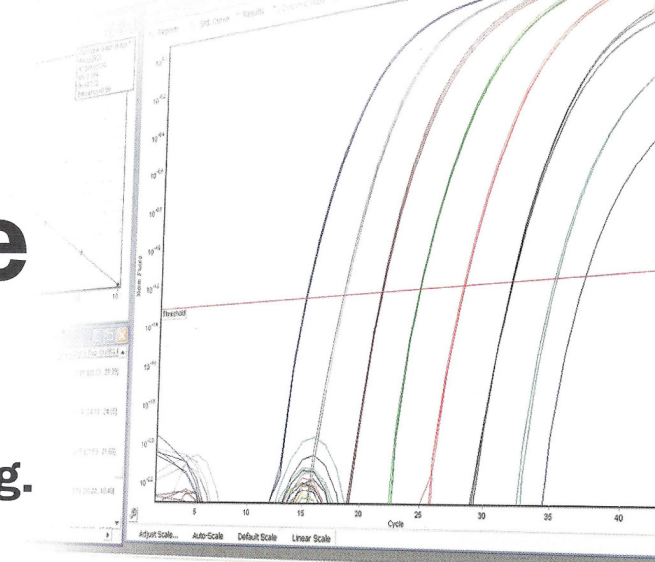


How reliable are your results?

Reference Standards for PCR Testing.



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>	102-7003	<i>Mycoplasma hyorhinis</i>
102-2003	<i>Mycoplasma orale</i>	102-8003	<i>Acholeplasma laidlawii</i>
102-3003	<i>Mycoplasma gallisepticum</i>	102-9003	<i>Spiroplasma citri</i>
102-4003	<i>Mycoplasma pneumoniae</i>	102-0002	<i>Mycoplasma Set</i> ,
102-5003	<i>Mycoplasma synoviae</i>		all EP 2.6.7 listed species
102-6003	<i>Mycoplasma fermentans</i>		

Products for the control of microbials in cell cultures, biopharmaceuticals and water

