

# KINETIC CHROMOGENIC ENDOTOXIN DETECTION SYSTEMS

Validation Support • Technical Service  
Training • Assay • Detection • Analysis

## **The Complete Solution - Sensitivity, Flexibility and Compliance in Chromogenic Endotoxin Testing**

Combining Assay, Detection, Analysis, with world class Technical Service, Training, and Validation Support, Associates of Cape Cod, Inc. offers diverse options for conducting endotoxin testing.

# THE COMPLETE SENSITIVITY, FLEXIBILITY AND COMPLIANCE

*The Associates of Cape Cod, Inc. (ACC) Chromogenic Endotoxin Detection System includes Pyrochrome® chromogenic reagent, the Pyros Kinetix® Flex Incubating Kinetic tube reader and user-friendly 21 CFR Part 11 Compliant Pyros® EQS Endotoxin Quantitation Software. The system allows for fully USP BET<sup>1</sup> compliant endotoxin tests, high sensitivity and an economical sample to LAL ratio providing a broad range of options for conducting endotoxin testing.*

*Other options include the BioTek® ELx808 IU™ Plate Reader and Gen5™ Secure Software that provides the flexibility to collect and analyze data for microplate users. Gen5 Secure Software is customized, 21 CFR Part 11 compliant software for the ELx808™ Incubating Microplate Reader. Gen5's interface provides easy access to all major functions of the software including reading parameters, plate layout, data reduction, on-line help wizards, tutorials and Associates of Cape Cod, Inc.'s endotoxin specific assay protocols.*

## KINETIC CHROMOGENIC ENDOTOXIN DETECTION SYSTEMS

# SOLUTION IN CHROMOGENIC ENDOTOXIN TESTING

## Assay

### Pyrochrome® - Kinetic Chromogenic Endotoxin Testing

Pyrochrome is a versatile reagent that is used to perform quantitative kinetic or endpoint assays. It is a sensitive reagent that can be used for testing in compliance with the USP, EP and JP bacterial endotoxins test chapters<sup>1</sup>.

## Detection

### Pyros Kinetix® Flex – for Chromogenic assays

The Pyros Kinetix® Flex<sup>2</sup> is an optical tube reader that enables both chromogenic and turbidimetric assays to be run in compliance with the USP, EP, and JP bacterial endotoxins test chapters<sup>1</sup>. The Pyros Kinetix Flex tube reader is available in three configurations: 32, 64 or 96 eight mm wells. Each well has a detector that identifies changes in the optical density of a sample. The test in each well is independently actuated, which assures accurate timing and allows the operator to add more samples while an assay is in progress.

### BioTek® ELx808 IU™ Plate Reader

The BioTek® ELx808 IU™, manufactured by BioTek® Instruments, is an incubating absorbance microplate reader that provides the ability to collect and analyze data.

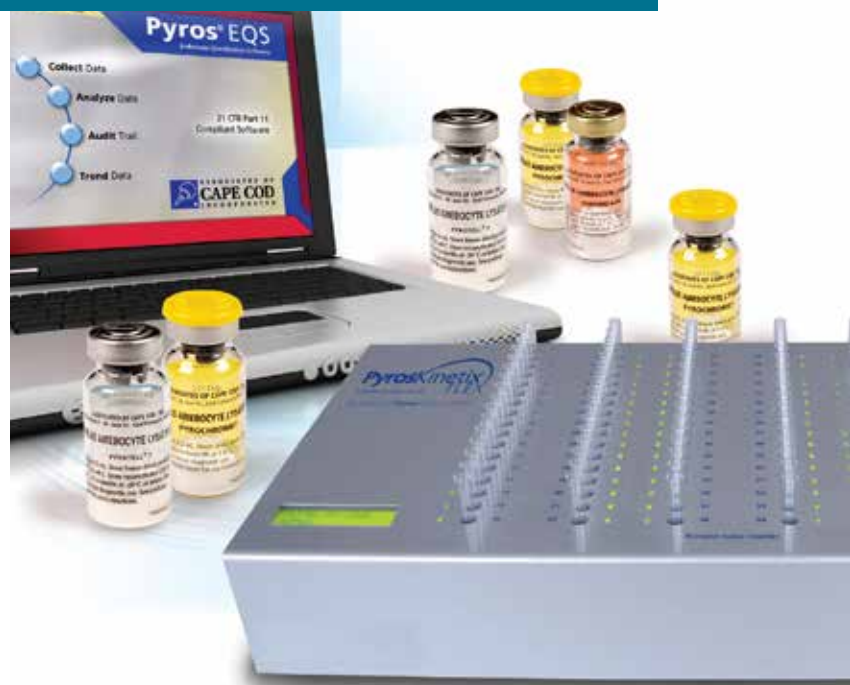
## Analysis

### Pyros® EQS

Endotoxin Quantitation Software Pyros EQS is intuitive, easy-to-use software that is designed specifically for endotoxin testing and can be used with the Pyros Kinetix Flex tube reader. Pyros EQS is a sophisticated 21 CFR Part 11 compliant, software solution that provides efficient, accurate analysis and reporting.

### Gen5™ Secure Software

Gen5 Secure Software is customized, 21 CFR Part 11 compliant software for the ELx808™ Incubating



Microplate Reader. Gen5's interface provides access to all major functions of the software including reading parameters, plate layout, data reduction, on-line help wizards, tutorials and ACC's endotoxin specific assay protocols.

## Technical Service, Training, and Validation Support

ACC offers its customers extensive technical support. Our Technical Service and representatives in the field are experienced professionals who provide customer assistance for the full range of ACC products and services. Assistance with selecting a test method or reagent is always available by telephone, email, and in person, through workshops, on-site training, or on-site support. Customers who have questions about individual products, test methods, instrumentation, and/or software are invited to call our staff.

### Reference

<sup>1</sup>Bacterial Endotoxins Test. Chapter <85>. United States Pharmacopeial Convention, Rockville, MD, USA, 2010.

<sup>2</sup>Pyros®, Pyros Kinetix® Flex, Pyrochrome® and Glucashield® are trademarks of Associates of Cape Cod, Inc. All other trademarks mentioned are the property of their respective owners.

# ASSAY



## Pyrochrome®

*Pyrochrome® sets the standard for quality and redefines the way chromogenic reagents should perform.*

### Features & Benefits

- Maximum sensitivity of 0.001 EU/mL
- Option to use a sample to LAL volume ratio of 4:1 or 1:1
- Highly cost effective chromogenic reagent
- No pre-incubation required - results can be available within 1 hour: Reduces labor and increases turn-around-time
- Single Step Assays: Reduces time, lab errors and the potential for contamination

### General Product Description

Pyrochrome is offered with either Pyrochrome Buffer or with Glucashield buffer for endotoxin-specific testing. Pyrochrome can be used with the Pyros Kinetix® Flex tube reader at a 1:1 and economical 4:1 sample to LAL ratio.

Pyrochrome can be used for a wide variety of sample types, ranging from standard water testing to samples requiring high sensitivity, such as intrathecal products and those requiring high dilutions to overcome interference.

It is also offered in a diazo kit for endpoint tests. The diazo reagents shift the absorption wavelength making it especially useful for testing samples with color interference.

### Sensitivity

The maximum sensitivity of Pyrochrome is 0.001 EU/mL when run in Pyros Kinetix Flex tube reader or incubating microplate reader with Glucashield Buffer.

### Sample to LAL Ratio

In the Pyros Kinetix Flex tube reader, Pyrochrome can be used at an economical ratio of 4:1 using 50 µL of reagent per well or at 1:1 using 100 µL/well. In a microplate reader, the reagent is used at a ratio of 1:1 and a volume of 50 µL/well (60 tests/vial) or 100 µL/well (30 tests/vial).

CHROMOGENIC  
REAGENTS

## Performing the Test

The Pyrochrome – sample mixture is incubated in an optical reader at  $37\pm 1^\circ\text{C}$  and read at a wavelength of 405 nm, except when the diazo kit is used. Time to results is dependent on the required assay sensitivity. Software will analyze the data to provide endotoxin results.

## Reconstitution

Pyrochrome lysate is reconstituted with an optimized Pyrochrome reconstitution buffer (C1500-5). Pyrochrome can also be reconstituted with Glucashield buffer (GB051-5), a (1→3)-β-D-Glucan inhibiting buffer, to render the assay endotoxin specific.

## Stability

Once reconstituted, Pyrochrome is stable for 8 hrs. when stored at 2–8°C.

## Packaging

Pyrochrome is offered with a choice of reconstitution buffer and is recommended for use with the 10 ng/vial Control Standard Endotoxin (CSE, EC010). Certificates of Analysis, specific to the Pyrochrome and CSE lot, can be obtained from ACC or online at [www.acciusa.com](http://www.acciusa.com).

## Pyros Kinetix® Flex – Chromogenic assays

*Designed with flexibility and efficiency in mind, the PK Flex provides flexible options for conducting endotoxin testing.*

The Pyros Kinetix® Flex and Pyros® EQS 21 CFR Part 11 compliant Software combine to provide a complete system for efficient, accurate endotoxin testing.

# DETECTION



## Features & Benefits

- Precise Temperature Control: Incubator temperature is held to  $37^\circ\text{C} \pm 0.5^\circ\text{C}$
- Solid State Design: Low instrument maintenance
- Two Wavelength Settings
- Uses Low Cost Depyrogenated Disposables Accessories
- Broad Sensitivity Range: No other system is more sensitive; As high as 0.001 EU/mL with Pyrochrome® lysate
- Increased Efficiency: The ability for end-users to add samples to an existing assay in order to efficiently utilize all wells. Software provides quantitative sample results while assay continues to run
- Flexible Testing: Variable volumes and ratios can be utilized, ability to maximize product MVD (Maximum Valid Dilution)
- Reduced Lysate Usage: As little as 50 µL per test

## System Specifications

Capacity: 32, 64 or 96 reaction test tubes

### Power Requirement:

100 to 240 VAC @ 50 / 60 Hz

Light Source: LED

### Dimensions & Weight:

PKF32 - 9.25" x 10" x 3.125" / 6 lbs 15 oz

PKF64 - 9.25" x 14" x 3.125" / 11 lbs 5 oz

PKF96 - 9.25" x 18" x 3.125" / 15 lbs 14.5 oz

Temperature Range: 37°C ± 0.5°C

### Warranties, Parts and Service

For details on extended warranties, repairs and recalibrations, contact your supplying office or for services outside the US, contact your local distributor.

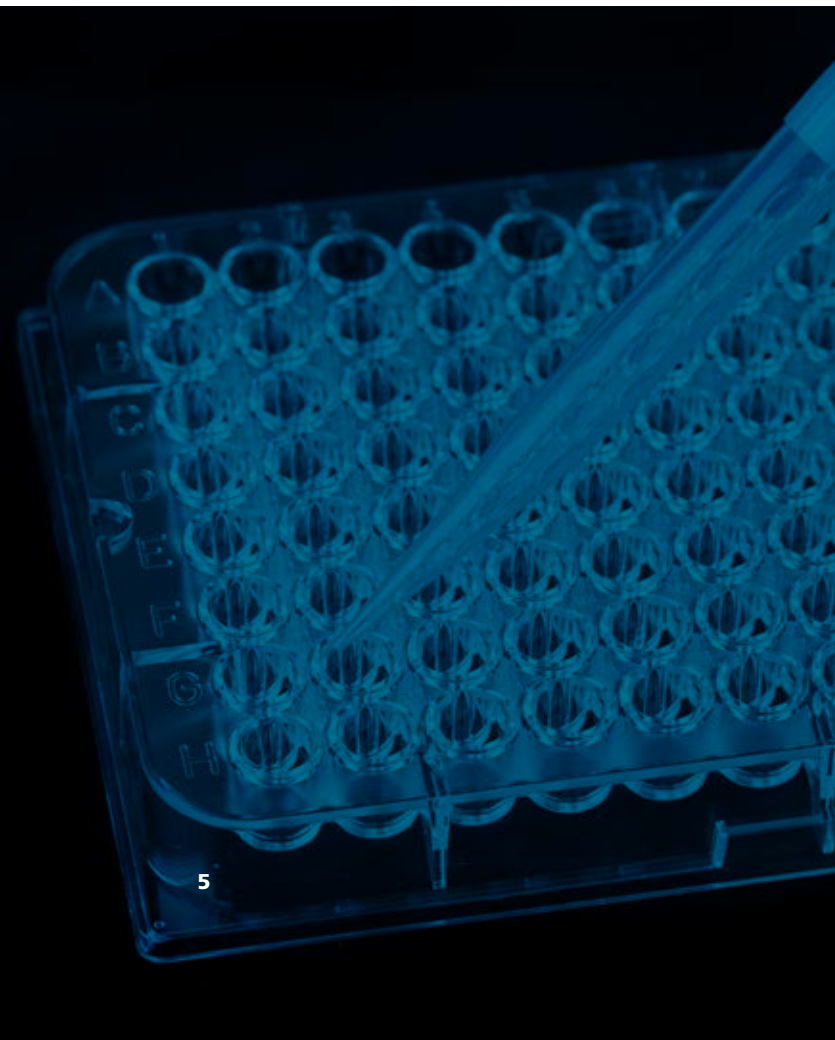


## ELx808 IU™ Absorbance 96 Well Microplate Reader

The BioTek® ELx808 IU™, manufactured by BioTek® Instruments, is an incubating absorbance microplate reader that provides the ability to collect and analyze data. The ELx808 IU™ comes equipped with an on-board diagnostic self-test to confirm and document reader performance. All calculations are performed automatically. The ELx808 IU™ utilizes fast kinetics to measure in intervals as short as 6 seconds. A 4-Zone™ Temperature Control system and unique heated track/carrier design provide for minimal evaporation and edge effect. The ELx808 IU™ incorporates a staggered optical design to eliminate channel-to-channel cross talk.

### Features of the ELx808IU™ Plate Reader

- Programmable and variable shaking speed
- End-point, kinetic and well-scanning capabilities
- On-board data analysis, including curve-fitting
- Precise reporting
- Can be used for a wide range of applications



# ANALYSIS

## Pyros® EQS - Endotoxin Quantitation Software

### Features & Benefits

- Designed to be 21 CFR Part 11 Compliant: Meets regulatory compliance requirements of the FDA
- Oracle® Database: Unlimited data storage with the industry standard in pharmaceutical databases. Secure storage and back-up utilizing Oracle supplied functionality
- Choice of network client-server or stand-alone workstation configuration: Flexibility to meet the needs of small to very large laboratory configurations
- Enhanced Reporting Options, including the ability to export to MS Word®, Excel®, Crystal Reports® and Adobe® PDF file formats: Variety of template formats for ease of reporting
- Runs Multiple Standard Curves: Ability to run endotoxin potency determinations
- Flexible Operation: Background data collection permits other applications to run while collecting data. Data collection continues locally, even if network connection to database is lost
- Enhanced for use with Pyros Kinetix® Flex: Broad Sensitivity Range: As low as as 0.001 EU/mL. Individually timed reactions; allows for continuous addition of samples during operation
- Easy user-friendly installation: Auto-installs any pre-requisite applications



Pyros EQS writes to an Oracle® database, the industry standard in data security. It has multiple access levels for improved security, detailed audit trails, and built-in trending by date range, technician, sample type and LAL lot. The software provides enhanced reporting options, flexible operation modes and incorporates electronic signatures, as well as a supervisor sign-off on completed tests. The application also offers two choices for calculating Coefficient of Variations (CVs), and a summarized Pass/Fail Report. Pyros EQS is LIMS compatible through multiple export options.

Software Validation Protocols provide the end user with a comprehensive set of integrated documents to guide them through the system validation process. A Validation Plan outlines the tasks and documentation required to perform the validation. A Requirements Specification, the foundation of the validation process, clearly delineates the system's required functions and expected performance. Detailed instructions guide users step-by-step through the IQ/OQ, and PQ processes. Stress Test procedures are included as well as Change Control and Maintenance guides.

The image shows a computer monitor displaying the Pyros EQS software interface. The screen features a navigation menu on the left with options: 'Collect Data', 'Analyze Data', 'Audit Trail', and 'Trend Data'. The main area of the screen displays '21 CFR Part 11 Compliant Software' and the logo for 'ASSOCIATES OF CAPE COD INCORPORATED'. In the foreground, a microplate reader is visible, with a microplate being processed. The entire scene is overlaid with a semi-transparent blue filter.

# ENDOTOXIN QUANTITATION SOFTWARE

## Gen5™ Secure Software

### Incubating Microplate Reader Software

Designed by engineers focused on microplate instrument technology for microplate users, Gen5 works the way you do. Gen5\* Secure Software is customized, 21 CFR Part 11 compliant software for the ELx808™ Incubating Microplate Reader. Gen5's contemporary interface provides easy access to all major functions of the software including reading parameters, plate layout, data reduction, on-line help wizards, tutorials and ACC's endotoxin specific assay protocols.

*\*Trademark of Bio-Tek Instruments, Inc.*



# TECHNICAL SERVICE, TRAINING, AND VALIDATION SUPPORT



Assistance with selecting a test method or reagent sensitivity is always available from our Technical Service Department, and representatives in the field. Our staff and distributors can help with characterization, validation or routine testing. The LAL Update®, our newsletter, includes useful technical articles and is available on our website. Our Contract Test Service regularly performs characterization and method development and can provide results by all test methods. Regardless of which method is selected, you can always be assured of the full support of ACC.

ACC offers its customers extensive technical support. Our Technical Service department is staffed with experienced professionals who provide customer assistance for the full range of ACC products and services. Technical support is available by telephone, email, and in person, through workshops, on-site training, or on-site troubleshooting. Customers who have questions about individual products, test methods, instrumentation, and/or software are invited to call our staff.

## **Software Validation Protocols**

ACC offers Validation Protocols that provide the end user with a comprehensive set of integrated documents to guide them through the system validation process. The protocol files in Microsoft® Word format allows users to edit the documents to meet their company's specific validation requirements.

## **Reagent Transfer Protocol (RTP)**

The Reagent Transfer Protocol document (RTP) is used to validate the change from another manufacturer to ACC LAL reagents. If changing LAL reagent manufacturers, ACC offers assistance with guidance and instructions for using the Validation Protocol. This can be used as verification of the validation process. The Reagent Transfer Protocol is designed to assist users in completing validation of their switch from the current LAL reagent to an ACC product. During this process, if the user requires any assistance you will be able to obtain help and advice through the Technical Services department of ACC.

## Pyrochrome® Chromogenic Test Kit

3.2 mL/vial (approx. 60 tests/vial)

Each kit contains Pyrochrome and Recon. Buffer

CD060	60 Test Kit (diazo format)
C1500-5	5 x 60 tests/vial
C1500-25	25 x 60 tests/vial
CG1500-5	Pyrochrome with Glucashield Buffer 5 x 60 tests/vial
CG1500-25	Pyrochrome with Glucashield Buffer 25 x 60 tests/vial

## Chromo-LAL

#C0031-5 3.2 mL/Vial 5 Pack (150 tests)

## Pyros Kinetix® Flex

PKF32	Pyros Kinetix Flex 32-well (includes instrument, software and validation)
PKF64	Pyros Kinetix Flex 64-well (includes instrument, software and validation)
PKF96	Pyros Kinetix Flex 96-well (includes instrument, software and validation)

## Microplate Reader

PPS04	ELx808 Incubating Microplate Reader, (software sold separately)
ELXP	Universal Test Plate for ELx808 reader

## SOFTWARE PRODUCTS

### Pyros Kinetix® Software

PEQS11	Pyros EQS Software and Manual (21 CFR Part 11 Compliant)
PEQS	Pyros EQS Software and Manual (without compliance features)
PEQS11-VAL-PKF	Pyros EQS Software Validation Package (PK Flex)
PEQS-OR	One year renewal for Oracle® database in Pyros® EQS software

### Microplate Reader Software

Gen5	Gen5™ Secure Software
5320500	Gen5™ installation qualification pkg.
PQPE	Product Qualification Package, ELx808

## Accessory Products

### LAL Reagent Water (LRW)

LRW is intended for reconstitution of LAL reagents and CSE, and to dilute samples and standards for LAL assays. LRW is not for human or animal injection. LRW contains less than 0.001 EU/mL endotoxin and less than 1.56 pg/mL glucan.

W0051-10	5.5 mL/bottle, 10 bottles/pack
W020P	20 mL/bottle, 10 bottles/pack
W0504	50 mL/bottle
W050P	50 mL/bottle, 5 bottles/pack
W1004	100 mL/bottle
W100P	100 mL/bottle, 4 bottles/pack
WP0501	50 mL/Plastic bottle
WP050C	50 mL/Plastic bottle, 30 bottles/pack
WP1001	100 mL/Plastic bottle
WP100C	mL/Plastic bottle, 30 bottles/pack
WP5001	500 mL/Plastic bottle
WP500C	500 mL/Plastic bottle, 12 bottles/pack
WP10001	1L/Plastic bottle
WP1000C	1L/Plastic bottle, 12 bottles/pack

### Pyrotubes®

TK100-10	8 x 75 mm borosilicate glass for Pyros Kinetix® Flex 50 tubes/pack, 10 packs/carton
TB050	10 x 75 mm borosilicate glass for turbidimetric method 52 tubes/pack,
TB240-5	12 x 75 mm borosilicate glass (for dilutions only) 42 tubes/pack, 5 packs/carton
TB013-5	13 x 100 mm borosilicate glass (for dilutions only) 18 tubes/pack, 5 packs/carton

### Pyroplates®

CA961	96-well microplate, 1 each
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### Precision Pipette Tips

PPT25	250 µL tips, 96 tips/box, 10 boxes/pack
PPT10	1000 µL tips, 96 tips/box, 8 boxes/pack

### Glucashield® (1→3)-β-D-Glucan Inhibiting Buffer

Glucashield buffer is used to reconstitute LAL and render the reagent insensitive to (1→3)-β-D-Glucan interference by effectively blocking the Factor G pathway of the endotoxin clotting cascade. For use with Pyrotell Multi-Test Vials, Pyrotell-T, Pyrochrome® and Chromo-LAL.

GB051-5	Glucashield Buffer 5.5 mL/vial (5 pack)
GB051-25	Glucashield Buffer 5.5 mL/vial (25 pack)

### Control Standard Endotoxin,

#### Escherichia coli O113:H10

E0005-1	0.5 µg/vial (1 vial)
E0005-5	0.5 µg/vial (5 pack)
E0125-1	125 µg/vial (1 vial)
E0125-5	125 µg/vial (5 pack)
EC010-5	10 ng/vial (5 pack)

**Racks** - All are acrylic test tube racks that fit 8 x 75 mm test tubes

TTR32	PK Flex test tube rack (numbered 1-32)
TTR64	PK Flex test tube rack (numbered 33-64)
TTR96	PK Flex test tube rack (numbered 65-96)

### Warranties, Parts & Services

Extended Warranties - 1 Year Agreement

WPKX32	Pyros Kinetix® Flex 32-well format (on-site calibration included)
WPKX64	Pyros Kinetix® Flex 64 well format (on-site calibration included)
WPKX96	Pyros Kinetix® Flex 96 well format (on-site calibration included)
PEQS-OS	On-site Pyros® EQS service (per day, plus travel expenses)

### Parts

PN002223	PK Flex Serial Cable
PN002224	PK Flex USB
PN002225	Twin PK Flex Serial Cable
PN002226	Twin PK Flex USB
PT008	Lamp for ELX808
ELX540	540 nm Filter, ELx808 microplate reader for diazo endpoint assays

### Calibrations

(performed at ACC Facility)

CAL02	Calibration for Pyros Kinetix
CAL06	Calibration for Pyros Kinetix Flex

### Calibrations

(performed at customer site - continental US)

CAL03	On-site Calibration for Pyros Kinetix
CAL07	On-site Calibration for Pyros Kinetix Flex
CALRU	Rush On-site Calibration

### Validations

(performed at customer site - continental US)

PEQS-VAL	Pyros EQS: On-site Validation for Pyros Kinetix or Pyros Kinetix Flex
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### Private Workshops

WKSP01	On-site One Day LAL Workshop (per workshop, up to 5 attendees)
WKSP02	On-site Two Day LAL Workshop (per workshop, up to 5 attendees)
WKSP03	On-site Three Day LAL Workshop (per workshop, up to 5 attendees)
WSEQ01	Workshop Equipment Rental (per workshop)
WSCT01	Additional Workshop Trainer (per day)

### LAL Consulting

CSOS01	On-site Consulting Services (per day)
SCOS01	On-site Service Call (per day)



ASSOCIATES OF  
**CAPE COD**  
INCORPORATED

*Specialists in Endotoxin and Glucan Detection*

**Corporate Headquarters**

**Associates of Cape Cod, Inc.**

124 Bernard E. Saint Jean Drive  
East Falmouth, MA 02536-4445 USA  
Tel: (888) 395-ACC1(2221) or  
(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)

**United Kingdom**

**Associates of Cape Cod Int'l., 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)

[www.acciuk.co.uk](http://www.acciuk.co.uk)

Company Registration Number:  
BR002906

**Germany**

**Associates of Cape Cod, Inc.**

**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@acciusa.de](mailto:service@acciusa.de)

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

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