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HOW RELIABLE ARE YOUR RESULTS?

Reference Materials

Defined genomic DNA from microorganisms relevant for hygiene and contamination control.

Genomic DNA Extracts

Application

- Conventional and qPCR
- Specificity testing

These preparations contain genomic DNA extracted from low passage and defined microorganisms, prepared by phenol/chloroform extraction and subsequent column absorption methods. The DNA extract was partially sequenced to confirm identity. Titration was done by optical density measurement against a weight calf thymus DNA standard.

Content

1 vial with genomic DNA extract with 10 ng +/- 2 ng, freeze-dried
1 vial with 200 µl 10 mM Tris-HCl buffer, pH 8.5, for dissolving the DNA

Order information

Cat. No.	Species
51-0116	*Acholeplasma laidlawii*
2127-30007	*Acinetobacter bamanii*
2128-30187	*Aeromonas hydrophila*
2101-00819	*Aspergillus fumigatus*
51-0031	*Bacillus cereus*
51-0010	*Bacillus subtilis*
2129-02046	*Bacillus thueringiensis*
51-3415	*Bordetella parapertussis*
51-5571	*Bordetella pertussis*
2130-07288	*Burkholderia capacia*
2102-04688	*Campylobacter jejuni*
51-1386	*Candida albicans*
2103-11226	*Candida glabrata*
2104-11947	*Candida guiliermondii*
2105-70624	*Candida haemulonii*
2106-30039	*Citrobacter freundii*
2125-90874	*Candida tropicalis*
2107-04595	*Citrobacter koseri*
51-0792	*Clostridium acetobutylicum*
2108-00756	*Clostridium perfringens*
51-0053	*Enterobacter aerogenes*
2110-30054	*Enterobacter cloacae*
2111-20680	*Enterococcus casseliflavus*
2112-30633	*Enterococcus durans*
51-0478	*Enterococcus faecalis*
2113-20477	*Enterococcus faecium*
2114-20160	*Enterococcus hirse*
51-0083	*Escherichia coli*
2115-08579	*Escherichia coli* 0157:H7

Cat. No.	Species
51-1368	*Fluoribacter bozemanae* (syn. *Legionella bozemanae*)
2131-05934	*Geobacillus stearothermophilus*
2132-30104	*Klebsiella pneumoniae*
2133-70603	*Klebsiella pneumoniae*, ESBL+
51-1723	*Lactobacillus acidophilus*
51-1370	*Legionella dumofii*
51-1533	*Legionella jordanis*
51-0101	*Legionella pneumophila*
51-1514	*Legionella pneumophila subsp. fraseri*
51-1515	*Legionella pneumophila subsp. pascullei*
51-3361	*Methicilin-resistant Staphylococcus aureus* (MRSA)
2134-30164	*Morganella morganii*
51-0030	*Micrococcus luteus*
51-0129	*Mycoplasma arginini*
51-0162	*Mycoplasma arthritidis*
51-0117	*Mycoplasma fermentans*
51-0115	*Mycoplasma gallisepticum*
51-0195	*Mycoplasma genitalium*
51-0111	*Mycoplasma hominis*
51-0130	*Mycoplasma hyorhinis*
51-0112	*Mycoplasma orale*
51-1746	*Mycoplasma penetrans*
51-0119	*Mycoplasma pneumoniae*

Cat. No.	Species
51-0113	*Mycoplasma salivarium*
51-0124	*Mycoplasma synoviae*
2135-10036	*Neisseria meningitidis*
2136-13387	*Proteus vulgaris*
51-0071	*Pseudomonas aeruginosa*
2116-04479	*Proteus mirabilis*
51-7058	*Salmonella enterica*
2117-30121	*Serratia marcescens*
2137-04782	*Shigella flexneri*
2138-05570	*Shigella sonnei*
51-0164	*Spiroplasma citri*
51-0231	*Staphylococcus aureus*
51-0044	*Staphylococcus epidermidis*
2118-20328	*Staphylococcus hominis*
2119-20263	*Staphylococcus haemolyticus*
2122-20480	*Streptococcus bovis*
2123-06176	*Streptococcus dysgalactiae*
2126-20523	*Streptococcus mutans*
51-0566	*Streptococcus pneumoniae*
2139-20068	*Streptococcus sanguinis*
2120-20229	*Staphylococcus saprophyticus*
2121-50170	*Stenotrophomonas maltophilia*
51-0177	*Ureaplasma urealyticum*
2140-04780	*Yersinia enterocolitica*
2141-08992	*Yersinia pseudotuberculosis*

PCR Quantification Standards

Application

- Conventional and qPCR
- Standard curves, evaluation of assay performance
- Preparation of dilution series for quantification
- Low titer (e.g. 3 x LOD_{95}) controls

Standardization and quantification of nucleic acid detection is a difficult task as there are no reliable standards for low nucleic acid copy numbers. Detection methods such as PCR and NASBA are prone to inhibition caused by many substances commonly found in plant and animal tissues, food matrices and extraction solutions. When co-purified with DNA or RNA, inhibitors reduce amplification efficiency, causing an underestimation of the quantity of target nucleic acid or even false-negative results.

Minerva Biolabs calibration reagents contain genomic DNA extracted from low passage and defined microorganisms. The DNA is manufactured by means of phenol/chloroform extraction with ethanol precipitation and subsequent column absorption methods. The DNA extract was partially sequenced and the sequence aligned to confirm identity. Titration was done after photometric quantification of the preparation standard and dsDNA fluorometric quantification against a synthetic standard.

For the first time, qPCR user are able to include a precise low count of DNA copies in their assays, providing them with a true value for the estimation of detection limits and the comparison of different detection methods.

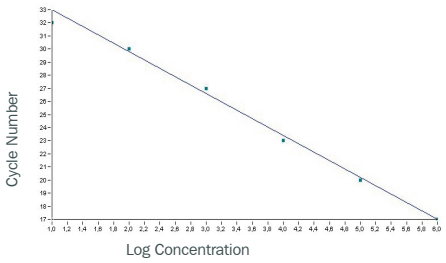
Content

1 vial with DNA, $1x10^8$ genomes, freeze-dried
3 vials with 2 ml of Tris-HCl buffer, 10 mM, pH 8.5., for dissolving the DNA and preparing dilutions

Order information

Cat. No.	Species
52-0116	*Acholeplasma laidlawii*
52-5571	*Bordetella pertussis*
52-0083	*Escherichia coli*
52-0101	*Legionella pneumophila*
52-0129	*Mycoplasma* arginini
52-0117	*Mycoplasma fermentans*
52-0115	*Mycoplasma gallisepticum*
52-0130	*Mycoplasma hyorhinis*
52-0112	*Mycoplasma orale*
52-0119	*Mycoplasma pneumoniae*
52-0124	*Mycoplasma synoviae*
52-0164	*Spiroplasma citri*
52-0071	*Pseudomonas aeruginosa*

Standard Curve



Real-time Amplification Plot

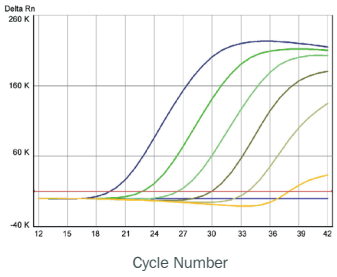


Fig. Quantification of *Mycoplasma pneumoniae* DNA. Logarithmic plot of fluorescence vs cycle number (Venor®GeM qEP, platform: ABI Prism® 7500). Template DNA ranging from $2x10^5$ - 2 genome equivalents.

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10CFU™ Sensitivity Standards

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

Application

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 a high ratio of dead mycoplasma particles and correspondingly a high GU*:CFU ratio. All strains have been obtained from official culture collections 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 indispensible. 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

Catalogue Number

102-1003	*Mycoplasma arginini*	102-6003	*Mycoplasma fermentans*
102-2003	*Mycoplasma orale*	102-7003	*Mycoplasma hyorhinis*
102-3003	*Mycoplasma gallisepticum*	102-8003	*Acholeplasma laidlawii*
102-4003	*Mycoplasma pneumoniae*	102-9003	*Spiroplasma citri*
102-5003	*Mycoplasma synoviae*	102-0002	Mycoplasma Set

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