



Product Information

2019



As wholly owned subsidiary of Associates of Cape Cod, Inc. (USA), we are your reliable partner in all aspects of LAL testing. ACC is a company which is leading in the field of bacterial endotoxin and (1→3)- β -D-glucan detection.

We supply high quality reagents. These reagents are not only used for the **determination of bacterial endotoxins**, they can also be used for the quantification of (1→3)- β -D-glucans. We are the only supplier who offers a CE marked clinical diagnostic kit, FUNGITELL[®], for the detection of (1→3)- β -D-glucans as an **indicator of invasive fungal infections**.

We supply:

- Quality control reagents for the detection of endotoxins and glucans
- Instruments and software including system qualification (IQ, OQ, PQ)
- All accessory products required for the detection of endotoxins and glucans

However, we are not only an ISO 9001:2015 certified supplier, complementary we offer:

- Services
- Seminars
- Training (also on-site)
- ILPQ, an international proficiency test for the Bacterial Endotoxins Test (BET)

Due to our understanding we are a fully-fledged service provider and aware of our responsibility to be part of your quality control.

Regardless whether we enable your favorite delivery date, make reservations of your product portfolio or provide technical support.

Our competent team is happy to assist you!

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1 **Limulus Amebocyte Lysate (LAL)**

All our lysates (PYROTELL®, PYROTELL®-T, PYROCHROME® and CHROMO-LAL) are manufactured by Associates of Cape Cod, Inc. (License No. 700), validated against the Reference Standard Endotoxin and released by the FDA.

1.1 **PYROCHROME®: Chromogenic Test Kit (Method D and E, EP)**

PYROCHROME® is suitable for the **kinetic** as well as for the **endpoint method** (405 nm). It is offered with either reconstitution buffer or with GLUCASHIELD® a glucan inhibiting buffer.

Order No.	ACC-Catalog No.	Description	Packing Unit
26060PA-05	C1500-5	with reconstitution buffer	3.2 ml LAL (ca. 60 tests) 5 vials/pack
26060PGA-05	CG1500-5	with GLUCASHIELD®	5 vials/pack

1.2 **CHROMO-LAL: Kinetic chromogenic lysate (Method D, EP)**

Order No.	ACC-Catalog No.	Packing Unit
2832CA-05	C0031-5	3.2 ml LAL (ca. 32 tests) 5 vials/pack

1.3 **PYROTELL®-T: Turbidimetric lysate (Method C, EP)**

Order No.	ACC-Catalog No.	Packing Unit
2530TA-05	T0051-5	5 ml LAL (max. 100 tests) 5 vials/pack 25 vials/pack
2530TA-25	T0051-25	

Subject to changes and errors without prior notice.

1.4 PYROTELL®: Gel-clot lysate (Method A and B, EP)

Order No.	ACC-Catalog No.	Sensitivity	Packing Unit
0,2 ml LAL/single test vial (12 x 75 mm)			
20003A-50	GS003-5	0.03 EU/ml	50 vials/pack
20006A-50	GS006-5	0.06 EU/ml	50 vials/pack
20125A-50	GS125-5	0.125 EU/ml	50 vials/pack
20250A-50	GS250-5	0.25 EU/ml	50 vials/pack
2 ml LAL/vial (ca. 20 tests)			
22003A-05	G2003-5	0.03 EU/ml	5 vials/pack
22006A-05	G2006-5	0.06 EU/ml	5 vials/pack
22125A-05	G2125-5	0.125 EU/ml	5 vials/pack
22250A-05	G2250-5	0.25 EU/ml	5 vials/pack
5 ml LAL/vial (ca. 50 tests)			
25003A-05	G5003-5	0.03 EU/ml	5 vials/pack
25003A-25	G5003-25		25 vials/pack
25006A-05	G5006-5	0.06 EU/ml	5 vials/pack
25006A-25	G5006-25		25 vials/pack
25125A-05	G5125-5	0.125 EU/ml	5 vials/pack
25125A-25	G5125-25		25 vials/pack
25250A-05	G5250-5	0.25 EU/ml	5 vials/pack
25250A-25	G5250-25		25 vials/pack

1.5 PYROSATE® Kit

PYROSATE® is a FDA licensed rapid test in single test vials. You will get your results in less than 30 minutes for a sensitivity of 0.25 EU/ml.

The PYROSATE® kit contains test tubes (12 x 75 mm), one for sample and sample positive control each.

Order No.	ACC-Catalog No.	Sensitivity	Packing Unit
28PS003A-10	PSD030-10	0.03 EU/ml	10 tests/kit
28PS003A-30	PSD030-30	0.03 EU/ml	30 tests/kit
28PS125A-10	PSD125-10	0.125 EU/ml	10 tests/kit
28PS125A-30	PSD125-30	0.125 EU/ml	30 tests/kit
28PS250A-10	PSD250-10	0.25 EU/ml	10 tests/kit
28PS250A-30	PSD250-30	0.25 EU/ml	30 tests/kit
28PSPPA	PPT50		50 pipettes/pack

"PYROSATE® is well suited for performing endotoxin assays in full compliance with the Bacterial Endotoxins Test, USP chapter <85>, and EP chapter 2.6.14.

2 Reagents for clinical diagnostics

2.1 FUNGITELL® Serum assay kit for the detection of (1→3)-β-D-glucans

FUNGITELL® is a (1→3)-β-D-glucan-specific, kinetic chromogenic reagent. It is used for the rapid detection of (1→3)-β-D-glucans as an **indicator of invasive fungal infections**.

Each kit contains two vials each of FUNGITELL®- Reagent (55 tests/vial), reconstitution buffer, (1→3)-β-D-glucan-standard and reagent water as well as serum pre-treatment reagent.

Order No.	ACC-Catalog No.	Packing Unit
29FR110A	FT001	110 tests/kit

This is a CE marked and FDA 510(k) cleared Diagnostic Kit.

3 Research Products

The products listed below are offered for **research use only**. These products are not licensed for use in FDA regulated endotoxin detection studies or for diagnostic purposes.

3.1 GLUCATELL® Reagent kit for the detection of (1→3)-β-D-glucans

GLUCATELL® is a (1→3)-β-D-glucan-specific chromogenic reagent.

Each kit contains one respectively two vials each of GLUCATELL®- Reagent (55 tests/vial), reconstitution buffer, (1→3)-β-D-glucan-standard and reagent water and one or two microplates. Kits for the endpoint assay also contain reagents for diazo-coupling (540 - 550 nm).

Order No.	ACC-Catalog No.	Description	Packing Unit
29GE055A	GT003	Endpoint Assay kit with Diazo-reagents	55 tests/kit
29GK055A	GT004	Kinetic Assay kit	55 tests/kit
29GK110A	GT002		110 tests/kit

Subject to changes and errors without prior notice.

4 Endotoxins

4.1 Reference Standard Endotoxins (RSE)

Reference Standard Endotoxins (RSE) are the official standards of the European (EP) and American (USP) Pharmacopeial organisations. Both contain endotoxins of *E. coli* O113:H10 in a concentration of 10,000 units per vial.

Order No.	ACC-Catalog No.	Description	Packing Unit
31000U	-	RSE - USP	10,000 EU/vial
31200F	-	RSE - EP	10,000 I.U./vial

4.2 Control Standard Endotoxins (CSE)

Control Standard Endotoxins (CSE) are for routine testing. Their potency has to be determined against a Reference Standard Endotoxin (RSE) according to the LAL method and specific for the lot of lysate used. Associates of Cape Cod, Inc. (USA) determines the individual potency of the current lot of CSE for the respective lot of lysate. Corresponding certificates of analysis will be included to the shipment.

Order No.	ACC-Catalog No.	CSE, <i>E. coli</i> O113:H10	Packing Unit
32500A	E0005-1	500 ng*	1 vial/pack
32500A-05	E0005-5		5 vials/pack
32125A	E0125-1	125 µg*	1 vial/pack
32125A-05	E0125-5		5 vials/pack
32010A-05	EC010-5	10 ng**	5 vials/pack

*This Control Standard Endotoxin can also be used as a depyrogenation control vial for the validation of dry heat sterilization processes.

**This Control Standard Endotoxin is for the use with PYROCHROME® only.

4.3 Endotoxin for validation of dry heat sterilization processes

Order No.	ACC-Catalog No.	Description	Packing Unit
35DCV10E	-	Depyrogenation Control Vials > 10.000 EU/vial	10 vials/pack

Subject to changes and errors without prior notice.

5 Water and buffer for the Bacterial Endotoxins Test

5.1 LAL Reagent Water (LRW) in plastic bottles with screwed cap

LAL Reagent Water (LRW) is manufactured in accordance with a validated procedure. This water (LRW) is under strict quality control in accordance with EP and USP and fulfills the following specifications:

- content of endotoxin: < 0.001 EU/ml
- content of (1→3)-β-D-glucan: < 1.56 pg/ml

Order No.	ACC-Catalog No.	Volume	Packing Unit
4000050H-30	WP050C	50 ml	30 bottles/pack
4000100H-30	WP100C	100 ml	30 bottles/pack
4000500H-12	WP500C	500 ml	12 bottles/pack
4001000H-12	WP1000C	1,000 ml	12 bottles/pack

5.2 GLUCASHIELD® glucan inhibiting LAL reconstitution buffer

GLUCASHIELD® is a glucan inhibiting buffer for reconstitution of PYROTELL®, PYROTELL®-T, PYROCHROME® and CHROMO-LAL. By using GLUCASHIELD® the LAL reagent becomes endotoxin-specific.

Order No.	ACC-Catalog No.	Volume	Packing Unit
40105GSA-05	GB051-5	5.5 ml	5 vials/pack

5.3 PYROSOL® LAL reconstitution buffer

PYROSOL® is a buffer for reconstitution of PYROTELL® and PYROTELL®-T, especially for testing of high concentrated electrolytic samples, bicarbonate-solutions as well as samples with a pH-range outside the requested specification (pH 6 - 8). For the gel-clot method with PYROTELL® this buffer is also available with a pH indicator.

Order No.	ACC-Catalog No.	Volume	Description	Packing Unit
40105MPA-05	BR051-5	5.5 ml	with pH indicator (for gel-clot method only)	5 vials/pack
40105OPA-05	BC051-5	5.5 ml		5 vials/pack
40155OPA	BC554-1	55 ml		1 vial/pack

Subject to changes and errors without prior notice.

6 Depyrogenated Reaction and Dilution Tubes

PYROTUBE® tubes are manufactured by Associates of Cape Cod, Inc. in accordance to a validated dry heat depyrogenation process. These high-quality tubes are under strict quality control in accordance to EP and USP and meet the following specifications:

- content of endotoxin: < 0.001 EU/ml
- content of (1→3)-β-D-glucan: < 3.125 pg/ml

6.1 PYROTUBE® reaction tubes for gel-clot method (soda lime glass)

Order No.	ACC-Catalog No.	Description	Packing Unit
50010MKE	TS05C	PYROTUBE®-C 10 x 75 mm with thread and screwed polypropylene cap	50 tubes/pack
500100KE-10	TS050-10	PYROTUBE®-S 10 x 75 mm	10 packs/carton 52 tubes/pack

6.2 PYROTUBE® reaction tubes for turbidimetric method (borosilicate glass)

Order No.	ACC-Catalog No.	Description	Packing Unit
5000007E-10	TK050-10	PYROTUBE®-K 7.9 x 75 mm for PYROS Kinetix® Flex Tube Reader	10 packs/carton 50 tubes/pack
5000009E-10	TB050-10	PYROTUBE®-B 9.75 x 75 mm for LAL-5000 Tube Reader	10 packs/carton 52 tubes/pack

6.3 PYROTUBE® dilution tubes (borosilicate glass)

Order No.	ACC-Catalog No.	Description	Packing Unit
5016100E-10	TB160-10	PYROTUBE®-A 16 x 100 mm	10 packs/carton 10 tubes/pack
5000012E-10	TB240-10	PYROTUBE®-D 12 x 75 mm	10 packs/carton 42 tubes/pack

7 Microplates

7.1 PYROPLATE® microplates (sterile, free of endotoxins and glucans)

Microplates, uncoated, made of polystyrol, with 96 wells, flat bottom, with lid, individually packed. All microplates meet the following specifications:

- content of endotoxin: < 0.005 EU/ml
- content of (1→3)-β-D-glucan: < 5 pg/ml

Order No.	ACC-Catalog No.	Packing Unit
5039600A-10	CA961-10	10 plates/pack

Subject to changes and errors without prior notice.

8 Other Consumables

8.1 PYROCLEAR® pipette tips (free of endotoxins and glucans)

PYROCLEAR® pipette tips are suitable for various commercial pipettes. Packed in plastic boxes, autoclavable.

Order No.	ACC-Catalog No.	Volume	Packing Unit
6300250A	PPT25	up to 250 µl	96 tips/box 10 boxes/pack
6301000A	PPT10	up to 1000 µl	8 boxes/pack

8.2 Depyrogenated sample containers (borosilicate glass) with screwed polypropylene cap

All containers meet the following specification:

- content of endotoxin: < 0.001 EU/ml

Order No.	ACC-Catalog No.	Volume	Packing Unit
5020010MKE	-	10 ml	50 containers/pack

8.3 Plastic sample containers with screwed cap

These labelled containers meet the following specifications:

- content of endotoxin: < 0.001 EU/ml
- content of (1→3)-β-D-glucan: < 3.125 pg/ml

Order No.	ACC-Catalog No.	Volume	Packing Unit
5030030SEL-25	-	30 ml	25 containers/pack
5030030SEL-400	-	30 ml	~400 containers/pack

Subject to changes and errors without prior notice.

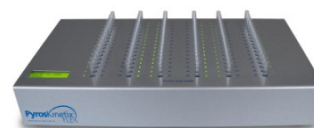
9 Instruments & Software for the Quantitative Endotoxin Detection

Ask for your individual offer, tailored to your particular needs. We are happy to assist!

9.1 PYROS Kinetix® Flex Tube Reader

The PYROS Kinetix® Flex Tube Reader is an optical tube reader that runs both chromogenic and turbidimetric assays in compliance with the USP, EP and JP bacterial endotoxin test chapters.

- 32, 64 and 96 wells
- for the detection of endotoxins (detection limit: **0.001 EU/ml**) to be used with:
 - PYROCHROME® for the chromogenic LAL method
 - PYROTELL®-T for the kinetic turbidimetric LAL method
 - PYROTUBE®-K reaction tubes (7.9 x 75 mm) made of borosilicate glass



Order No.	ACC-Catalog No.	Description
73032PKFSCV	PKF32	PYROS Kinetix® Flex Tube Reader with 32 wells*
73064PKFSCV	PKF64	PYROS Kinetix® Flex Tube Reader with 64 wells*
73096PKFSCV	PKF96	PYROS Kinetix® Flex Tube Reader with 96 wells*

* All instruments including:

- Software with manual (FDA 21 CFR Part 11 Compliant)
- Validation Protocol Package (IQ, OQ, PQ, SQ)
- Tube Rack

9.2 ELx808™ IU Microplate Reader

The ELx808™ IU Microplate Reader is a photometer for the quantitative endotoxin and glucan detection.

- 96 wells
- for the detection of endotoxins (detection limit: **0.005 EU/ml**) to be used with:
 - PYROCHROME® for the chromogenic LAL method
 - CHROMO-LAL for the kinetic chromogenic LAL method
 - PYROTELL®-T for the kinetic turbidimetric LAL method
- for the detection of (1→3)-β-D-glucans (detection limit: **3.125 pg/ml**) to be used with:
 - FUNGITELL®
 - GLUCATELL®



Order No.	Catalog No.	Description
74100ELX	ELx 808 IU	ELx808™ IU Microplate Reader
74260SMP	GEN5SECURE	Gen5™ Secure Software with Manual (FDA 21 CFR Part 11 compliant)
74360SMP	GEN5	Gen5™ Software with Manual
74400LIP	-	loan or replacement instrument

Further accessories and validation documents are available on request

All prices are without VAT and delivery costs. Subject to changes and errors without prior notice.

9.3 Instrument specific services

Order No.	ACC-Catalog No.	Description
73400CRP	CAL06	Calibration: PYROS Kinetix® FlexTube Reader*
73400CRPO	CAL07	Calibration on-site: PYROS Kinetix® FlexTube Reader**
74400CRP	-	Calibration: ELx808™ IU *
74400CRPO	-	Calibration on-site: ELx808™ IU **
73000PKFQUAL	-	System Qualification (IQ, OQ, PQ, SQ) Installation, configuration and introduction of a Quantitative System On-site Trainings

* Calibration performed at our facility

** Without travel expenses

10 Laboratory Accessories

10.1 Tube Racks

Order No.	ACC-Catalog No.	Description
90008RSAPKF32	TTR32	Tube rack: 32 bore-holes: Ø = 8 mm, numbered 1-32 (for PYROS Kinetix® Flex Tubes 7.9 x 75 mm)
90008RSAPKF64	TTR64	Tube rack 32 bore-holes: Ø = 8 mm; numbered 33-64 (for PYROS Kinetix® Flex Tubes 7.9 x 75 mm)
90008RSAPKF96	TTR96	Tube rack 32 bore-holes: Ø = 8 mm, numbered 65-96 (for PYROS Kinetix® Flex Tubes 7.9 x 75 mm)
90011RSS	-	Tube rack: 60 bore-holes in 6 rows: Ø = 11 mm (for Gel-Clot tubes 10 x 75 mm)
90013RSS	-	Tube rack: 50 bore-holes in 5 rows: Ø = 13 mm (for Gel-Clot Single Test Vials 12 x 75 mm)
90018RSS	-	Tube rack: 48 bore-holes in 4 rows: Ø = 18 mm (for Dilution Tubes 16 x 100 mm)

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11 Services

11.1 ACC Inter Laboratory Performance Qualification (ILPQ) for the BET

The international ILPQ, a proficiency test for the Bacterial Endotoxins Test (BET) takes place every spring and autumn. You will get further information on request.

Order No.	ACC-Catalog No.	Description
ILPQ-A	-	ILPQ-A The service includes: I) Sample II) Anonymous assessment III) Final report IV) Certificate of participation
ILPQ-B	-	ILPQ-B In addition to the assessment of service ILPQ-A: Comments whether or not the test has been performed in accordance with the regulatory requirements.

11.2 BET Seminars and Workshops

Both BET seminars are divided in introductory, practical and advanced courses, which can be booked together or individual.

Dates for our training courses in English and further information on request.

➤ Kinetic chromogenic & Kinetic turbidimetric Method

Order No.	ACC-Catalog No.	Description
SEMINAR-K	-	Introductory, Practical and Advanced Course

➤ Gel-clot Method

Order No.	ACC-Catalog No.	Description
SEMINAR-F	-	Introductory, Practical and Advanced Course

➤ GLUCATELL® Workshop

Order No.	ACC-Catalog No.	Description
WORKSHOP-G	-	Laboratory Course: Detection of (1→3)-β-D-Glucans

➤ FUNGITELL® Workshop

Order No.	ACC-Catalog No.	Description
WORKSHOP-F	-	Laboratory Course: Use of FUNGITELL® as an indicator of invasive fungal infections

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General Terms and Conditions (T&C)
Associates of Cape Cod Europe GmbH

1. Area of Application

- (a) These terms of sale and delivery are applicable to all business relations between the company Associates of Cape Cod Europe GmbH (hereafter ACC Europe) and its customers (hereafter Purchaser) for the sale and delivery of merchandise.
- (b) Provisions which are at variance with these terms and conditions are only valid if they are confirmed in writing by ACC Europe. This also applies if ACC Europe supplies services without reservation in the knowledge of the customer's conflicting or differing terms and conditions.
- (c) In case of uncertainty or dispute the German language version of these general terms and conditions prevails (see www.acciusa.de).

2. Use of Products

- (a) The delivered Products are to be kept and used in compliance with the Instructions for Use provided with each product.
- (b) ACC Europe Products are not provided for resale or transfer to any third party without the prior written consent of ACC Europe. In the absence of a valid distribution agreement from ACC Europe, no distribution, except for purposes of disposal, is allowed for any Products purchased from ACC Europe.

3. Prices, risk taking and Set-off

- (a) All our prices do not include the valid value added tax.
- (b) Our invoices are due to pay net without deduction within 30 days upon receipt of invoice.
- (c) Goods are assumed to be supplied "ex-works", unless the contract confirmation states different terms.
- (d) The customer is only entitled to set-off rights if his counter-claims are found to be legally valid, are undisputed or acknowledged by us. The customer is entitled to exert a right of retention if his counter-claim is based on the same contract relationship.

4. Liability for Defective Goods

- (a) Claims on the part of the customer in respect of defective goods require that the latter has properly fulfilled his obligation to examine and locate faults in accordance with § 377 HGB and complied with the information and direction of use concerning storage and usage.
- (b) If a defect is present in the purchased goods, ACC Europe is entitled to choose whether to correct the fault or supply a new, defect-free replacement. If ACC Europe opts to correct the fault, the company is obliged to bear all expenses required for the correction, especially transport, travel, work and material costs, unless such costs are increased by the fact that the purchased goods were transported to a different location than the original shipping location.
- (c) If the service fails, the customer is entitled at his own choice to demand withdrawal or diminution.
- (d) ACC Europe is liable in accordance with the statutory regulations if the customer makes valid claims for compensation due to deliberate or gross negligence, including deliberate or gross negligence on the part of our representatives or our assistants. If ACC Europe is not accused of deliberate infringement of contract, the liability to pay compensation is limited to the typical predictable damage.
- (e) ACC Europe is liable in accordance with the statutory regulations if a significant contract obligation is culpably infringed; in this case the liability to pay compensation is limited to the typical predictable damage.
- (f) The liability on account of culpable injury to life, limb or health is unaffected; this applies also to compulsory liability in accordance with product liability law.
- (g) Liability is excluded if the regulations are at variance with the foregoing.
- (h) The term of limitation for claims relating to defective goods is one year, commencing with the transfer of risk.
- (i) The term of limitation in the case of legal recourse in accordance with §§ 478, 479 BGB is unaffected; the period is five years, commencing on the date of delivery of the defective item.

5. Overall Liability

- (a) Liability to pay compensation in addition to that included under 4. is excluded regardless of the legal nature of the validated claim. This applies in particular to claims for reimbursement of debts at conclusion of contract, to other infringements of obligations, or to tort claims for compensation of property damage in accordance with § 823 BGB. Liability for wilful conduct is unaffected by this.
- (b) The limitation as described under (a) also applies if the customer demands reimbursement of needless expenses instead of making a claim for compensation.

6. Reservation of Title

- (a) ACC Europe reserves title to the purchased items until all payments relating to the contract have been received.
- (b) The customer is responsible for storing and handling the purchased items in compliance with the information and Instructions for Use; in particular he must take out adequate insurance for the purchased items to their new value at his own cost, covering damage caused by fire, water and theft. Where maintenance and inspection work is necessary, the customer must carry this out promptly at his own cost.
- (c) In the case of distraint or other intervention on the part of third parties, the customer must promptly inform ACC Europe of this circumstance, so that ACC Europe can petition the court in accordance with § 771 ZPO. If the third party is not in a position to refund the legal and extra-legal costs of a petition to ACC Europe in accordance with § 771 ZPO, the customer is liable for the shortfall.

7. Data Protection and Secrecy

- (a) You will find our detailed privacy policy on our homepage www.acciusa.de.

8. Jurisdiction and Domicile

- (a) If the customer is a "Kaufmann" in terms of HGB (German Commercial Code), then jurisdiction is the place of business of ACC Europe; however, ACC Europe is also entitled to make claims against the customer at the court of his place of residence.
- (b) The legal relationships of the parties shall be governed by German law with exclusion of the United Nations Convention of 11 April 1980 on Contracts for the International Sale of Goods.



Contact Information

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Sales Order Processing	+49 - 6105 - 9610 21
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Sales North Germany & Switzerland	+49 - 173 - 7418 048
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Sales South Germany & Austria	+49 - 172 - 1317 477
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Sales Fungitell	+49 - 172 - 8213 194
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Technical Support	+49 - 6105 - 9610 26 +49 - 172 - 1317 336
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Seminars ILPQ (Inter Laboratory Performance Qualification)	+49 - 6105 - 9610 14 +49 - 6105 - 9610 26
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Quality Management	+49 - 6105 - 9610 12
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Please provide the following information together with your order:

- company name
- billing and delivery address
- contact person
- telephone and fax number, e-mail address
- your purchase order number
- VAT registration number
- product description, quantity and order number

Delivery time:

- within 1 - 2 working days Monday - Wednesday, if receipt of order until 1:00 p.m. (Germany, Europe: air freight)
- within 2 - 3 working days (Europe: shipment by truck)
- express supply against additional charge

Notes