ViruSure GmbH

Mycoplasma Detection by qPCR

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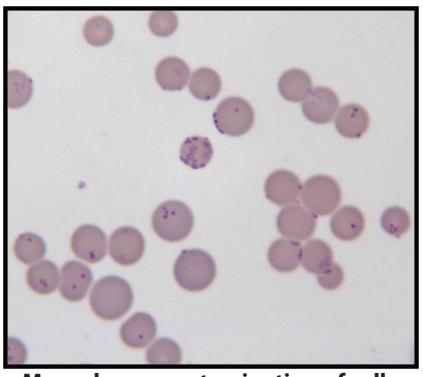
Mycoplasmas are among the biggest contaminant concerns in biological products and although Mycoplasma do not kill contaminated cells, they can have a variety of effects on cultured cells, such as altered metabolism, slowed proliferation and chromosomal aberrations, which can compromise the quality of biopharmaceutical products.

Due to their diversity, their small size, and the absence of a bacterial wall, they cannot be observed by light microscopy and are therefore difficult to detect. ViruSure has developed and validated its own Real- Time PCR detection method (nucleic acid amplification technique, NAT) following European Pharmacopeia and ICH guidelines and is using it already for routine release testing.

The Assay

The assay is performed in accordance to European Pharmacopeia (EP) section 2.6.7, where NAT is now considered as an alternative to the cell culture method after suitable validation. The method detects all Mycoplasma species described in the EP, and in addition ViruSure has confirmed detection of the additional strains requested by the Japanese Pharmacopoeia (JP):

- Mycoplasma gallisepticum (EP)
- Acholeplasma laidlawii (EP + JP)
- Mycoplasma fermentans (EP + JP)
- Mycoplasma hyorhinis (EP+ JP)
- Mycoplasma orale (EP + JP)
- Mycoplarma synoviae (EP + JP)
- Spiroplasma citri (EP + JP)
- Mycoplasma pneumoniae (JP)
- Mycoplasma arginini (EP + JP)
- Mycoplasma salivarium (JP)



Mycoplasma contamination of cells revealed by staining

The NAT uses a TaqMan Assay where the primers and the probe bind to a highly conserved region of the mycoplasma genomes, the 16S rRNA. Detection of all mycoplasma strains has been validated and met the European and Japanese Pharmacopeia defined Limit of Detection for the Mycoplasma qPCR assay of at least 10 CFU per ml.

Assay Controls

Specific controls to ensure system suitability and to exclude assay interference from the test sample matrix are always included, according to the acceptance criteria defined by ViruSure Quality systems for PCR assays.

Advantages

The qPCR method is a highly sensitive method and compared to the standard culture method, which takes 28 days, it is an extremely rapid method where even testing of multiple samples can be done within a few days.

To find out more about these services, as well as our full range of biosafety testing service, please contact us via email at: virus_safety@virusure.com.

ViruSure GmbH
Tech Gate Science and Technology Park,
Donau City Strasse 1, A-1220 Vienna, Austria
Telephone: +43-1-2699-120
Telefax: +43-1-2699-12022
E-Mail: virus_safety@virusure.com
virusure.com