minerva biolabs®

Genomic DNA Extracts, PCR Quantification Standards, 10CFU™ and 100CFU™ Sensitivity Standards

Genomic & Microbial Reference Materials

- ✓ Genomic DNA extracts of defined microorganisms for specificity testing in conventional and qPCR
- ✓ PCR quatification standards of mycoplasma and bacterial genomic DNA for applications in conventional and qPCR
- ✓ 10CFU™ and 100CFU™ Sensitivity Standards for validating robustness and sensitivity of molecular methods for mycopplasma detection as required by the *European Pharmacopoeia,* Chapter 2.6.7, USP <1071> and by the *Japanese Pharmacopoeia,* Chapter G3

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Genomic DNA Extracts

Background & Description

- Conventional and qPCR
- Specificity testing

These preparations contain genomic DNA extracted from defined microorganisms at low passage, extracted by subsequent column absorption methods. The DNA extract is then partially sequenced to confirm identity and titrated.

Content

1 vial with genomic DNA extract with 10 ng ± 2 ng, freeze-dried; 1 vial with 200 µl Tris-HCl buffer (10 mM, pH 8.5) for DNA rehydration

Ordering Information

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*
51-5571	*Bordetella pertussis*
2130-07288	*Burkholderia cepacia*
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
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*
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 equinus* (syn. *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	*Yer sinia enterocolitica*
2141-08992	*Yersinia pseudotuberculosis*

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PCR Quantification Standards

Background & Description

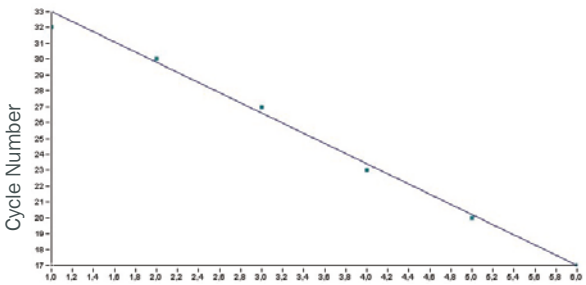
- Conventional and qPCR
- Standard curves, evaluation of assay performance
- Preparation of dilution series for quantification
- Low titer (e.g. 3 x LOD_{95}) controls

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 extract from low passage and defined microorganisms. The DNA is extracted by 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.
By using the PCR Quantification Standards, qPCR users can include a precise low count of DNA copies in their assays. This will serve as an exact reference value for the estimation of detection limits and for the comparison between different detection methods.

Content
1 vial with DNA, $1x10^8$ genome copies, freeze-dried; 3 vials with 2 ml of Tris-HCl buffer (10 mM, pH 8.5) for rehydration and preparation of serial dilutions

Standard Curve



Real-time Amplification Plot

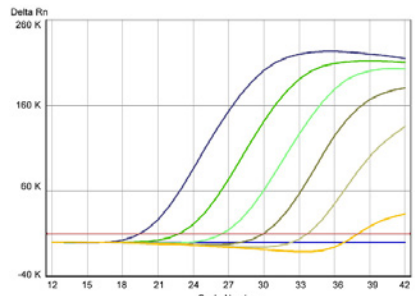


Fig. Quantification of Mycoplasma pneumoniae DNA. Logarithmic plot of fluorescence vs cycle number (Venor®GeM qEP, platform: ABI Prism® 7500). Template DNA ranging from 2x105 - 2 genome equivalents.

Ordering Information

Catalog Number

Cat. No. 52-0116	*Acholeplasma laidlawii*	Cat. No. 52-0130	*Mycoplasma hyorhinis*
Cat. No. 52-5571	*Bordetella pertussis*	Cat. No. 52-0112	*Mycoplasma orale*
Cat. No. 52-0083	*Escherichia coli*	Cat. No. 52-0119	*Mycoplasma pneumoniae*
Cat. No. 52-0101	*Legionella pneumophila*	Cat. No. 52-0124	*Mycoplasma synoviae*
Cat. No. 52-0129	*Mycoplasma arginini*	Cat. No. 52-0164	*Spiroplasma citri*
Cat. No. 52-0117	*Mycoplasma fermentans*	Cat. No. 52-0071	*Pseudomonas aeruginosa*
Cat. No. 52-0115	*Mycoplasma gallisepticum*	Cat. No. 52-0103	*Mycoplasma salivarium*

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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*

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