

REFERENCE MATERIALS

How reliable are
your results?

Precise reference materials for DNA analysis.

10CFU™ Sensitivity Standards

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



Applications

European Pharmacopoeia 2.6.7 “Mycoplasma” requires a sensitivity of 10 CFU/ml sample volume for NAT-based methods like PCR to replace the traditional culture method. This feature of the test method must be shown by the performing lab as part of the robustness testing in presence of the sample matrix. As most cell culture labs and production facilities cannot accept vital mycoplasma in their facility or do not have access to a microbiology lab able to cultivate mycoplasma, these preparations allow safe and reliable validation of the procedure.

The mycoplasma have been cultivated in culture broth described in EP 2.6.7, titrated immediately in culture broth and plated for quantification in colony forming units (CFU/ml). Each dilution series has been performed in multiple by different operators for highest precision. The mycoplasma broth was harvested in the early logarithmic phase of the growth to avoid an atypical high ratio of dead mycoplasma particles and correspondingly a high GU*:CFU ratio. All strains have been obtained from the National Collection of Type Cultures (NCTC), UK, and cultivated in low passages.

Each vial contains 10 CFU of inactivated mycoplasma. By adding the sample matrix of interest a sample according to EP 2.6.7 is prepared which has to be tested positive by the method applied. Obviously, the inactivated sample material is not suitable for the culture method anymore. As a result of proficiency tests on DNA amplification methods for mycoplasma detection it became obvious that in means of highest sensitivity DNA extraction is indispensable. The extract can directly be used for PCR.

* Please note: This standard material was not titrated for genome copies (GU) as EP 2.6.7 does not provide sensitivity limits on DNA level. No guarantee for a particular GU:CFU ratio is provided with this product and the ratio may vary from lot to lot.

Package Content

3 vials with 10 CFU of the corresponding mycoplasma species, 2 negative control vials

For the mycoplasma set

2 vials with 10 CFU of each mycoplasma species listed in the EP 2.6.7 (18 vials in total), 2 negative controls

Order information

102-1003	<i>Mycoplasma arginini</i>
102-2003	<i>Mycoplasma orale</i>
102-3003	<i>Mycoplasma gallisepticum</i>
102-4003	<i>Mycoplasma pneumoniae</i>
102-5003	<i>Mycoplasma synoviae</i>

102-6003	<i>Mycoplasma fermentans</i>
102-7003	<i>Mycoplasma hyorhinis</i>
102-8003	<i>Acholeplasma laidlawii</i>
102-9003	<i>Spiroplasma citri</i>
102-0003	<i>Mycoplasma Set</i>

Genomic DNA Extracts

for Specificity Testing



Applications

Defined genomic DNA extracts are required for microorganism typing or more often as standard DNA for the validation of quality testing procedures in the biopharmaceutical industry. Genomic DNA extracts are for in vitro use only.

Contents

1 vial of genomic DNA extract, contains 10 ng +/- 2 ng DNA in 100 µl 10 mM Tris, pH 8.5.

Order information

Cat.-No. 51-0116	<i>Acholeplasma laidlawii</i>
Cat.-No. 51-0031	<i>Bacillus cereus</i>
Cat.-No. 51-0010	<i>Bacillus subtilis</i>
Cat.-No. 51-3415	<i>Bordetella parapertussis</i>
Cat.-No. 51-5571	<i>Bordetella pertussis</i>
Cat.-No. 51-1386	<i>Candida albicans</i>
Cat.-No. 51-0440	<i>Chlamydia trachomatis</i>
Cat.-No. 51-0478	<i>Clostridium acetobutylicum</i>
Cat.-No. 51-0053	<i>Enterobacter aerogenes</i>
Cat.-No. 51-0792	<i>Enterococcus faecalis</i>
Cat.-No. 51-0083	<i>Escherichia coli</i>
Cat.-No. 51-1368	<i>Fluoribacter bozemanæ</i> (syn. <i>Legionella bozemanæ</i>)
Cat.-No. 51-1723	<i>Lactobacillus acidophilus</i>
Cat.-No. 51-1370	<i>Legionella dumofii</i>

Cat.-No. 51-1533	<i>Legionella jordanis</i>
Cat.-No. 51-0101	<i>Legionella pneumophila</i>
Cat.-No. 51-1514	<i>Legionella pneumophila</i> subsp. <i>fraseri</i>
Cat.-No. 51-1515	<i>Legionella pneumophila</i> subsp. <i>pascullei</i>
Cat.-No. 51-3361	Methicilin-resistant <i>Staphylococcus aureus</i> (MRSA)
Cat.-No. 51-0030	<i>Micrococcus luteus</i>
Cat.-No. 51-0129	<i>Mycoplasma arginini</i>
Cat.-No. 51-0162	<i>Mycoplasma arthritidis</i>
Cat.-No. 51-0117	<i>Mycoplasma fermentans</i>
Cat.-No. 51-0115	<i>Mycoplasma gallisepticum</i>
Cat.-No. 51-0195	<i>Mycoplasma genitalium</i>
Cat.-No. 51-0111	<i>Mycoplasma hominis</i>

Cat.-No. 51-0130	<i>Mycoplasma hyorhinis</i>
Cat.-No. 51-0112	<i>Mycoplasma orale</i>
Cat.-No. 51-1746	<i>Mycoplasma penetrans</i>
Cat.-No. 51-0119	<i>Mycoplasma pneumoniae</i>
Cat.-No. 51-0113	<i>Mycoplasma salivarium</i>
Cat.-No. 51-0124	<i>Mycoplasma synoviae</i>
Cat.-No. 51-0164	<i>Spiroplasma citri</i>
Cat.-No. 51-0231	<i>Staphylococcus aureus</i>
Cat.-No. 51-7058	<i>Salmonella enterica</i>
Cat.-No. 51-0071	<i>Pseudomonas aeruginosa</i>
Cat.-No. 51-4479	<i>Proteus mirabilis</i>
Cat.-No. 51-0044	<i>Staphylococcus epidermidis</i>
Cat.-No. 51-0566	<i>Streptococcus pneumoniae</i>
Cat.-No. 51-0177	<i>Ureaplasma urealyticum</i>

PCR Calibration Reagents



Applications

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

The calibration reagents contain genomic DNA which was extracted at low passage from defined microorganisms. The extraction of the DNA was done by magnetic bead and column absorption methods. The DNA extract was partially sequenced and the sequence aligned to confirm identity. Titration was done after fluorometric quantification of the preparation against calibrated plasmid DNA. QC included qPCR against a synthetic and highly defined control plasmid.

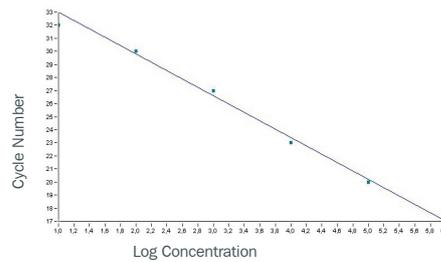
Contents

1 vial (green cap) of Calibration Reagent DNA, 100 µl, contains approx. 10^6 genomes/µl.
3 vials (white cap) with 1 ml of Tris-HCl buffer, 10 mM, pH 8.5.

Order information

Cat.-No. 52-0116	<i>Acholeplasma laidlawii</i>
Cat.-No. 52-5571	<i>Bordetella pertussis</i>
Cat.-No. 52-0440	<i>Chlamydia trachomatis</i>
Cat.-No. 52-0101	<i>Legionella pneumophila</i>
Cat.-No. 52-0129	<i>Mycoplasma arginini</i>
Cat.-No. 52-0117	<i>Mycoplasma fermentans</i>
Cat.-No. 52-0115	<i>Mycoplasma gallisepticum</i>
Cat.-No. 52-0130	<i>Mycoplasma hyorhinis</i>
Cat.-No. 52-0112	<i>Mycoplasma orale</i>
Cat.-No. 52-0119	<i>Mycoplasma pneumoniae</i>
Cat.-No. 52-0124	<i>Mycoplasma synoviae</i>
Cat.-No. 52-0164	<i>Spiroplasma citri</i>
Cat.-No. 52-0071	<i>Pseudomonas aeruginosa</i>

Standard Curve



Real-time Amplification Plot

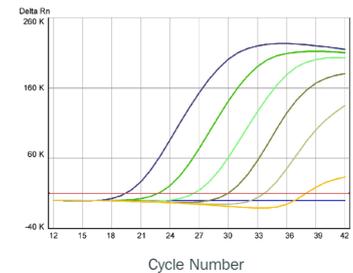


Fig. Quantification of *Mycoplasma pneumoniae* DNA. Logarithmic plot of fluorescence vs cycle number (Venor[®]Mp, platform: ABI Prism[®] 7500). Template DNA ranging from 2×10^5 - 2 genome equivalents.