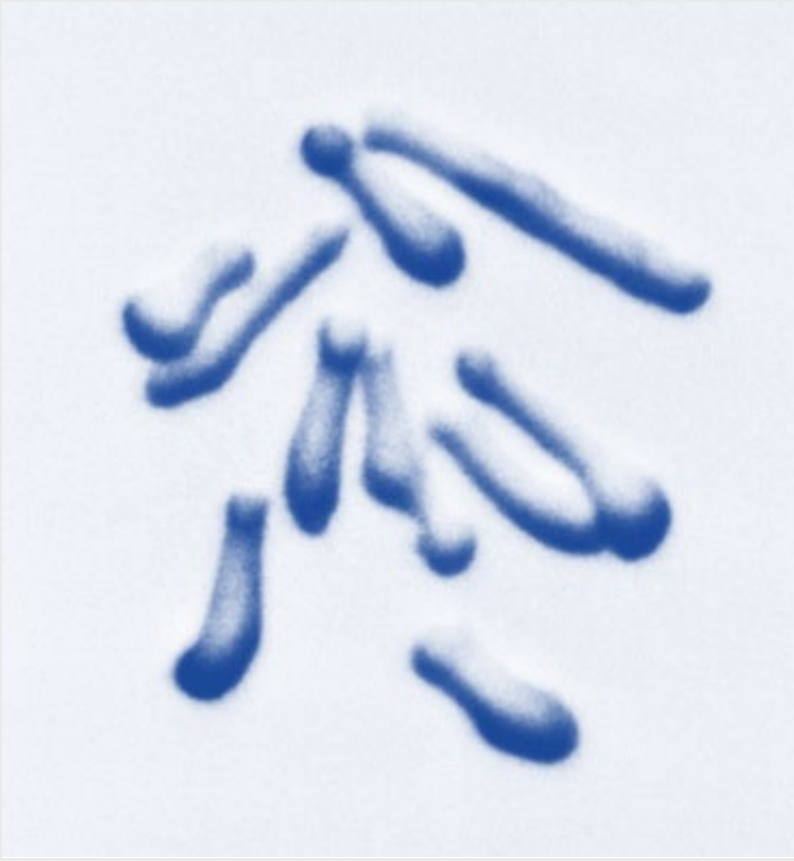
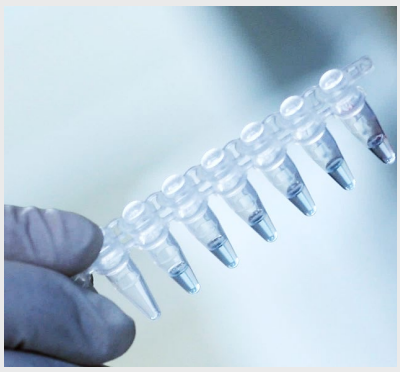
mycosafe®

Mycosafe® Mycoplasma DNA Reference Standards

Validation Standards & Controls
for NAT-based Mycoplasma Detection
Methods according to
EP 2.6.7., USP <63> & JP G3
for Application in Pharma QC, Cell & Gene
Therapies, and Regenerative Medicine



11 Pharmacopoeia Mycoplasma Reference Strains



Titer Format
100 GC
per µL

2 Product-Relevant Non-Pharmacopoeia Mycoplasma Reference Strains

User Guide

GC-Calibrated
Genomic DNA Preparations of
Certified Mycoplasma Reference Strains

October 2021

Cover Images
Scanning electron micrograph displaying 10 single mid-log phase mycoplasma cells that correspond to 10 genome copies (GC). Mycosafe® Mycoplasma DNA Reference Standards are purified genomic DNA preparations that are calibrated at 100 GC/µL.

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Publication Number RSDNAUG03-102021

Mycosafe® Mycoplasma DNA Reference Standards
Validation Standards & Controls for NAT-based Mycoplasma Detection Methods according to EP 2.6.7., USP <63> & JP G3

User Guide

GC-Calibrated Genomic DNA Preparations of Certified Mycoplasma Reference Strains
Titer Format 100 GC per 100 µL

October 2021

Table of Content

1. Mycosafe® Mycoplasma DNA Reference Standard Products

This User Guide refers to the products of GC-calibrated mycoplasma DNA preparations listed below for use as an alternative option to live or inactivated mycoplasma cell preparations. These are easy-to-use frozen purified DNA preparations from culture-grown late-log phase cells of (i) all 10 pharmacopoeia mycoplasma type strains, (ii) the pharmacopoeia cultivar α reference strain, and (iii) 2 important product-relevant non-pharmacopoeia mycoplasma type strains that are available as Mycosafe® Single-Strain DNA Reference Standards and convenient Mycosafe® Multi-Strain DNA Reference Standard Validation & Control Sets in a titer format of 100 GC/µL that allows easy dilution steps to obtain low-titer preparations. This DNA-100 product format is provided in product units of 100 µL in cryovials. All Mycosafe® Mycoplasma DNA Reference Standard Products are traceable to authentic reference cultures of the National Collection of Type Cultures (NCTC) and the American Type Culture Collection (ATCC) and represent DNA preparations derived from low-passage level cultures that represent ≤ 15 passages from the original reference culture to comply with EP 2.6.7. (1), USP <63> (2) and JP G3 (3).

1.1 Mycosafe® Single-Strain DNA Reference Standards

Mycosafe® Single-Strain DNA Reference Standards
Product Format

Product Format	**DNA-100**
Calibrated Total GC Titer	**100 GC/µL**
Product Unit	**100 µL**

Product/Order Numbers

Mycoplasma Reference Strain	Product/Order No.
Pharmacopoeia Type Strains (T)	
***Acholeplasma laidlawii* PG8^T** NCTC 10116 ATCC 23206	Al-T-DNA-100
***Mycoplasma arginini* G230^T** NCTC 10129 ATCC 23838	Ma-T-DNA-100
***Mycoplasma fermentans* PG18^T** NCTC 10117 ATCC 19989	Mf-T-DNA-100
***Mycoplasma gallisepticum* PG31^T** NCTC 10115 ATCC 19610	Mg-T-DNA-100
***Mycoplasma hyorhinis* BTS7^T** NCTC 10130 ATCC 17981	Mh-T-DNA-100
***Mycoplasma orale* CH19299^T** NCTC 10112 ATCC 23714	Mo-T-DNA-100
***Mycoplasma pneumoniae* FH^T** NCTC 10119 ATCC 15531	Mp-T-DNA-100
***Mycoplasma salivarium* PG20^T** NCTC 10113 ATCC 23064	Msa-T-DNA-100
***Mycoplasma synoviae* WVU 1853^T** NCTC 10124 ATCC 25204	Ms-T-DNA-100
***Spiroplasma citri* R8-A2^T** NCTC 10164 ATCC 27556	Sc-T-DNA-100

Mycoplasma Reference Strain	Product/Order No.
Pharmacopoeia 'Non-Cultivable' Cultivar α Reference Strain (Alpha)	
***Mycoplasma hyorhinis* DBS 1050** ATCC 29052	Mh-Alpha-DNA-100
Product-Relevant Non-Pharmacopoeia Type Strains (T)	
***Mycoplasma bovis* PG45^T** NCTC 10131 ATCC 25523	Mb-T-DNA-100
***Mycoplasma hominis* PG21^T** NCTC 10111 ATCC 23114	Mho-T-DNA-100

1.2 Mycosafe® Multi-Strain DNA Reference Standard Validation & Control Sets

Categories of Mycosafe® Multi-Strain DNA Reference Standard Validation & Control Sets	
EPUSP10	**All-in-One Validation Set according to EP 2.6.7. and USP <63>,** consisting of all 9 EP/USP mycoplasma type strains, including the type strains of *M. gallisepticum*, *M. synoviae* and *S. citri,* plus the 'non-cultivable' *M. hyorhinis* cultivar α reference strain
EPUSP7	**Complete Basic Validation Set according to EP 2.6.7. and USP <63>,** consisting of all 6 non-avian and non-plant EP/USP mycoplasma type strains, plus the 'non-cultivable' *M. hyorhinis* cultivar α reference strain
JP10	**All-in-One Validation Set according to JP G3.**, consisting of all 9 JP mycoplasma type strains including the type strains of *M. synoviae* and *S. citri,* plus the 'non-cultivable' *M. hyorhinis* cultivar α reference strain
JP7	**Complete Basic Validation Set according to JP G3**, consisting of all 7 non-avian and non-plant JP mycoplasma type strains
EPUSPJP5	**Small Basic Validation Set according to EP 2.6.7., USP <63> and JP G3.,** consisting of the 5 EP/USP/JP mycoplasma type strains of *A. laidlawii, M. arginini, M. fermentans*, *M. hyorhinis* and *M. pneumoniae*
EPUSPJP3	**Control Set for Routine Mycoplasma Testing according to EP 2.6.7., USP <63> and JP G3,** consisting of the 3 EP/USP/JP mycoplasma type strains of *A. laidlawii, M. orale* and *M. pneumoniae*

Mycosafe® Multi-Strain DNA Reference Standard Validation & Control Sets Product Format					
	Product Format	DNA-100			
	Calibrated Total GC Titer	100 GC/µL			
	Product Unit	100 µL			
	Product Units/Set	3-10			
Product/Order Numbers					
Mycoplasma Reference Standard Strain Set Category	**Product/Order No.**		**Mycoplasma Reference Standard Strain Set Category**	**Product/Order No.**	
EPUSP10	EPUSP10-DNA-100		**JP10**	JP10-DNA-100	
EPUSP7	EPUSP7-DNA-100		**JP7**	JP7-DNA-100	
EPUSPJP5	EPUSPJP5-DNA-100				
EPUSPJP3	EPUSPJP3-DNA-100				

2. Scope of Use

Mycosafe® Mycoplasma DNA Reference Standards are frozen mycoplasma DNA preparations calibrated at a convenient GC titer of 100 GC/µL for use in

(i) quality control of biopharmaceuticals and cell & gene therapy products as **Validation Standards** and as **External Controls** in NAT-based mycoplasma testing applications, and

(ii) laboratory *in vitro* research purposes.

Mycosafe® Mycoplasma DNA Reference Standards are not for any human or animal therapeutic or diagnostic use.

3. Intended Use

Mycosafe® Mycoplasma DNA Reference Standards are intended for use as reference material and controls in in-process and release mycoplasma testing by **NAT-based mycoplasma detection methods** according to EP 2.6.7. (1), USP <63> (2) and JP G3 (3). They are mycoplasma genomic DNA preparations calibrated at 100 GC/µL that are designated for use in Real-Time PCR testing (i) to carry out **suitability tests of the selected Real-Time PCR test system** and an **initial feasibility study** before using cell-based Mycosafe® Culture Reference Standard Products in the viable or inactivated product format, or (ii) **if safety regulations prevent the handling of live mycoplasma cell preparations** and (iii) the **use of mycoplasma DNA preparations** instead of inactivated mycoplasma cell preparations **is preferred**.

For the generic validation of a mycoplasma NAT method mycoplasma cell preparations must be applied as reference standards according to the mycoplasma NAT validation guidelines in EP 2.6.7. (1) and JP G3 (3), since the validation of the procedure also requires an evaluation of the DNA extraction efficiency based on intact mycoplasma cells. CFU-equivalent genome copies can nevertheless alternatively be used at various stages during an NAT validation study, and this particularly refers to initial feasibility studies. Likewise, in the test itself, Mycosafe® Mycoplasma DNA Reference Standards may be used as external positive controls.

Therefore, at least for parts of the generic and product-specific validation of NAT-based mycoplasma detection methods, such as those of the currently commercially available Real-Time PCR mycoplasma detection systems, Mycosafe® Mycoplasma DNA Reference Standards are appropriate for use as **Validation Standards** if their application is duely justified. As pointed out above, this justification applies either to initial suitability and feasibility tests, or if Mycosafe® Mycoplasma Culture Reference Standards in the viable product format can due to facility or laboratory safety regulations not be used, and mycoplasma DNA preparations as alternative reference standards are preferred by the user over inactivated mycoplasma cell preparations. Likewise, Mycosafe® Mycoplasma DNA Reference Standards are appropriate for use as **External Controls** during routine application of validated Real-Time PCR mycoplasma test methods.

4. Composition & Specifications

Mycosafe® Mycoplasma DNA Reference Standards are comprised of genomic DNA purified from certified mycoplasma reference strains grown to late-log phase in FRIIS, FREY or Mycosafe® ABO™ medium. The calibration using TE buffer as diluent (see below) to a concentration of 100 GC/µL following DNA quantification is based on the published genome size for each mycoplasma species or the corresponding mycoplasma reference strain from whose culture the DNA is prepared.

Mycosafe® Mycoplasma DNA Reference Standard Products are supplied frozen in product units of 100 µL DNA aliquots contained in 1.5-mL plastic cryovials. The verified mycoplasma species identity of each Mycosafe® Mycoplasma DNA Reference Standard Product, the traceability to an authentic reference culture of a specified mycoplasma reference strain from the NCTC and/or the ATCC, the low passage level of the late-log phase reference strain culture from which the DNA was extracted and purified, as well as the calibrated GC titer of 100 GC/µL are stated in a corresponding **lot-specific Certificate of Analysis (CoA)**.

5. Materials for Optional Use but not Provided

Diluent
A diluent may be required to obtain the desired concentration of mycoplasma genome copies (GC) that is suitable for the intended use.
For the preparation of diluted DNA preparations, the use of Tris-EDTA buffer solution (TE buffer, for molecular biology) as diluent is recommended.

6. Instructions for Use

6.1 Preparation for Use

Thawing
(i) For thawing, the frozen mycoplasma DNA-100 reference standard material is warmed at room temperature and then kept on ice prior to use for direct spike inoculation without further dilution, or for preparation of an appropriate working dilution.

Optional Preparation of Working Dilutions
(ii) After thawing of the frozen mycoplasma DNA reference standard material at room temperature it may be - if required or desired - diluted with TE buffer (for molecular biology) to obtain the desired number of total mycoplasma genome copies in an appropriate spike inoculation volume that is suitable for the intended use.
(iii) The final dilution and the required dilution steps must be based on the titer of the total number of mycoplasma genome copies that is specified each with 100 GC/µL in the corresponding CoA.
(iv) The dilution steps with the TE buffer diluent must be carried out on ice after thawing of the frozen mycoplasma DNA reference standard material.
(v) The diluted mycoplasma DNA reference standard material must be kept on ice if not immediately used.

Spike Inoculation
(vi) The product sample material to be spiked must be ready for spike inoculation as soon as the mycoplasma DNA reference standard material is ready to be used in the desired concentration of total genome copies, either undiluted or in the desired working dilution.
(vii) The ready-to-use undiluted or diluted mycoplasma reference standard material should be mixed prior to use by gently pipetting up and down a few times or briefly vortexing the vial for 1-2 seconds at low speed to obtain an optimal homogeneous suspension of mycoplasma genome copies.

6.2 Spike Inoculation Doses

Mycosafe® Mycoplasma DNA Reference Standard Products are designed for single, few, several or multiple spike inoculations at the same time, depending on the target sample spike level and the applied spiking procedure (direct spiking of test sample replicates, or spiking of a larger test sample volume prior to aliquoting into identical test sample replicates), including the volume of the product sample material and the number of sample replicates to be spiked. Examples for different Spike Inoculation Doses per mL test sample replicate are given below.

Product Format		DNA-100
Spike Inoculation Dose 100 GC per mL Test Sample		
Spike Inoculation Volume Size Range per Dose Undiluted Ready-to-Use*		**1 µL**
Optional Dilution for Spike Inoculation**		●
Number Doses per Product Unit* **	**Single (1-5)**	●
	Few (6-25)	●
	Several (26-100)	●
	Multiple (> 100)	
Spike Inoculation Dose 10 GC per mL Test Sample		
Appropriate Dilution Required for Spike Inoculation**		●
Number Doses per Product Unit** **	**Single (1-5)**	●
	Few (6-25)	●
	Several (26-100)	●
	Multiple (> 100)	●
Spike Inoculation Dose 1 GC per mL Test Sample		
Appropriate Dilution Required for Spike Inoculation**		●
Number Doses per Product Unit** **	**Single (1-5)**	●
	Few (6-25)	●
	Several (26-100)	●
	Multiple (> 100)	●

*The exact volume of spike inoculum needs to be individually calculated for each test or test series and is depending on the product sample volume to be spiked
**To be determined
***Undiluted or diluted
****Diluted

6.3 Repeated Use after Storage & Disposal

(i) The remaining unused undiluted and diluted mycoplasma DNA reference standard material may be either stored at ≤ - 20°C or long-term preferentially at ≤ - 60°C for further single use (see under Section 7 below) or disposed by autoclaving (see under Section 8 below). For long-term storage and multiple use, it is recommended to divide the undiluted or diluted mycoplasma DNA preparations into several aliquots, each for separate use as required.

(ii) Typically, the undiluted or diluted DNA preparations are used only once to avoid DNA degradation by repeated freeze/thaw cycles (see under Section 7 below). The remaining unused undiluted or diluted mycoplasma DNA reference standard material is therefore usually disposed immediately.

6.4 Summary of Instructions for Use

(i) If necessary, determining the working dilution required to obtain the desired spike concentration for the product sample material to be spiked, particularly when low spike levels are targeted.

(ii) Removing the cryovial containing the undiluted frozen mycoplasma DNA reference standard material from the ≤ -20°C (or ≤ -60°C) freezer.

(iii) Thawing of the frozen DNA material by warming at room temperature (< 1 min) and keeping it on ice after thawing.

(iv) Conducting the required dilution steps - if required - on ice using TE buffer (for molecular biology) kept on ice as diluent.

(v) Keeping the ready-to-use undiluted or diluted mycoplasma DNA reference standard material on ice if not immediately used.
(vi) Mixing the ready-to-use undiluted or diluted mycoplasma DNA reference standard material prior to use by gently pipetting up and down a few times or by briefly vortexing the vial for 1-2 seconds at low speed.
(vii) Having the product sample material to be spiked ready for spike inoculation with the ready-to-use undiluted or diluted mycoplasma DNA reference standard material.
(viii) Storing the unused undiluted or diluted mycoplasma DNA reference standard material at ≤ -20°C (or ≤ -60°C) for optional further single use or disposing by autoclaving.

6.5 Additional Notes

(i) For successful use of Mycosafe® Mycoplasma DNA Reference Standards, they should not be used beyond their shelf life indicated in the corresponding CoA.
(ii) Deviations from the described Instructions for Use may affect the results.
See also under Section 9 below.

7. Storage & Stability

The frozen Mycosafe® Mycoplasma DNA Reference Standard Products have a high stability during long-term storage at ≤ -20°C.

Once received, they must be stored properly at ≤ - 20°C prior to thawing for use up to the expiration date specified in the corresponding lot-specific CoA. For optimal long-term stability, storage at ≤ -60°C is recommended. Exposure to higher temperatures than ≤ - 20°C can adversely affect the stability of the mycoplasma DNA reference standard material.

After use for spike inoculation, the rest of the undiluted or diluted mycoplasma DNA reference standard material may be stored at ≤ - 20°C (or ≤ -60°C) for further single use. Repeated freeze/thaw cycles must be avoided as they may result in DNA degradation and consequent alterations in the titer of GC/µL.

If the mycoplasma DNA reference standard material is diluted and not immediately used after dilution, users should determine the shelf life of the diluted preparations according to their own assessment based on experience, method of preparation, storage conditions and use. When stored at ≤ - 20°C, a shelf life of 1 year for single use from the date of preparation, i.e., the date of dilution, is recommended to be issued for the freshly prepared diluted mycoplasma DNA reference standard material.

8. Precautions

Mycosafe® Mycoplasma DNA Reference Standards consist of purified mycoplasma DNA, i.e., of non-infectious material, and have the Biosafety Level 1. General laboratory precautions and good laboratory practise should however be employed when handling Mycosafe® Mycoplasma DNA Reference Standard Products, by wearing proper personal protective equipment, such as an appropriate laboratory coat, protective eye wear and disposable gloves. Mycosafe® Mycoplasma DNA Reference Standards are therefore to be used by trained laboratory personnel only, that has experience in the handling of purified microbial DNA.

Users of Mycosafe® Mycoplasma DNA Reference Standards assume all risk and responsibility in connection with the receipt, handling, storage, disposal, transfer and use of these products. Refer to the **Material Safety Data Sheet (MSDS)** for more detailed information.

Disposal Measures

Mycosafe® Mycoplasma DNA Reference Standard Products do not contain any hazardous substances but are nevertheless considered as biohazard. The remaining unused material or the remaining unused material derived therefrom by dilution must therefore - unless not stored at ≤ -20°C for further single use (see under Section 7 above) – be disposed as biohazard waste by using an autoclave

(i) in accordance with the implemented laboratory protocol for disposal of biohazard materials, and
(ii) in accordance with all national and local regulations.

9. Warranty & Limitations

Mycosafe® Mycoplasma DNA Reference Standards are warranted to meet the specifications given in the CoAs and related Mycosafe® Product Information Material. The warranty, expressed or implied, is limited and the stated characteristics and specifications in the corresponding CoAs cannot be guaranteed when

(i) Mycosafe® Mycoplasma DNA Reference Standards are employed for applications other than the intended use described in this User Guide,
(ii) the procedures employed are different to the directions and instructions given in this User Guide,
(iii) Mycosafe® Mycoplasma DNA Reference Standards are repeatedly thawed and refrozen,
(iv) Mycosafe® Mycoplasma DNA Reference Standards are stored improperly at higher temperatures than ≤ -20°C, and
(v) Mycosafe® Mycoplasma DNA Reference Standards are used after the expiration date has passed.

Mycosafe® Mycoplasma DNA Reference Standard Products are supplied with the condition that users are responsible for their safe storage, handling, and use. Prof Rosengarten and Mycosafe® Consulting assume no liability for any direct, indirect, consequential, or incidental damages resulting from the use, the results of use, or the inability to use Mycosafe® Mycoplasma DNA Reference Standard Products.

10. Restrictions

Mycosafe® Mycoplasma DNA Reference Standards contain trade secrets and intellectual property of Prof Renate Rosengarten and may not be modified, copied or replicated by users, or not be transferred by users to any third party in whole or in part.

The rights granted to the user by purchasing Mycosafe® Mycoplasma DNA Reference Standard Products are personal to the user. The user may not resell or distribute Mycosafe® Mycoplasma DNA Reference Standard Products or any part thereof in any way.

11. References

(1) European Pharmacopoeia, 10th Edition, Chapter 2.6.7., Mycoplasmas, 2020.
(2) United States Pharmacopoeia, 43rd Edition, Chapter 63, Mycoplasma Tests, 2020.
(3) Japanese Pharmacopoeia, 18th Edition, Mycoplasma Testing for Cell Substrates used for the Production of Biotechnological/Biological Products, in: Chapter G3 Biotechnological/Biological Products, 2021.

12. User Guide at a Glance

Mycosafe® Single-Strain DNA Reference Standards	**13 Mycoplasma Reference Strains** • 10 pharmacopoeia type strains (EP 2.6.7., USP <63>, JP G3) • 1 pharmacopoeia 'non-cultivable' cultivar α reference strain (EP 2.6.7., USP <63>, JP G3) • 2 product-relevant non-pharmacopoeia type strains • Purified genomic DNA from late-log phase cultures traceable to authentic reference cultures of the NCTC and the ATCC • Strain passage level: P5 to P14 • For detailed information, see the Mycosafe® Reference Standards Product Flyer
Mycosafe® Multi-Strain DNA Reference Standard Validation & Control Sets	**10 Strain Set Categories** • EPUSP10, EPUSP7 • JP10, JP7 • EPUSPJP5, EPUSPJP3 For detailed information, refer to the Mycosafe® Reference Standards Product Flyer
Product/Titer Format & Product Unit Size	**Product Format** • DNA-100 **Calibrated GC/µL** • 100 **Product Unit Size** • 100 µL For detailed information, refer to the Mycosafe® Reference Standards Product Flyer
Scope of Use	• Validation Standards, and External/Positive Controls in NAT-based mycoplasma testing methods for quality control of biopharmaceuticals and cell & gene therapy products • Laboratory *in vitro* research purposes
Intended Use	• Intended for use as Validation Standards and External Controls for in-process and release mycoplasma testing by NAT-based mycoplasma detection methods according to EP 2.6.7., USP <63> and JP G3 (i) to carry out suitability tests of the selected Real-Time PCR test system and an initial feasibility study before using cell-based Mycosafe® Culture Reference Standard Products in the viable or inactivated product format, or (ii) if safety regulations prevent the handling of live mycoplasma cell preparations, and (iii) the use of mycoplasma DNA preparations instead of inactivated mycoplasma cell preparations is preferred
Compositon & Specifications	• Genomic DNA purified from certified mycoplasma reference strains grown to late-log phase in FRIIS, FREY or Mycosafe® ABO™ medium and calibrated to a concentration of 100 GC/µL based on the published genome size for each mycoplasma species or the corresponding mycoplasma reference strain from whose culture the DNA is prepared • Supplied frozen in product units of 100 µL aliquots contained in 1.5 plastic cryovials • Specifications stated in lot-specific Certificates of Analysis (CoAs): (i) the mycoplasma species identity; (ii) the traceability to an authentic reference culture of a certified mycoplasma reference strain from NCTC and/or ATCC; (iii) the passage level of the late-log phase culture from which the DNA was extracted and purified; (iv) the calibrated GC titer
Materials for Optional Use but not Provided	• Tris-EDTA buffer solution (TE buffer, for molecular biology) as diluent to obtain the desired spike inoculation doses of mycoplasma genome copies that are suitable for the intended use
Instructions for Use	• Thawing of the frozen mycoplasma DNA reference standard material at room temperature (< 1 min) • If required, conducting suitable dilution steps on ice using TE buffer (for molecular biology) as diluent to obtain the desired working dilution • Keeping the ready-to-use undiluted or diluted mycoplasma DNA reference standard material on ice if not immediately used • Mixing the ready-to-use undiluted or diluted mycoplasma DNA reference standard material prior to use by gently pipetting up and down a few times or by briefly vortexing the vial for 1-2 seconds at low speed • The unused undiluted or diluted mycoplasma DNA reference standard material may be stored at ≤ - 20°C (or ≤ - 60°C) for further single use, or disposed by autoclaving
Storage & Stability	• High stability during storage at ≤ -20°C, for long-term stability storage at ≤ -20°C is recommended • After application, the remaining undiluted or diluted mycoplasma DNA reference standard material may be stored at ≤ - 20°C for further single use • If the mycoplasma DNA reference standard material is diluted and not immediately used after dilution, users should determine the shelf life of the diluted preparation according to their own assessment based on experience, method of preparation, storage conditions and use. When stored at ≤ - 20°C, a shelf life of 1 year for single use from the date of preparation, i.e., the date of dilution, is recommended to be issued for the freshly prepared diluted mycoplasma DNA reference standard material
Precautions	• Mycosafe® Mycoplasma DNA Reference Standards have the Biosafety Level 1 as they do not contain any hazardous substances, but they are nevertheless considered as biohazard • General laboratory precautions and good laboratory practise should be employed: Handling by trained laboratory personnel only, that has experience in the handling of purified microbial DNA and wears proper personal protective equipment • The remaining unused mycoplasma DNA reference standard material or the remaining unused material derived therefrom by dilution must be - unless not stored at ≤ -20°C for further single use - disposed as biohazard waste by using an autoclave in accordance with the implemented laboratory protocol for disposal of biohazard materials, and in accordance with all national and local regulations • For detailed information, refer to the Mycosafe® Mycoplasma Reference Standards Material Safety Data Sheet (MSDS) for mycoplasma DNA preparations
Warranty & Limitations	• Product warranty is limited to the characteristics and specifications stated in the corresponding CoA • The stated characteristics and specifications cannot be guaranteed (i) for applications other than the intended use, (ii) when the procedures employed are different to the given directions and instructions, (iii) when repeated thawing/freezing cycles are applied, (iv) when higher temperatures than ≤ - 20°C are applied for long-term storage, (v) when the expiration date has passed
Restrictions	• Product changes, copies and replications as well as the transfer, resale and distribution in whole or in part by users to third parties are prohibited

Related Mycosafe® Products, Consultancy & Licensing Options

1. Alternative Mycosafe® Reference Standard Product Formats

Mycosafe® Viable Mycoplasma Culture Reference Standards
Total Cell Titer: 1000, 100, 10 CFU/100 µL
Product Unit: 250 µL

Mycosafe® Inactivated Mycoplasma Culture Reference Standards
Total Cell Titer: 1000, 100, 10 CFU/100 µL
Product Unit: 250 µL

For detailed information, refer to the Mycosafe® Reference Standards Product Flyer

2. Mycosafe® Mycoplasma Expert Consultancy

Scientific, Regulatory- & Business-Related Mycoplasma Expert Advisory Support Options
Risk Assessments & Mycoplasma Safety Concepts: Biopharmaceuticals · ATMPs · Raw Materials

For detailed information, please contact Prof Rosengarten at renate.rosengarten@mycosafe-consulting.com

3. Mycosafe® Licensing Options

Mycosafe® ABO™ Universal Mycoplasma Rapid Enrichment Medium
for Real-Time PCR Hybrid Assays according to the forthcoming revised Mycoplasma Testing Guidelines of EP 2.6.7.
Non-commercial product licensing options

Mycosafe® UREA™ Ureaplasma Rapid Enrichment Medium
for Real-Time PCR Hybrid Assays according to the forthcoming revised Mycoplasma Testing Guidelines of EP 2.6.7.
Commercial & non-commercial product licensing options

Mycosafe® ALPHA™ Selective Medium
for 'non-cultivable' cultivar α strains according to the forthcoming revised Mycoplasma Testing Guidelines of EP 2.6.7.
Commercial & non-commercial product licensing options

Mycosafe® SF™ Serum-Free Mycoplasma Culture Media
for preparation of mycoplasma antigens
Commercial & non-commercial product licensing options

Mycosafe® Mycoplasma Images
Selection of high-quality authentic mycoplasma images for any marketing project related to products for mycoplasma detection and culture- and NAT-based mycoplasma testing solutions
Exclusive, semi-exclusive & non-exclusive image licensing options

Mycosafe® Know-How
End-to-End Rapid Mycoplasma Testing Solutions
Commercial & non-commercial know-how licensing options

For detailed information, please contact Prof Rosengarten at renate.rosengarten@mycosafe-consulting.com

Contact for Further Information

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