detection of mycoplasma contamination. It can be used in combination with cell culture enrichment, for direct screening of cell cultures or after DNA extraction for EP compliant testing of cell culture derived biologicals, like autologous transplants (ATMPs), sera, cell culture media and therapeutic anti- body 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 compliant release testing.	Applicable in research for direct testing of cell cultures and cell culture derived biologicals.	Applicable in research for direct testing of cell cultures and cell culture derived biologicals.	Applicable in research and industry: For direct screening of cell cultures and biologicals. For EP 2.6.7 compliant release testing.
Type of PCR	Conventional, endpoint PCR	Conventional, endpoint PCR	Conventional, endpoint PCR	Probe assay for qPCR
Device Requirement	PCR cycler / Agarose gel electrophoresis and DNA staining system / Pipetting equipment / Tube centrifuge	PCR cycler / Agarose gel electrophoresis and DNA staining system / Pipetting equipment / Tube centrifuge	PCR cycler / Agarose gel electrophoresis and DNA staining system / Pipetting equipment / Tube centrifuge	qPCR cycler / Pipetting equipment / Tube centrifuge
Kit Components	Primer sets and nucleotides / 10x reaction buffer / Positive control DNA / Internal amplification control / PCR grade water	Primer sets, nucleotides, internal amplification control and polymerase / Rehydration buffer / Positive control DNA / PCR grade water	Primer sets, nucleotides and internal amplification control DNA, filled in 0.2 ml PCR reaction tubes / Rehydration buffer including gel loading buffer and running dye Positive controls, filled in 0.2 ml PCR reaction tubes / PCR grade water	Primer sets, nucleotides and polymerase / Rehydration buffer / Internal amplification control / Positive control DNA / PCR grade water
Package Sizes	CatNo. 11-1025 \rightarrow 25 Tests CatNo. 11-1050 \rightarrow 50 Tests CatNo. 11-1100 \rightarrow 100 Tests CatNo. 11-1250 \rightarrow 250 Tests	CatNo. 11-8025 \rightarrow 25 Tests CatNo. 11-8050 \rightarrow 50 Tests CatNo. 11-8100 \rightarrow 100 Tests CatNo. 11-8250 \rightarrow 250 Tests	CatNo. 11-7024 → 24 Tests CatNo. 11-7048 → 48 Tests CatNo. 11-7096 → 96 Tests CatNo. 11-7240 → 240 Tests	CatNo. 11-9025 \longrightarrow 25 Tests CatNo. 11-9100 \longrightarrow 100 Tests CatNo. 11-9250 \longrightarrow 250 Tests
Sample Volume per PCR	$2\mu l$ for screening / 10 μl for EP 2.6.7 compliant testing	2 μl	2 μΙ	$2\mu l$ for screening / 10 μl for EP 2.6.7 compliant testing
EP 2.6.7 Compliance	Yes, after appropriate sample preparation and process validation	No	No	Yes, after appropriate sample preparation and process validation
Validation	Validation report available on request	Not provided	Not provided	Validation report available on request
Result Evaluation	Gel analysis	Gel analysis	Gel analysis	Cycler based, real-time PCR
Required Consumables	PCR reaction tubes / Polymerase	PCR reaction tubes	No	PCR reaction tubes
Optional Consumables	Optional for process monitoring: Internal Control DNA extra (Cat. No. 11-1905) Optional for process validation according to EP 2.6.7: 10CFU [™] Sensitivity Standards available for all EP listed mycoplasma species (e.g. <i>Mycoplasma orale</i> , Cat. No. 102-2003)			Optional for process monitoring: Internal Control DNA extra (Cat. No. 11-1905) Optional for process validation according to EP 2.6.7: 10CFU [™] Sensitivity Standards available for all EP listed mycoplasma species (e.g. Mycoplasma orale, Cat. No. 102-2003) Optional for quantification: PCR Calibration Reagents for all EP listed mycoplasma species (e.g. Mycoplasma orale DNA, Cat. No. 52-0112)
Shelf Life and Storage	Components can be stored at +2 to +8°C for at least 6 months. After rehydration the reagents must be stored at -18°C.			

