



ASSOCIATES OF  
**CAPE COD**  
INCORPORATED

[www.acciusa.com](http://www.acciusa.com)

# Overview

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## History

The *Limulus* Amebocyte Lysate (LAL) test was developed using the North American horseshoe crab in the 1960s at the Marine Biological Laboratory in Woods Hole, MA by Drs. Jack Levin and Frederik Bang. ACC was founded in 1974 by Dr. Stanley Watson, then a scientist at the Woods Hole Oceanographic Institution. In 1977, ACC became the first company to be licensed by the FDA for the production of LAL reagents for endotoxin testing of healthcare products. In 1997, the company was purchased by Seikagaku Corporation, Japan. ACC is now a subsidiary of Seikagaku Biobusiness Corporation. Seikagaku is a pioneer in the field of endotoxin detection, making reagents from the Asian horseshoe crab and were the first company to make the chromogenic test method available commercially. In 2004, ACC completed the transfer of manufacturing operations to a new, 80,000 square foot state-of-the-art manufacturing facility.

ACC founded an industry, and built an exceptional company utilizing one of the oldest, and most interesting local resources, the horseshoe crab. The company goes to great lengths to remain an environmentally friendly member of the community, and is proud of the results. From humble beginnings producing a research reagent in Dr. Watson's garage, ACC has grown into a world class organization with a global network of offices and distributors. The company continues to develop new products and expand its capabilities to meet the needs of its valued customers.

### Introduction to *Limulus* Amebocyte Lysate (LAL) for Endotoxin and Glucan Detection

LAL reagents used to detect endotoxin and glucans are prepared from an extract (lysate) from the amebocytes of the horseshoe crab, *Limulus polyphemus*. Clotting in the LAL triggered by endotoxin, a cell wall component of gram-negative bacteria. (1→3)-β-D-glucan, a material found in fungal cell walls, plant tissue, in some algae and in some bacteria, also activates LAL. LAL contains the proteins of the clotting mechanism and allows for highly sensitive tests for both endotoxin and (1→3)-β-D-glucan. Activation of the endotoxin and (1→3)-β-D-glucan clotting mechanisms are initiated by separate receptors, and ACC offers reagents to allow clear distinction between these substances.



Corporate Headquarters  
Associates of Cape Cod, Inc.  
124 Bernard E. Saint Jean Drive  
East Falmouth, MA 02536-4445  
T (508) 540-3444 • F (508) 540-8680  
Online: [www.acciusa.com](http://www.acciusa.com)

UK Office  
Associates of Cape Cod Int'l Inc.  
Deacon Park, Moorgate Road  
Knowsley, Liverpool L33 7RX, United Kingdom  
T (44) 151-547-7444 • F (44) 151-547-7400  
Online: [www.acciuk.co.uk](http://www.acciuk.co.uk)

European Office  
PYROQUANT DIAGNOSTIK GmbH  
Opelstrasse 14  
D-64546 Mörfelden-Walldorf, Germany  
T (49) 61 05-96 10 0 • F (49) 61 05-96 10 15  
Online: [www.pyroquant.de](http://www.pyroquant.de)

## Ordering Information

Customer service representatives are available to assist you with orders, pricing requests, Certificates of Analysis, and reserving specific product lots.

## Sales Offices

### Corporate Office

#### United States of America

##### Associates of Cape Cod, Inc.

124 Bernard E. Saint Jean Drive  
 East Falmouth, MA 02536-4445, USA  
 Tel: (508) 540-3444; (800) LAL-TEST  
 Fax: (508) 540-8680  
 E-mail: [custservice@acciusa.com](mailto:custservice@acciusa.com); Web: [www.acciusa.com](http://www.acciusa.com)

### International Offices

#### United Kingdom

##### Associates of Cape Cod International, Inc.

Deacon Park, Moorgate Road  
 Knowsley, Liverpool L33 7RX  
 United Kingdom  
 Tel: (44) 151-547-7444  
 Fax: (44) 151-547-7400  
 E-mail: [info@acciuk.co.uk](mailto:info@acciuk.co.uk); Web: [www.acciuk.co.uk](http://www.acciuk.co.uk)  
 Company Registration Number: BR002906

#### Germany

##### PYROQUANT DIAGNOSTIK GmbH

Opelstrasse 14  
 D-64546 Mörfelden-Walldorf, Germany  
 Tel: (49) 61 05-96 10 0  
 Fax: (49) 61 05-96 10 15  
 E-mail: [service@pyroquant.de](mailto:service@pyroquant.de); Web: [www.pyroquant.de](http://www.pyroquant.de)

#### Outside the U.S.

Please contact your local office for information regarding method of payment. For a list of your country specific distributors please see [www.acciusa.com](http://www.acciusa.com).

Please provide the following information when placing your order:

- Company Name
- Billing Address
- Shipping Address
- Contact Name
- Telephone Number
- Fax Number



- Purchase Order Number
- Date Needed
- Products To Be Ordered
  - Catalog Number
  - Amount & Unit (5 vials, 11 packages, etc.)
  - Specific Lot Number (if desired) ACC will ship the requested lot number if available; otherwise a substitute lot number will be shipped.
  - Any additional information that will assist in processing your order (description, required certificates, etc.)

### Method of Payment

#### For United States

- Check (in US dollars) made payable to Associates of Cape Cod, Inc.
- Wire Transfer (contact Accounts Receivable for routing information)
- Credit Card (AMEX,® VISA,® MasterCard®). If payment is to be made by credit card, the following information is required: Type of Credit Card, Card Number, Credit Card Security Code Expiration Date of Card, Name (as it appears on the card).

### Additional Information

For US and Canadian customers not paying by credit card, the standard terms are Net 30 days. ACC reserves the right to adjust credit status as customer credit history necessitates. Please refer to the Terms and Conditions accompanying your quotation or invoice.

*Product listings and fill sizes are subject to change at any time without prior notice.*

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## Product Reserve Option

Upon request, Associates of Cape Cod, Inc. (ACC) will reserve specific lots of product for a period of up to one year. ACC's Product Reserve Option applies to reagent products in accordance with the following terms:

- Customer agrees to purchase the entire reserve by the reserve agreement expiry date, which can be up to one year from the order acceptance date. Accepted orders are firm, and no return of reserved orders will be allowed.
- A standing purchase order or blanket purchase order is required. Shipments may be made on request and must reference the Reserve number or Purchase Order number.
- Acceptance of a reserve by the customer and ACC shall be communicated by signing the reserve notification letter and faxing it back to ACC at (508) 540-8680.
- For product still remaining on reserve within 30 days of the reserve expiration date, customer service will notify the customer that a final shipment and matching invoice for the remaining balance will take place within 30 days.

## Technical Service

Associates of Cape Cod, Inc. (ACC) offers its customers extensive technical support. Our Technical Service department is staffed with experienced professionals who provide customer assistance with the full range of ACC products and services. Technical support is available by telephone, email, and if desired, in person, through workshops, on-site training, or on-site troubleshooting.

### LAL Support Services

Customers who have questions about individual products, test methods, instrumentation, and/or software are invited to call our staff to discuss the issue. ACC staff provide decades of LAL testing experience and can resolve most questions on the phone or by email.

### On-Site Consulting Services

ACC staff are available to visit client sites to assist investigations and trouble-shooting. These visits often address LAL testing procedures, in addition to identifying sources of contamination in test laboratories and manufacturing processes.

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### Contact Information

For technical information, and our online training brochure, see ACC's website at [www.acciusa.com](http://www.acciusa.com). LAL Update newsletters are available online, or by email. We can be reached at (800) 848-3248 or by email [techservice@acciusa.com](mailto:techservice@acciusa.com).



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## LAL Training Courses

ACC offers training courses on all aspects of endotoxin testing. Courses are conducted at our facility in East Falmouth, MA and other locations throughout the United States and world wide.

In order to achieve the level of training that you require, you may choose from several courses. We offer background and in-depth courses, as well as hands-on laboratory experience.

### LAL Methodology Background

This course is designed to introduce LAL methodologies to technicians who are new to LAL testing. Topics include:

- Endotoxins—What they are, where they come from, and why they are important
- LAL—What is it? How did it become used in a QC release test?
- Biochemistry—An overview of the LAL/endotoxin reaction, with emphasis on sources of interference
- Detailed demonstration of the test methods, including a discussion of laboratory set-up, materials, and aseptic techniques
- Specimen handling and preparation
- Practical approaches to specimen characterization and overcoming interference
- Technician and laboratory certifications and protocols for validation of the LAL test

### Hands-On Laboratory

The laboratory courses are designed to give the attendee hands-on experience conducting LAL tests. Participants practice setting up tests and learn to read and interpret results. Completion of the LAL Methodology Background course is strongly recommended before taking a laboratory course. Familiarity with general laboratory techniques is very useful.

Participants choose to work on one of the three LAL test methods: chromogenic, turbidimetric or gel-clot.

### In-Depth Topics

This course provides the experienced technician with a more detailed understanding of how an LAL testing program can be applied to quality assurance. Topics include:

- Microbial control of water systems and monitoring with LAL
- Depyrogenation by physical and chemical means and oven depyrogenation validation
- Techniques to test non-aqueous or highly interfering substances

- (1→3)-β-D-Glucan issues; contamination, recognition, and investigation
- Medical device sample preparation and validation of extraction protocols
- Regulatory considerations and documentation

### Hemodialysis Specialty Topics

This is an introductory level course specifically for technicians who are testing water and hemodialysis solutions in hemodialysis facilities or hospital clinical laboratories.

Topics are the same as the LAL Methodology Background course but are focused on the hemodialysis application. Attendees obtain hands-on laboratory experience in this course.

### Contract Training

ACC can customize an LAL workshop for you and your staff and conduct it at your facility or ours. Instructors work with you to create a training program tailored to your specific requirements. Contact Technical Services at (800) 848-3248 to discuss contract training options, available dates, and pricing.

### On-Site LAL Workshops

- #WKSP01 -----1 Day Workshop  
up to 5 Attendees
- #WKSP02 -----2 Day Workshop  
up to 5 Attendees
- #WKSP05 -----Additional Attendees

### Course Schedule and Fees

For course dates and fees, please check our website at [www.acciusa.com](http://www.acciusa.com). The LAL training course schedule can be found in the Calendar section of the website as well as the LAL Products section of the website. To receive additional information, our annual course schedule, or to register for a course, call Customer Service (800) 525-8378—in North America. For information on training courses outside the United States, contact your local office or distributor.



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124 Bernard E. Saint Jean Drive  
East Falmouth, MA 02536-4445  
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(508) 540-3444  
Fax: (508) 540-8680  
[www.acciusa.com](http://www.acciusa.com)

**Customer Service:**

[custservice@acciusa.com](mailto:custservice@acciusa.com)

**Technical Service:**

[techservice@acciusa.com](mailto:techservice@acciusa.com)

**Contract Test Service:**

[testservice@acciusa.com](mailto:testservice@acciusa.com)

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[www.pyroquant.de](http://www.pyroquant.de)