Deutsches Referenzbüro für Ringversuche und Referenzmaterialien

medical devices

chemical-physical

microbiological

product catalogue 2021 / 2022

In the fields:

- Sterilization residuals
- Extraction of metals
- Degradation products from ceramics
- Loss of mass in polymeric medical devices
- Sterilization of medical devices
- Identification of microorganisms
- Bacterial filter efficiency of medical face masks

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3 DRRR - The company

Deutsches Referenzbüro für Ringversuche und Referenzmaterialien GmbH (DRRR GmbH)

Proficiency testing provider

The DRRR offers laboratories from the processing industry as well as official and private laboratories all aspects of quality assurance from one single source. Our focus is on food, consumer goods, packaging, building materials, plastics (polymers) and textiles, as well as microbiological analysis in these categories.

More than 500 PT's in 2020

Accreditation ISO/IEC 17043:2010 (A2LA)

The DRRR is an accredited proficiency testing provider by A2LA according to ISO/IEC 17043:2010. The accreditation is valid only for the scope listed in the annex of the accreditation certificate [#5494.01].

In the product catalogue in the column "Accreditation" it is marked accordingly whether the proficiency test is covered by the scope of A2LA or whether the proficiciency test is not covered by the scope of accreditation.

Accredited PT-provider

Accreditation DIN EN ISO/IEC 17043:2010 (DAkkS)

The DRRR is an accredited proficiency testing provider by DAkkS according to DIN EN ISO/IEC 17043:2010. The accreditation is valid only for the scope listed in the annex of the accreditation certificate [D-EP-17063-01-00].

In the product catalogue in the column "Accreditation" it is marked accordingly whether the proficiency test is covered by the scope of DAkkS or whether the proficiciency test is not covered by any scope of accreditation.

Reference material producer

We offer many certified reference materials as well as advise on quality matters and quality assurance training in the laboratory and the production.

High-quality reference material

Customer support

We provide advice to our customers in all question of validation of chemical-physical, microbiological, organoleptic and physical-mechanical analysis or statistical questions.

Any time competent contact persons

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4 News

Medical devices

The term medical device covers all instruments, substances, objects, machines and software that are used in humans for physical therapeutic and diagnostic purposes. In Germany alone there are over 450,000 different medical devices on the market. The ISO 10993 series of standards describes the testing of medical devices for their biological safety. Biocompatibility testing must be carried out for all new approvals and in case of changes to products. In our new proficiency test programme we focus on chemical characterisation on the one hand and offer 10 new interlaboratory tests in addition to the already existing microbiological proficiency tests in the field of medical devices. In addition to the "tests for sterilization on medical devices according to ISO 11737-1 for various microorganisms", which have been established few years ago and have been accredited since 2020, the field will also be further developed in the year 2021, e.g. by proficiency tests for "test methods for medical face masks (EN 14683)", "tests for in-vitro cytotoxicity (ISO 10993-5)" or the examination of endoscopes. “

Ethylene oxide sterilization residuals - ISO 10993-7

Ethylene oxide (EO) is often used for the chemical sterilization of medical devices. As an alkylating agent, EO prevents the reproduction of microorganisms and is also effective at low temperatures. By aeration (desorption) the EO is removed from the product, but there is a possibility that EO residues remain on the medical device. Particularly high residues are found in the sterilization of polyethylene, polyvinyl chloride and natural rubber. In patients, EO can cause allergic reactions up to anaphylactic shock. Chronic exposure to EO can lead to toxic damage. Therefore, testing for EO sterilization residues in medical devices is essential.

Extraction of metals - ISO 10993-12

For patient safety, medical devices must not exceed certain limits for the emission of heavy metals. These can enter the product through the manufacturing process and through catalysts or synthesis reagents and can cause serious damage to health. Therefore the extraction of metals from medical devices must be checked.

Qualitative characterization - ISO 10993-18

In the course of the investigation of biological safety, a medical device must be qualitatively characterized. For this purpose, we offer a proficiency test in which medical devices are to be qualitatively identified, e.g. by means of DSC or FTIR.

Quantitative characterization - ISO 10993-18

The quantitative characterization of a medical device is very complex. For our new proficiency test program we have decided to offer two aspects of quantitative characterization as proficiency tests. On the one hand, the (semi-)quantitative element composition of medical devices is to be checked by means of X-ray fluorescence analysis. On the other hand the extractable formaldehyde content in medical devices will be investigated.

Quantification of degradation products from ceramics - ISO 10993-14

Ceramics are used in medical devices, dentistry and orthopedics, among others. It can contain foreign elements in very small quantities. When ceramic medical devices are used, chemical decay can occur over time. In our proficiency tests, on the one hand, the mass of the dissolved material shall be determined and, on the other hand, the elements in the test solution shall be quantitatively determined.

Detection of loss of mass in polymeric medical devices - ISO 10993-13

Polymers are used in a wide variety of medical applications, e.g. as syringes, tubes, gloves and implants. During use, the material may be degraded or additives, e.g. plasticizers, may be released. Therefore it is important to investigate the loss of mass of medical devices in test solution.

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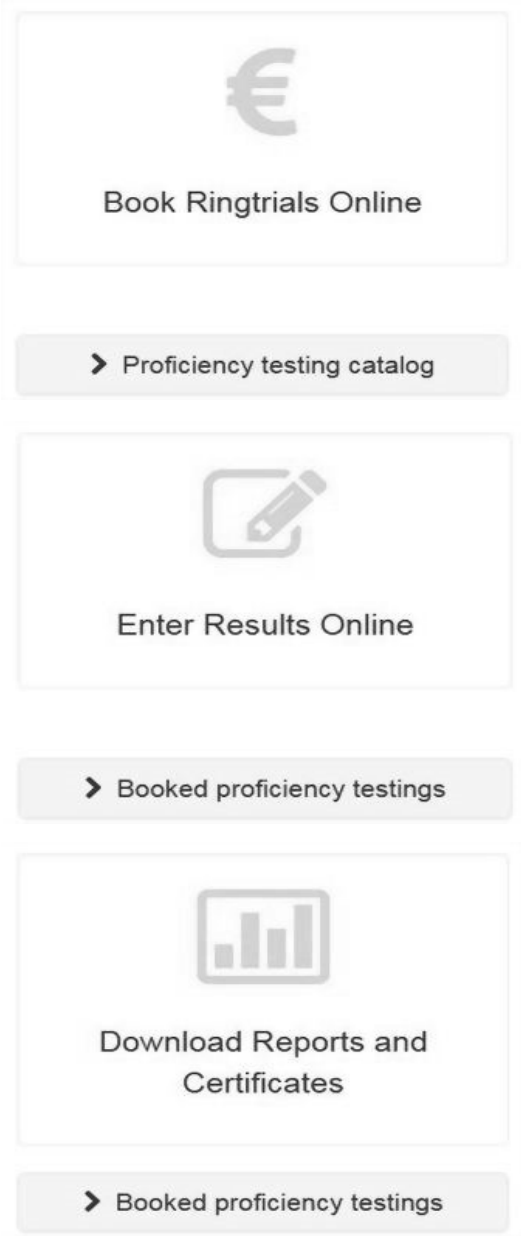
5 ODIN - proficiency testing online

Simply brilliant, your proficiency testing with ODIN (Online Data Information Network).

- Fast and easy online registration / online announcement in our online catalogue
- Direct management and booking of the proficiency testing
- Overview about the registered proficiency testing schemes
- Fast and secure submission of your results via ODIN
- Online access to individual customers reports and certificates
- Supervisor rights available to overview all PTs of a multi-site company
- Saving of costs through booking and submission of your results via ODIN



Secure payment with IRIS (Internet Remuneration Information Service).

- Easy and safe payment by credit card
- Overview about all invoices
- Fast and secure online access

You can also pay your invoice via banktransfer or bank check.

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6 Proficiency testing organisation

- A precise planning and organisation of each proficiency testing round

- 2 weeks before we will dispatch the samples you will get an announcement with the proficiency testing details

- All materials send out are in line with a homogeneity test and stability test; therefore we reserve the right to purchase the sample and engage the testing take through external qualified subcontractors

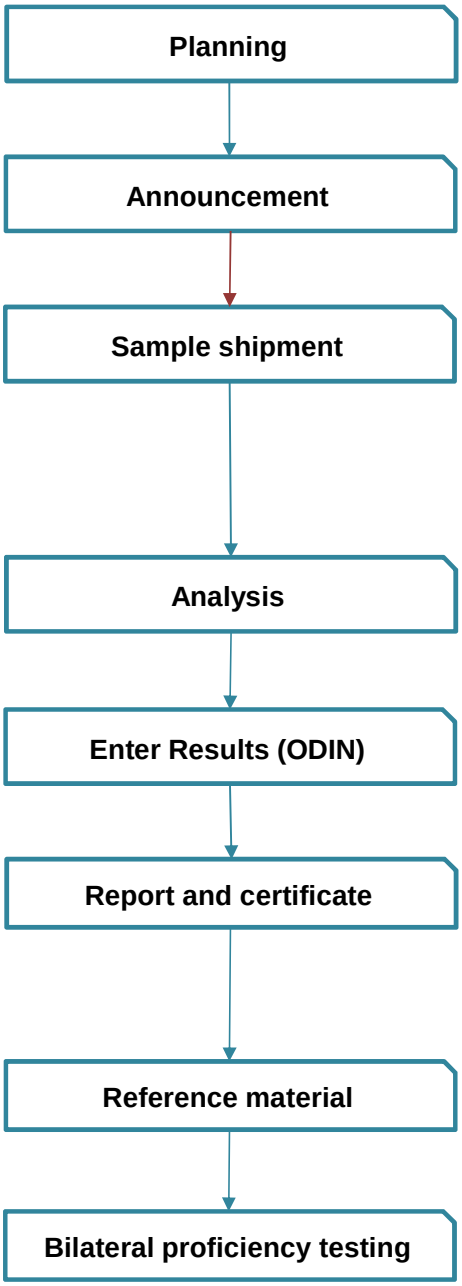
- After receiving the samples you will have a period of 4 weeks for analysing

- Mail back the results via internet by using our result sheets in an Excel file or fill out our result sheets online in ODIN

- At the latest 3 weeks after the deadline you will get the report (optional by login in ODIN, as hardcopy by regular mail or as pdf-file by e-mail) incl. participation certificate with overview of your lab performance

- After the proficiency testing we can offer you reference materials

- Possibility to perform a bilateral proficiency testing (bPT)



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7 Benefits of proficiency testing

Why take part in proficiency testing?

• Participation in proficiency testing schemes is required by international standards or national facilities, organizations and customers

• Participants can compare, assure and improve their own performance and quality against other laboratories worldwide

• Laboratories can recognize how well they have been completed with the applied method compared to the other laboratories

• Saving on the costs of testing

• Unquestionable lab performance towards customers, authorities and certification authorities

• Saving on the costs of lab development and maintenance

• Saving on the costs of lab development and maintenance

• Saving on production costs by avoiding waste of raw material

Your benefits in DRRR proficiency testing schemes

• Objective and independent impression of your quality and your performance of your routine testing method compared to the other participating laboratories

• Saving the costs, because you have the opportunity to analzye more samples and more parameters in one proficiency testing

• External demonstration of your performance with the results of the proficiency testing

• Build up of your own external quality assurance system with our statistical tools (contains statistical control charts, MS-Excel evaluation files and reference materials). With these tools incorporated your external quality assurance rays unmatched confidence

• Detailed planning and organization of your proficiency testing and an easier, faster and better communication with us

Image source: iStock.com/3dts

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8 Statistical methods

We work according to:

- ISO Guide 31 / 35
- DIN EN ISO 17034
- DIN EN ISO/IEC 17020 / 17025 / 17043
- ISO 13528

Homogenous and stable sample material

Laboratory performance:

by calculation of the following paramters:

- z-score
- z'-score
- CRD-Wert

Calculation of precision data acc. to ISO 5725-2 in many proficiency testing schemes

Statistical models:

Depending on the type of the distribution of the data, different statistic models are used:

- Conventional statistics (all values)
- Conventional statistics (no outliers)
- Robust statistics
(Hampel estimator, Q-method)
- Robust statistics
(Median, MAD/nIQR)
- Expert laboratory (expert decision)

Selection of statistical method with the chi²-fit test

Method-specific evaluation according to the reference method (if available)

Additional extended method evaluation (in case data are available)

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9 Z'-score > 2: What to do?

You are not satisfied with your laboratory performance: What can you do?

Due to your showed laboratory performance you have been asked by the accreditation body, the monitoring authority or your customer to initiate measures to improve your laboratory performance.
These measures are often connected with considerable efforts in the laboratory and you only have a short time frame. In many cases the proof of a successful measure processing, by participation in a new proficiency testing round, is only possible in the following year. Until now it does not exist a possibility for a spontaneous performance review to equalize a previous unsatisfactory proficiency testing result.

New: The bilateral proficiency testing (bPT)!

You can book and perform individually and flexibly the bilateral proficiency testing during a determined time period.
You receive a proficiency testing sample for analyzing. You submit the results of the testing. After that you will get your proof of performance as a z'-score calculation in the form of a certificate within 1 - 2 weeks.

The performance evaluation refers to the previous regular proficiency testing, so that you can connect the bPT to the regular proficiency testing round. The used sample material is derived from a previous proficiency testing round and provides the possibility of a comparable performance evaluation with the regular proficiency testing.

Your terms and conditions:

You have participated in the regular DRRR-proficiency testing and you would like to verify your performance. The report of this proficiency testing is not older than ten weeks. You register within these ten weeks for the bPT and the performance is confirmed by the DRRR. The testing period is dependent on the technical factors (parameter, matrix etc.) and will be agreed individually*. When this time is over after the sample shipment and you do not have sent us your results in this time, we can not evaluate your results and issue a certificate for you.
(* normally not longer than 1 - 2 weeks)
The bPT is not in the scope of accreditation of the DRRR. The realization of the bPT depends on the availability of the material.

Costs for the bPT 75,00 € + sample material and shipping costs

Alternative you can also order reference material.

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10 Proficiency testing

Features

The inspectors of the DRRR-team are represent in different national and international committees and working groups. Thus we ensure that the DRRR quality assurance systems are available for new and up-to-date questions in all cases, if the laboratories start to establish the routine method. Due to the intensive professional exchange in the committees, it is ensured that the proficiency testing design is conformed to the new developments and the laboratories have the highest possible benefits in a participation in the proficiency testing.

national and international committees and working groups

Testing with matrix reference

Whenever possible, real matrices e.g. films, textiles, cardboard and cosmetics are used. This ensures that our proficiency testing schemes have an actual matrix reference and the sample preparation is part of the proficiency testing.

Matrix reference

Statistical evaluation

Take advantage of our statistical evaluation system. The evaluation of the proficiency testing is based on the highest scientific and statistical level. Therefore the participating laboratories have a very precise feedback on their actual performance.

Evaluation

Laboratory Measurement

By using our market-leading statistical evaluation, additional information such as laboratory uncertainty and various scattering of each laboraotires can be presented.

Market-leading statistical evaluation

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11 chemical-physical proficiency testing

For your registration we recommend to use our online catalogue (ODIN) or the registration forms on our homepage (www.DRRR.de). You can also use the registration forms on page 13 of this catalogue.

medical devices

Art. No.	proficiency testing type	requested parameters	period	price *	additional samples **	Accredi-tation
2010375	Ethylene oxide sterilization residuals (ISO 10993-7) 1	**CAS 75-21-8 (Ethylene oxide), CAS 107-07-3 (Ethylene chlorohydrin)**	Jun. 21	379 €	127 €	-
2010377	Ethylene oxide sterilization residuals (ISO 10993-7) 2	**CAS 75-21-8 (Ethylene oxide), CAS 107-07-3 (Ethylene chlorohydrin)**	Jun. 21	379 €	127 €	-
2010379	Extraction of metals from medical devices (ISO 10993-12)	**Cadmium, lead, iron, aluminum, copper, zinc, mercury, nickel and arsenic (min. 5 of the metals contained)**	Jun. 21	379 €	127 €	-
2010381	Qualitative characterization of medical devices (ISO 10993-18)	**qualitative identification of the material, e.g. different plastics**	Jul. 21	379 €	127 €	-
2010383	Quantitative characterization of medical devices (ISO 10993-18) using X-ray fluorescence analysis	**Determination of the elements using XRF**	Jul. 21	379 €	127 €	-
2010385	Quantitative characterization of medical devices (ISO 10993-18) - Formaldehyde	**Formaldehyde**	Jul. 21	379 €	127 €	-
2010387	Identification and quantification of degradation products from ceramics (ISO 10993-14) 1	**Mass of the filter residue and mass of the dissolved material**	Mai. 21	379 €	127 €	-
2010389	Identification and quantification of degradation products from ceramics (ISO 10993-14) 2	**Quantitative determination of the elements in the test solution**	Mai. 21	379 €	127 €	-
2010391	Detection of loss of mass in polymeric medical devices (ISO 10993-13) 1	**Loss of mass of the sample in the test solution water**	Aug. 21	379 €	127 €	-
2010393	Detection of loss of mass in polymeric medical devices (ISO 10993-13) 2	**Loss of mass of the sample in the test solution water**	Aug. 21	379 €	127 €	-

Suitable laboratory equipment is required for participation in the proficiency testing schemes.

** price only valid by online result release and report in ODIN / price for result release by mail/fax plus 40,00 € / price for report by post plus 40,00 €*
*** additional submitted result sheets by e-mail, post or fax will be charged as additional sample sets*

[A] = Proficiency test under scope of A2LA accreditation
[D] = Proficiency test under scope of DAkkS accreditation

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12 microbiological proficiency testing

For your registration we recommend to use our online catalogue (ODIN) or the registration forms on our homepage (www.DRRR.de). You can also use the registration forms on page 13 of this catalogue.

medical devices

Art. No.	proficiency testing type	requested parameters	period	price *	additional samples **	Accredi-tation
2010696	testing for sterilization of medical devices 1 (ISO 11737-1) risk group 1	**aerobic total count quantitative** (2 samples)	Jun-21	450 €	160 €	[A]
2010964	testing for sterilization of medical devices 2 (ISO 11737-1) risk group 1	**yeasts quantitative** (2 samples)	Jun-21	450 €	160 €	[A]
2010966	testing for sterilization of medical devices 3 (ISO 11737-1) risk group 1	**moulds quantitative** (2 samples)	Jun-21	450 €	160 €	[A]
2010968	testing for sterilization of medical devices 4 (ISO 11737-1) risk group 1	**aerobic spores quantitative** (2 samples)	Jun-21	450 €	160 €	[A]
2010281	Tests for in vitro cytotoxicity (ISO 10993-5)	**Tests for in vitro cytotoxicity (ISO 10993-5)** (2 samples)	Nov-21	450 €	160 €	-
2010283	Testing the germ tightness of packaging materials risk group 1	**Testing the germ tightness of packaging materials** (2 samples)	Nov-21	450 €	160 €	-
2010657	Identification of microorganisms using MALDI-ToF risk group 2	**Identification of microorganisms using MALDI-ToF** (1 sample)	Nov-21	350 €	123 €	[A]
2010321	Test method Medical face masks (EN 14683)	**Bacterial filter efficiency where appropriate also pressure difference** (1 sample á 12 face masks)	Nov-21	450 €	160 €	-
2010567	microbiological analysis of endoscopes risk group 2	**Germ identification on rinse water** (3 samples)	Sep-21	450 €	160 €	-

** price only valid by online result release and report in ODIN / price for result release by mail/fax plus 40,00 € / price for report by post plus 40,00 €*
*** additional submitted result sheets by e-mail, post or fax will be charged as additional sample sets*

[A] = Proficiency test under scope of A2LA accreditation
[D] = Proficiency test under scope of DAkkS accreditation

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13 registration form proficiency testing

Deutsches Referenzbüro für Ringversuche und Referenzmaterialien

Article No. / proficiency testing type	period	result release and report online (ODIN)	result release by e-mail / fax; report by e-mail	report by postal delivery	additional sample sets

For proficiency testing schemes labelled with "risk group 2, or 3" we need a permission or an exemption for working with pathogenic microorganisms of your lab if existing in your country (e.g. "infection protection law (IfSG)" in Germany). The appropriate form you can find in the product catalogue on page 20.**

Up to nine additional result sheets can be returned for chemical-physical, microbiological and physical-mechanical proficiency testing rounds are free of charge. As a participant, you benefit from our international recognized proficiency testing schemes. By submitting up to ten result sheets you are now enabled to run international comparisions to check different methods and different lab technicians with one proficiency testing round. Your benefit: Participating in DRRR-proficiency testing services save costs for your quality assurance! If you need additional sample sets, you have the opportunity to order it according to our latest product catalogue.

Please note, that the free of charge service is only valid for returning result sheets by ODIN. If you send us your results by mail, fax or postal delivery, the additional result sheet will be charged according the latest product catalogue as a sample set equivalent.

In very rare individual cases an accredited proficiency testing round will not be carried out within the scope of accreditation due to technical or organizational reasons. In these rare cases the DRRR will inform the participants before the start of the proficiency testing round, thus before the sample shipment. An immediately free cancellation for the participants is possible until the date of the sample shipment.

Your registration is an one-time order. It is only valid for one year. Cancelation fees apply when cancelling a registration. If you want to have a permanent-registration please tick the box on the right side.

Please send registration to:
fax-no. +49 (0)8 31/960 878-99
e-mail: info@DRRR.de
online via www.drrr.de/en/odin

O this registration is permanent-registration and valid until my cancelation

O An offer with the total costs is needed

O A Purchase order from the purchasing department will follow

DRRR-customer number _____

company _____

company (additional line) _____

contact person _____

street _____

post-code /city _____

country (if not Germany) _____

fon _____

fax _____

e-mail _____

e-mail for invoices _____

VAT-ID-No. (if available) _____

With your signature you agree with our general terms and conditions.

_____ date

_____ signature

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14 Sales terms and delivery conditions

Terms of payment

Our prices are net prices (plus 19% value added tax). Customers from European countries can provide us with their EU-VAT-Identification number, then they will be exempt from German value added tax.
Terms of payment: 8 days net, without deduction
Fees for specially required customs documents such as import permits or similar will be invoiced according to time and effort.

Our bank details:
Raiffeisenbank in Allgäuer Land / bank code 733 692 64
Account 102350 / IBAN DE 94733692640000102350
BIC code: GENO DEF1DTA
Sales tax ID no. DE254613132
tax number 127/124/32207

Terms of delivery

Shipping costs for reference materials and proficiency tests will be invoiced according to time and effort. All samples and packaging materials are the property of the DRRR. Samples that are used for non-destructive testing and are therefore not subject to destruction in the course of the proficiency test can be reclaimed by the DRRR upon request. The DRRR shall bear the shipping costs for the return transport if the materials are reclaimed.

Proficiency tests or reference materials marked “frozen” are shipped with our ADR safety tested frozen packaging system. A packaging fee is charged for the polystyrene box including cooling accumulators and air bubble film as well as the protective outer packaging. Frozen materials are shipped by express service. With the delivery of reference materials, you will receive a quality certificate with the details of the respective reference values as well as associated uncertainties.

Terms of delivery (risk group 1, 2 and 3)

Proficiency tests or reference materials marked with “Risk Group 1” are not subject to any participation restrictions according to § 44 IfSG (Infektionsschutzgesetz).

For proficiency tests or reference materials marked with “risk group 2, or risk group 3**”, we need a permission from your laboratory according to § 44 IfSG (Infektionsschutzgesetz) or similar. Please enclose a copy of the permission with your registration or order.

Our general terms and conditions (Allgemeine Geschäftsbedingungen) are valid!

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15 General terms and conditions

The German reference office for proficiency testing and reference materials GmbH (hereinafter referred to as DRRR) for freely agreed services, in particular testing, training and expert activities as well as reference materials.

§ 1 General terms and conditions

The client acknowledges the General Terms and Conditions and price lists valid at the time of placing the order. Deviating terms and conditions of individual clients cannot be accepted.
Collateral agreements, promises and other declarations by the employees of the DRRR are only binding if they are expressly confirmed in writing by the DRRR. This shall also apply to amendments to this clause.
If individual regulations within this contract or its components are ineffective, this does not affect the validity of the remaining regulations. The contracting parties shall have a duty, acting in accordance with the principles of good faith, to replace any invalid provision by one which is valid and which produces the same economic outcome as that intended by the invalid provision and providing that such replacement does not result in any change to the content of the contract; the same shall also apply analogously to any matter which requires regulation but for which no provision is made in these Terms and Conditions.

§ 2 Execution of the order

The orders accepted by the DRRR shall be carried out or expert opinions shall be prepared in accordance with the recognized rules of technology and – unless otherwise agreed in writing – in the manner customary at the DRRR. No responsibility shall be assumed for the correctness of the safety programs or safety regulations on which the tests are based, unless expressly agreed otherwise in writing.
The scope of the DRRR's work shall be specified in writing when the order is placed. If the proper execution of the order results in changes or extensions to the specified scope of the order, such changes or extensions shall be agreed in writing prior to execution. If the Customer can no longer be reasonably expected to adhere to the contract with regard to the changes or extensions, the Customer shall in this case be entitled to withdraw from the contract. However, according to § 649 BGB, the client must pay the agreed remuneration or, in the absence of an agreement, an appropriate remuneration.
The contractual services of the DRRR are deemed to have been rendered upon preparation of the respective final reports or expert reports.
A seminar registration can be cancelled free of charge for up to 6 weeks, after which the customer will be invoiced for the costs of the participants depending on the time and effort involved.

The following cancellation conditions apply to the cancellation of a proficiency testing:

Cancelation notification period:	Permanent registration (D)
	single (one-time) registration (E)
up to 3 months before the proficiency testing	no costs (D)
	50,00 € (E)
3 months before the proficiency testing start	50,00 € (D)
	half proficiency testing price (E)
sample shipment – deadline of the results	complete price of the proficiency testing and any further incurred costs (D & E)

§ 3 Deadlines

The order deadlines specified by the DRRR shall not be binding unless their binding nature has been expressly agreed in written form.

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§ 4 Warranty and liability

The integrity of the sample material to a defined condition is only guaranteed until the first border crossing in the case of foreign shipments.
Safety note: When sending materials of risk group 2, the DRRR must receive a letter from the recipient stating that the recipient is authorized to handle hazardous materials (e.g. pathogenic germs).
The DRRR's warranty only covers the services expressly commissioned to it pursuant to Section 2.
No warranty is thereby assumed for the correctness and functioning of the relevant overall system, measuring instruments or materials to which the examined or tested samples belong; in particular, the DRRR bears no responsibility for packaging, material selection and construction of the examined systems, measuring instruments or assemblies, unless these issues are expressly the subject of the order.
Even in the latter case, the warranty obligation and legal responsibility of the manufacturer are neither limited nor assumed.
The warranty obligation of the DRRR is limited to the rectification of an error or defect or, in the absence of a warranted characteristic, to the achievement of this characteristic within a reasonable period of time. If the rectification or creation of the characteristic fails, i.e. if it becomes impossible or unreasonable for the Customer or is refused or unduly delayed by the DRRR, the Customer shall be entitled to demand a reduction in the remuneration or rescission of the contract, at its discretion.
The DRRR shall not be liable for any work performed by the Customer in the event of incorrect proficiency tests or reference materials.
The DRRR only assumes liability for certain properties, in particular for the fact that the service is suitable for the purposes of the Customer, if a corresponding assurance of the properties in question has been given. Any liability for consequential damages from positive breach of contract due to warranted characteristics is excluded, unless the warranty was intended to protect against such consequential damages. Claims for damages of the client from §§ 463, 635 BGB due to the lack of assured characteristics remain unaffected.
If an error or defect that does not represent the absence of a warranted characteristic is due to a circumstance for which the DRRR is responsible, the DRRR shall only be liable for any damage incurred by the Customer as a result thereof per order up to a maximum amount that corresponds to the value of the order agreed in accordance with Section 2.
The materials may only be used for the corresponding scientific purpose by trained qualified personnel. The DRRR is in no case responsible and liable for used, unused or unusable samples.
The samples are intended for analytical purposes only. The DRRR assumes no liability if the samples are not used for the intended analytical purposes.
All materials are definitely not suitable for human consumption unless they are sensory materials. Oral ingestion of materials not intended for sensory purposes can be harmful to health.
In the case of sensory materials, it is the responsibility of the test persons themselves to check whether they can test the materials with regard to allergies. The ingredients of the sensory materials are declared.
All samples and packaging materials are the property of the DRRR. Samples that are used for non-destructive testing and are therefore not subject to destruction in the course of the interlaboratory comparison can be reclaimed by the DRRR upon request. The DRRR will bear the shipping costs for the return transport, if the materials are reclaimed.
The analytical properties of the material can only be guaranteed if the transport, storage and use conditions specified by the DRRR are observed.
For frozen samples, the DRRR only guarantees that the samples will be treated in accordance with the material properties stated in the data sheet. For frozen samples delivered to countries outside the EU, we can only guarantee the sample properties up to the first customs clearance point at the respective EU border.

§ 5 Exclusion of further liability and claims

The risk (transport and remuneration risk) shall pass to the Customer as soon as the goods have left the DRRR, regardless of whether the goods are transported by the Customer's own or third-party means of transport.
Claims for damages by the client are excluded. This does not apply to intent, gross negligence, breach of essential contractual obligations of the DRRR or the lack of properties guaranteed in writing.
All further claims of the client for direct and indirect damage – for whatever legal reason – in particular claims for damages due to positive breach of contract or from tort and for compensation for damage that did not occur on the object of the order itself are excluded. Irrespective of this, the client is obliged to take out the usual insurance against direct and indirect damage.

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§ 6 Remuneration and payment terms

Unless otherwise stated, the prices are in euros and do not include value added tax. This will be invoiced separately at the currently applicable rate in accordance with the applicable tax regulations.
The goods remain the property of DRRR until they have been paid for in full by the customer.
The fees according to the DRRR's currently valid List of Services shall apply to the calculation of the services unless a fixed price or another basis of assessment has been expressly agreed in writing. In the absence of a valid specification of services, individual contractual arrangements shall be made in each case.
Advances on costs can be requested. Partial invoices can also be issued in accordance with the services rendered. Partial invoices need not be marked as such. The receipt of an invoice does not mean that the DRRR has fully invoiced the order.
The fees are due for payment immediately after invoicing, at the latest by the date printed on the invoice (8 days net, without deduction). Unless another arrangement has been made. If payment is made at a later date, default interest of 2% above EURIBOR will be charged on the outstanding invoice amount for the period between the due date and receipt of payment.
Objections to the invoices of the DRRR must be notified in writing within a preclusive period of 14 days after receipt of the invoice, stating reasons.

§ 7 Confidentiality and copyright

The DRRR reserves the copyrights to the expert opinions, test results, calculations, etc. prepared by it.
The DRRR and its employees may not unauthorizedly disclose or exploit business and operating relationships that come to their knowledge in the course of their work.
The DRRR may take copies for its files of written documents that have been made available to the DRRR for inspection and that are of importance for the performance of the assignment.
If the proficiency test report and the laboratory code are sent by e-mail, no guarantee can be given that confidentiality will be ensured.

§ 8 Place of jurisdiction, place of performance, applicable law

The place of jurisdiction for the assertion of claims for both parties to the contract is Kempten, provided that the conditions according to § 38 of the German Code of Civil Procedure are met. This applies in particular to dunning proceedings.
The place of performance for all obligations arising from the contract is Kempten, the contractor's registered office.
The contractual relationship and all legal relationships are subject exclusively to the law of the Federal Republic of Germany applicable between domestic contracting parties, excluding the Uniform Law on the Sale of Goods and the United Nations Convention on Contracts for the International Sale of Goods.

§ 9 Guarantee of services and goods from cooperation partners

For reference materials sold on behalf of our cooperation partners, the following conditions apply with regard to liability and warranty:
The liability of our cooperation partners, their legal representatives and vicarious agents is limited to cases of intent, gross negligence, absence of a warranted characteristic and breach of an obligation, the non-compliance of which would endanger the purpose of the contract. The liability for proven damages due to grossly negligent conduct is limited to the amount of the contractual remuneration; no liability is assumed for consequential damages. Liability is limited to the use of the reference materials for the purposes described in the respective certificate.
Our cooperation partners guarantee the application of scientific diligence as well as compliance with the recognized rules of technology.
Our cooperation partners are entitled to rectify any defects that occur. If the rectification of defects fails, the client is entitled to demand a reduction of the remuneration or cancellation of the contract at his discretion. Further warranty claims are excluded.
The warranty is limited to the stated expiration date of the reference materials.
This applies to: ieLab, TGZ AQS Baden-Württemberg

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20 Permission for working with pathogenic microorganisms

Deutsches Referenzbüro für Ringversuche und Referenzmaterialien

Responsible person:

name, surname
street
post code, city
fon
e-mail

Please tick as approprate and enclose the necessary documents:

1 **Posession of a permission for working with pathogenic microorganisms if existing in your country?**

- O yes (please enclose copy)
- O no

2 **Posession of an exemption for working with pathogenic microorganisms if existing in your country?**

- O yes (please enclose verification document)
- O no

3 **Only for german customers the posession of a permission acc. to §44 IfSG (german infection protection law) or an exemption acc. §45 IfSG is obligatory.**

- O yes (please enclose copy or verification document)
- O no

Because of the fact that this permission usually is person-linked, so please inform us immediately if there is a turnover of staff and send an updated version of the permission to DRRR GmbH.

date signature

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