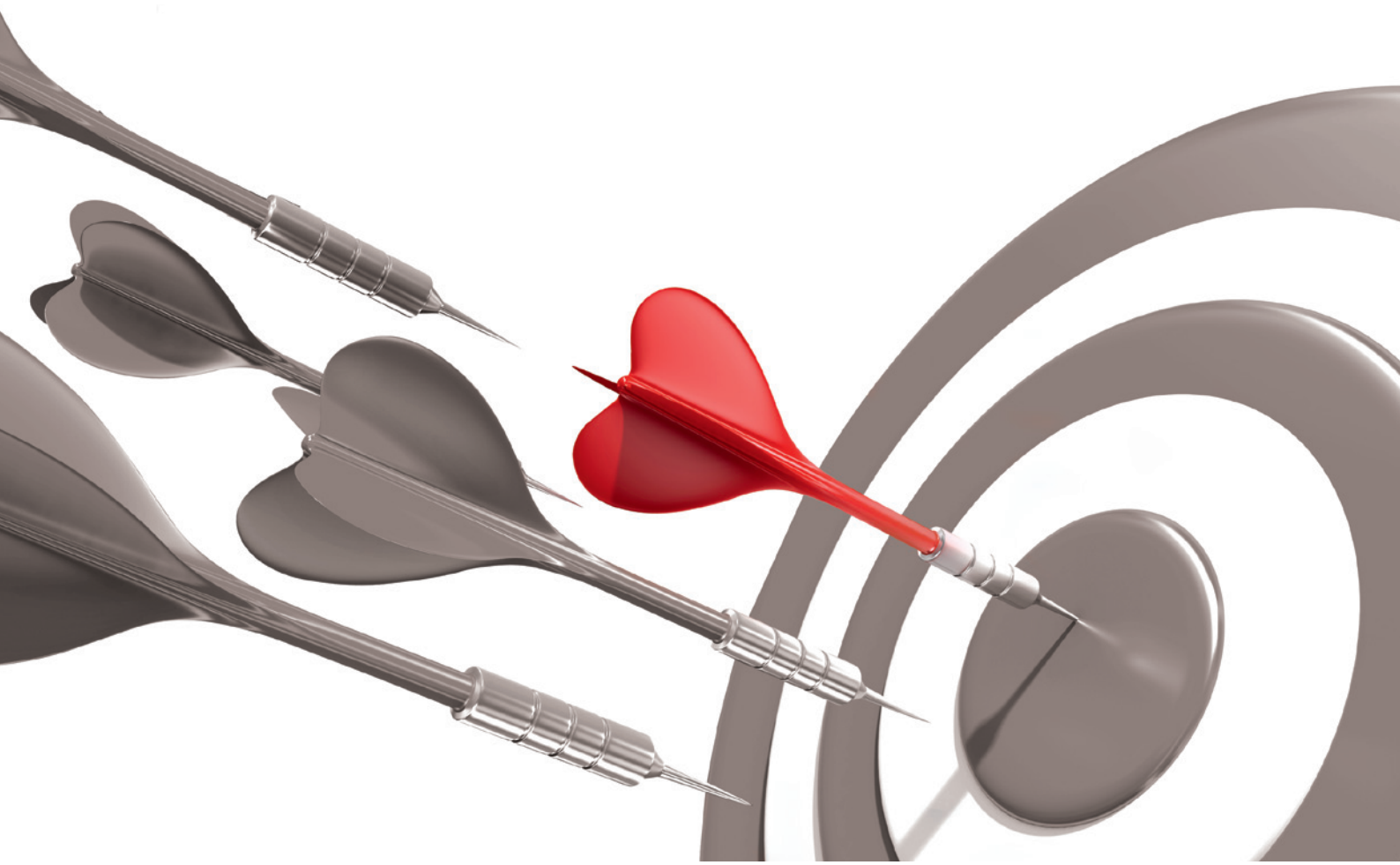
International Quality Assurance Program



For the detection of Mycoplasma applying nucleic acid amplification techniques.

minerva biolabs®

International Mycoplasma Quality Assurance Program for Nucleic Acid Detection Techniques

Minerva Biolabs GmbH is proud to organize proficiency tests for molecular mycoplasma detection methods. This methods may include contamination control testing of cell culture materials and biologicals rather than clinical diagnostics. The participation is mandatory for all accredited testing laboratories and was requested by the IRPCM Group "Cell Culture" of the International Organisation of Mycoplasmology (IOM). The aim of the collaborative study is a survey on the quality of mycoplasma testing and on long term to improve the reliability of NAT-based mycoplasma testing. The study will allow each individual laboratory an assessment of the accuracy and sensitivity of the tests carried out in international comparison. The study is organized on a semi-annual basis. An identical set of samples will be shipped to all participants and independently analyzed under individual conditions. The results are evaluated statistically. All participants receive the evaluation for information about the correctness of the analysis as well as an individual certificate of success, if 4 of 5 samples were analyzed properly. The evaluation is anonymous. The data might be published in respect of relevance and interest at conferences or in print media but not for commercial use. The mycoplasmas in the sample set will be titrated applying the culture method (CFU/ml) and using a qPCR method (GU/ml). The sample set may contain different sample matrices, concentrations and bacteria species. One sample set contains five samples. The samples contain the full bacteria particles. Before shipping the samples will be inactivated gently and lyophilized.

For providing the sample material, the logistical effort, the evaluation and preparation of documentation a fee of 130 € plus the statutory VAT and delivery charge will apply. Shipping fees: Germany: Economy 14.50 € | EU: 48.00 € | Outside EU: 85.00 €
Please check our web page for actual deadlines on registration, shipping of samples, submission of results as well as release of Certificates and Report. For participation a timely registration is required. Please take advantage of the submission form provided on our web page (PDF) and send the copy by fax or mail to Minerva Biolabs GmbH.

Terms and Conditions

1. Minerva Biolabs GmbH organizes the survey for quality control purposes only.
2. The proficiency test is open to every professional, carrying out laboratory tests.
3. A participation is only possible by accepting these terms by signing the registration form.
4. Samples and protocol sheets will be dispatched via courier service. In case of loss or damage of the sample material a replacement might only be possible if an immediate complaint was made.
5. Only report sheets received in due time can be considered. Additional result reports and certificates can be generated in justified cases, upon payment of a fee.
6. In case of a failing of the proficiency testing caused by the organization either no invoicing or a replacement of the samples applies. The related costs of reagents, time, etc. cannot be refunded.
7. The organizers are not liable for the improper use of the set of samples or the analysis results.
8. Jurisdiction is Berlin.

Frequently Asked Questions (FAQ)

What does "NAT-Mycoplasma" mean?
Nucleic Acid Amplification Test

So, does NAT mean PCR?
Not necessarily but including PCR. Any technique which is based on the detection of DNA can be used.

If I understand, the price is 130 € shipping charges. Will you supply just 1 sample set?
The charge of 130 € applies for each set of sample/shipment.

Following the results obtained by end-user, will you supply a kind of "official certificate of external quality assurance and a report"?
Yes. An official certificate for participation and/or results within the range will be issued mentioning the applied method. Additionaly, a summary of the study outcome will be provided.

Do all participants need to declare what method of detection they were using?
Yes, as this will give the participants a statistical overview on available test systems and their characteristics.

If I book via our local distributor, who will issue the certificate?
The distributor will receive the test samples and will forward them to the participant. The results will be transferred by the distributor to Minerva Biolabs for evaluation. The certificate will be issued by the distributor with the results supplied by Minerva. In this case Minerva will not be aware of end customers contact information.

Does an end-user who makes colorimetric detection, or Elisa or another detection method could participate?
No, as the material is inactivated colorimetric assays cannot be used. The inactivation method will disintegrate the protein structure which will not allow proper ELISA.

You say that you will supply a comparable set of 5 samples. But in fact for each participant, the set of 5 will be different? Some of participants will have 5 vials with mycoplasma; some other could have 3 positives and 2 negatives …?
All participants will receive exactly the same material. Material from different proficiency runs will differ in formulation.

Do participants using a home brew method receive some kind of official certificate that their in house test is ok when they participate?
Yes, all participants will receive a certificate which either states "participated" or "completed successfully" if their results are within the statistical range of all other reports.
For statistical reasons the result report form will have a section to address the type of test used. Here they can check "homemade".

Are those 5 samples enough for a customer to compare eg 2 or 3 different methods?
Each sample will contain a lyophilized pellet which should be rehydrated with 300 µl of water. This volume should be enough for many PCR reactions even in case a DNA extraction is required.

Is it allowed to compare our in house test to a commercial test by using this sample set? Is the price the same for using the samples for this purpose?
All participants are treated the same way. All participants who like to use the samples to compare different methods are welcome to do so. Purchase of the sample set does not imply an obligation to provide a result report.

I missed the deadline. Can I still participate?
Please inquire. A participation after a due deadline might be possible as long as the process for all other participants is not delayed. Otherwise, you are welcome to participate in the next round which will take place in a 6 months turn.

If I like to check my analytical process now, do you supply test material on demand?
We may have sample sets remaining which can be ordered for self-evaluation at any time (Order No. 41-5002). Please inquire.

Minerva Biolabs GmbH | Schkopauer Ring 13 | 12681 Berlin | Germany

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