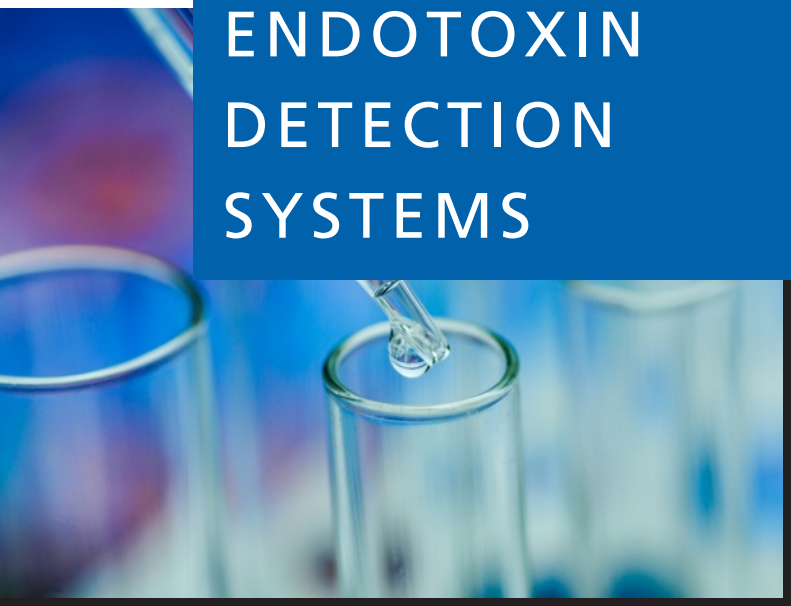
Associates of Cape Cod, Inc.
Your Endotoxin & Glucan Experts

CELEBRATING OUR 45 YEAR ANNIVERSARY

KINETIC ENDOTOXIN DETECTION SYSTEMS







Your Endotoxin Experts!

Associates of Cape Cod, Inc. offers diverse options for conducting endotoxin testing.

MEDICAL DEVICES
ISO 13485:2016
NSAI Certified

KINETIC CHROMOGENIC METHOD REAGENTS

The BET reagent is formulated with a synthetic substrate which produces a chromophore when cleaved by endotoxin activated enzyme. The test is read in a tube reader or an incubating microplate reader.

Pyrochrome® Reagent Chromogenic Endotoxin Testing



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.

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 BET 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).

Performing the Test

The Pyrochrome® sample mixture is incubated in an optical reader at 37±1°C and read at a wavelength of 405 nm. No pre-incubation is required and results can be available within 1 hour. However, 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 (CG1500-5), 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, EC010-5). Certificates of Analysis, specific to the Pyrochrome® and CSE lot, can be obtained from ACC or online at www.acciusa.com.

Pyrochrome® Chromogenic Test Kit

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

Each kit contains Pyrochrome® and a buffer

#C1500-5	Pyrochrome® with Reconstitution Buffer 5 pack (300 tests)
#C1500-25	Pyrochrome® with Reconstitution Buffer 25 pack (1500 tests)
#CG1500-5	Pyrochrome® with Glucashield® Buffer 5 pack (300 tests)
#CG1500-25	Pyrochrome® with Glucashield® Buffer 25 pack (1500 tests)

Chromo-LAL



Chromo-LAL is optimized for the kinetic chromogenic BET test method in microplate readers. Chromo-LAL is a buffered, stable and robust lysate, suitable for quantitative testing of a wide range of samples.

Sensitivity

The sensitivity for chromogenic assays is determined by the lowest standard concentration on the standard curve used for the assay. The maximum sensitivity of Chromo-LAL is 0.005 EU/mL.

Sample to BET Ratio

Reconstituted Chromo-LAL reagent is used at a ratio of 1:1 and a volume of 100 µL/well (30 tests/vial).

Performing the Test

The Chromo-LAL/sample mixture is incubated at 37±1°C and read in a microplate reader. Software is used to construct the standard curve and calculate the endotoxin concentrations.

Reconstitution

Chromo-LAL lysate is reconstituted with BET Reagent Water (LRW). It can also be reconstituted with Glucashield® buffer, a (1→3)-β-D-Glucan inhibiting buffer, to render the assay endotoxin specific.

Stability

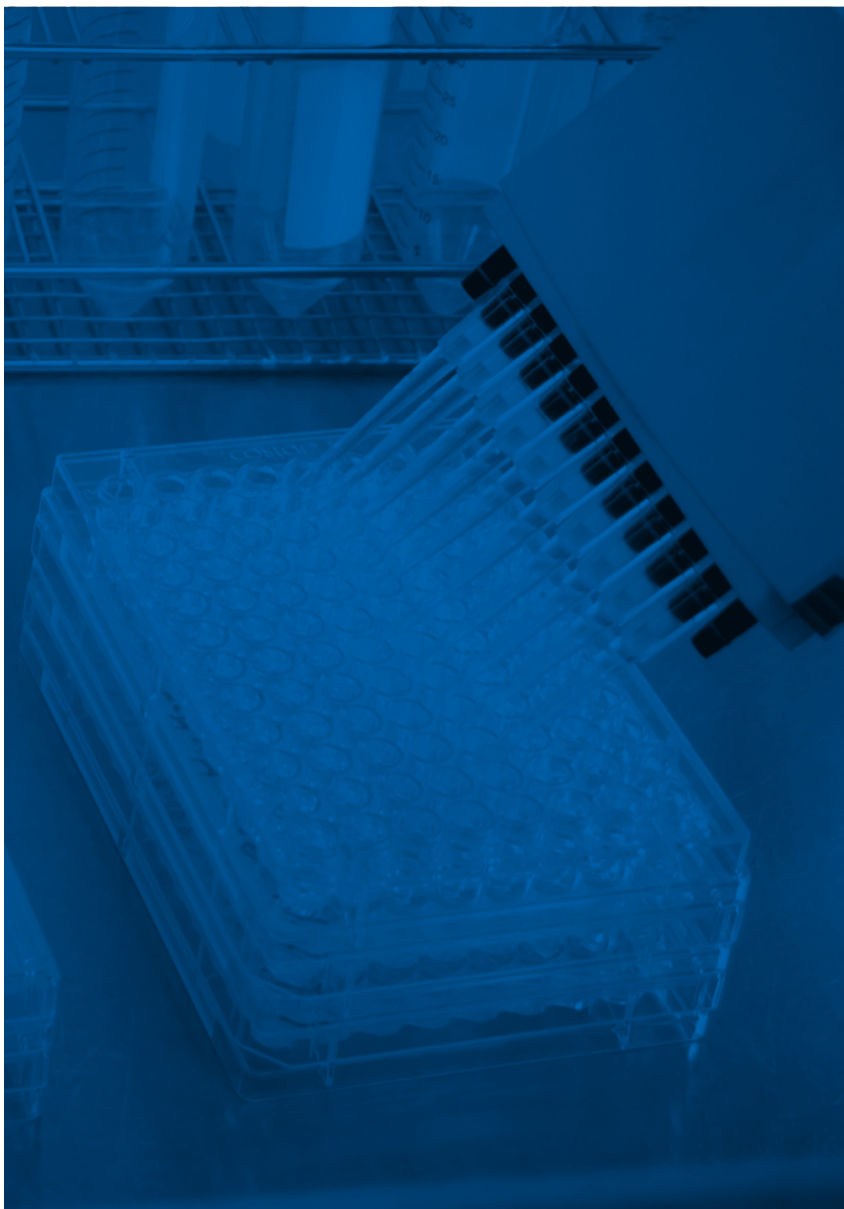
Once reconstituted, Chromo-LAL is stable for 24 hours if stored at 2–8°C. Chromo-LAL may be frozen once and will retain activity for 2 weeks if stored at or below -20°C.

Packaging

Each vial contains reagent for approximately 30 tests. It is recommended for use with 0.5 µg/vial Control Standard Endotoxin (CSE, E0005-1). Certificates of Analysis, specific to the Chromo-LAL and CSE lot, can be obtained from ACC or online at www.acciusa.com.

Chromo-LAL

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



KINETIC TURBIDIMETRIC METHOD REAGENT

The optical density (turbidity) increase that accompanies the clotting reaction is read in the Pyros Kinetix® Flex tube reader or in an incubating microplate reader.

Pyrotell®-T Reagent Turbidimetric Endotoxin Testing



Pyrotell®-T Turbidimetric reagent formulation is a versatile and cost effective solution for the determination of endotoxin. It can be used with the Pyros Kinetix® Flex tube reader and incubating microplate readers. When used with the Pyros Kinetix® Flex tube reader, Pyrotell®-T is a highly economic, flexible and sensitive BET assay.

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

Sensitivity

When used in a Pyros Kinetix® Flex tube reader the maximum sensitivity is 0.001 EU/mL. The unique formulation of Pyrotell®-T allows a wide selection of standard curves to be used, giving the user flexibility, speed and ease in performing assays.

Sample to BET Ratio

The ratio of sample to BET is determined by personal preference and sample chemistry (interference patterns). Reconstituted Pyrotell®-T reagent is used at a sample to lysate ratio of 1:1 or 4:1 and volume of 100 µL/well (48 tests/vial) or 50 µL/well (96 tests/vial), respectively.

Performing the Test

The Pyrotell®-T sample mixture is incubated in an optical reader at 37±1°C and read at a desired wavelength depending on the instrumentation and user choice. The time of incubation is dependent on the lowest standard concentration in the standard curve. Software is used to analyze the standard curve and calculate the endotoxin concentrations.

Reconstitution

Pyrotell®-T may be reconstituted with 5 mL of LAL Reagent Water (LRW), Pyrosol® buffer, or Glucashield® buffer, depending on the demands of the sample being tested. Pyrosol® buffer provides improved kinetics and extra pH buffering capacity. Glucashield® buffer, a (1→3)-β-D-Glucan inhibiting buffer, is used to render the assay endotoxin specific.

Stability

Once reconstituted, Pyrotell®-T is stable for 24 hours, if stored at 2–8°C. Pyrotell®-T may be frozen once and will retain activity for as long as 3 months if stored at or below -20°C.

Packaging

Pyrotell®-T is available in multi-test vials. Each vial contains reagent for approximately 96 tests (when used with the Pyros Kinetix® Flex tube reader and 4:1 sample to BET ratio) or 48 tests (when used with 1:1 ratio and/ or in a microplate reader). It is recommended for use with the 0.5 µg/ vial Control Standard Endotoxin (CSE, E0005-1). Certificates of Analysis, specific to the Pyrotell®-T and CSE lot, can be obtained from ACC or online.

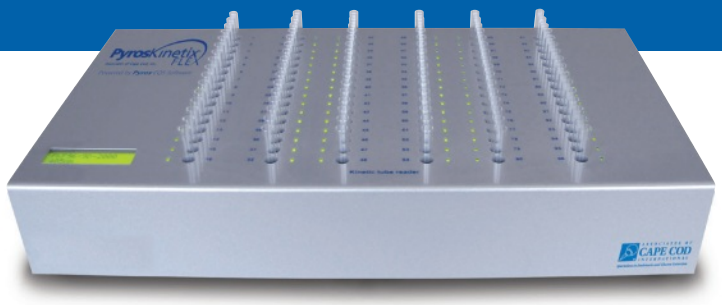
Pyrotell®-T Multi-Test

5 mL/vial (approx. 50 tests/vial)

#T0051-5 5 pack (250 tests)

#T0051-25 25 pack (1250 tests)

PYROS KINETIX® FLEX
CHROMOGENIC AND TURBIDIMETRIC TUBE READER



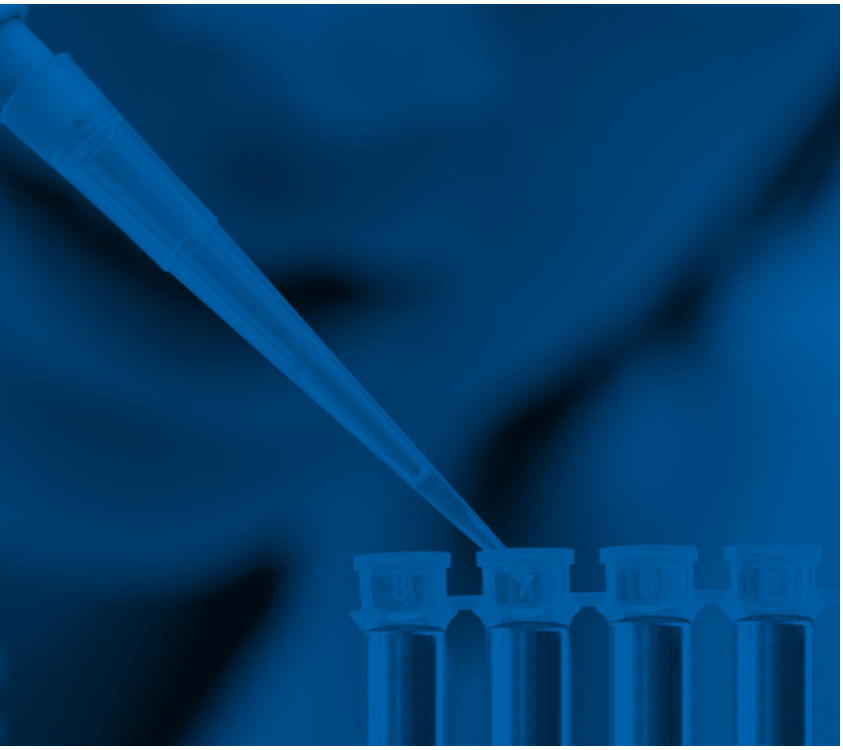
Pyros Kinetix® Flex

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

The Pyros Kinetix® Flex instrument and Pyros® eXpress 21 CFR Part 11 compliant Software provide a complete system for efficient and accurate endotoxin testing.

Features & Benefits

- Capable of running either Chromogenic and Turbidimetric testing in the same instrument
- Broad Sensitivity Range: No other system is more sensitive; As high as 0.001 EU/mL with either our Pyrochrome® chromogenic reagent or our Pyrotell®-T turbidimetric reagent



- Flexible Testing: Variable volumes and ratios can be utilized for increased efficiency, ability to maximize product Maximum Valid Dilution (MVD)
- Reduced Lysate Usage: As little as 50 µL per test
- Increased Efficiency: Unlike plate readers, end-users have the ability to add samples to an existing assay in order to efficiently utilize all wells. Software provides individual sample results while assay continues to run.
- Uses low cost depyrogenated glass disposable accessories.
- Solid State Design: Low instrument maintenance

System Specifications

Capacity: 32, 64 or 96 reaction 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

Precise Temperature Control: Incubator temperature is held to 37°C ± 0.5°C

Two Wavelength Settings (405 nm and 660 nm)

Warranties, Parts and Service

For details on extended warranties, repairs and recalibrations, contact your supplying US, UK, German office or your local representative/distributor.

KINETIC MICROPLATE SYSTEM



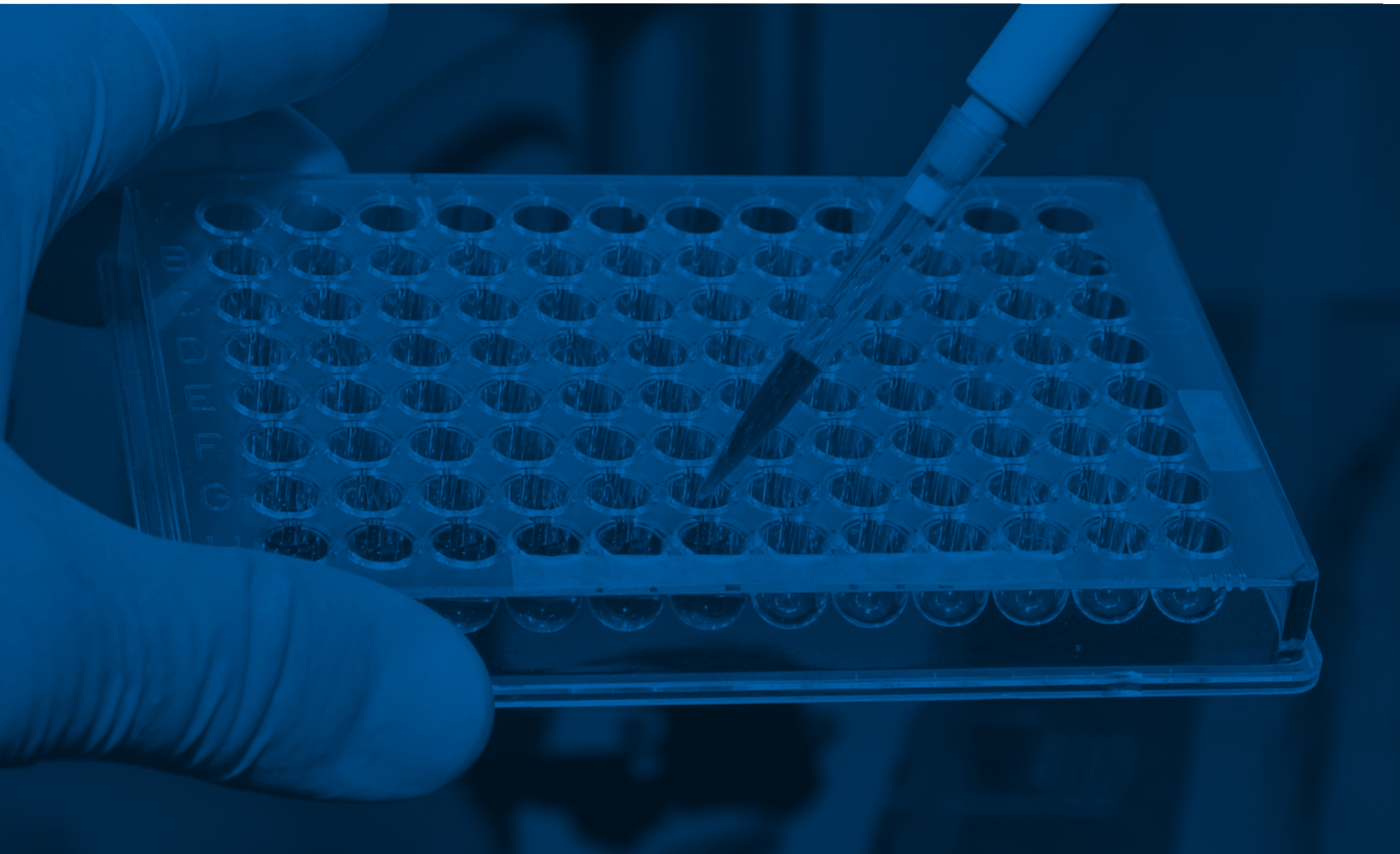
ELx808 IU™ Absorbance 96 Well Microplate Reader*

The BioTek® ELx808 IU™*, manufactured by BioTek® Instruments, is an incubating absorbance microplate reader that, along with our Pyros® eXpress 21 CFR Part 11 compliant Software, provides a complete system for efficient and accurate endotoxin testing. It 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 instrument incorporates a staggered optical design to eliminate channel-to-channel cross talk.

Features of the ELx808 IU™ 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

**Trademark of BioTek Instruments, Inc.*



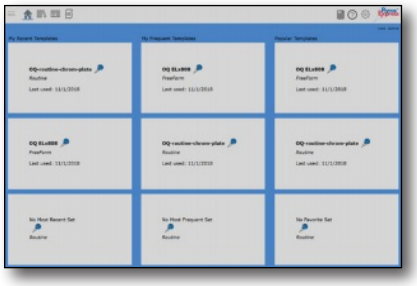
ANALYSIS SOFTWARE

Pyros® eXpress Software



Associates of Cape Cod, Inc. introduces the next generation of endotoxin and glucan detection analysis software that offers integrated solutions for your quantitative endotoxin and glucan detection testing, reporting needs, trending and data management.

Pyros® eXpress Software supports all of the quantitative endotoxin and glucan detection assays from Associates of Cape Cod, Inc., and allows users to quickly and efficiently test in a Quality Control environment. The Pyros® eXpress Software provides greater flexibility and versatility in the laboratory allowing you to work smarter and faster while maintaining regulatory compliance. Pyros® eXpress Software meets 21CFR Part 11 technical requirements for electronic records, signatures, audit trails as well as US and EU data integrity expectations.



Ease Of Use

Custom templates available on the home screen provides quick start options with minimal clicks to assay initiation.

A fully integrated product validation workflow provides guidance for a systematic and compliant testing process.

Custom permission settings help you control your testing environment and reduce laboratory errors:

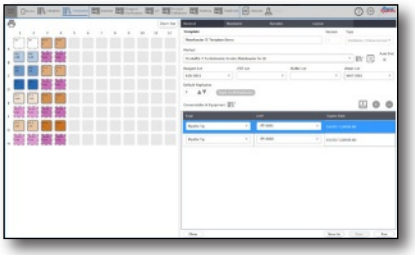
- Lysate/CSE matching to only allow the use of previously qualified reagents
- Optional Technician Qualification Requirements
- Supply/Equipment Expiry Safeguards



Efficiency

Product centric reporting with the Pyros Kinetix® Flex provides real time results for individual samples.

Reagent, Product and Supply Libraries help streamline test setup and reduces time spent on manual entry.



Versatility

Pyros® eXpress supports both plate and tube reader platforms resulting in greater flexibility and laboratory throughput for endotoxin and glucan testing.

KINETIC SYSTEM SUMMARY

Pyrochrome® Test Kit

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

Each kit contains Pyrochrome® and a buffer

#C1500-5	Pyrochrome® with Reconstitution Buffer 5 pack (300 tests)
#C1500-25	Pyrochrome® with Reconstitution Buffer 25 pack (1500 tests)
#CG1500-5	Pyrochrome® with Glucashield® Buffer 5 pack (300 tests)
#CG1500-25	Pyrochrome® with Glucashield® Buffer 25 pack (1500 tests)

Pyrotell®-T Multi-Test

5 mL/vial (approx. 50 tests/vial)

#T0051-5	5 pack (250 tests)
#T0051-25	25 pack (1250 tests)

Control Standard Endotoxin,

Escherichia coli O113:H10

#EC010-5	10 ng/vial (5 pack) for Pyrochrome
#E0005-5	0.5 µg/vial (5 pack) for turbidimetric

Pyros Kinetix® Flex

Incubating Kinetic Tube Reader

#PKF32	Pyros Kinetix® Flex 32-well (includes instrument, Pyros® EQS and validation doc)
#PKF64	Pyros Kinetix® Flex 64-well (includes instrument, Pyros® EQS and validation doc)
#PKF96	Pyros Kinetix® Flex 96-well (includes instrument, Pyros® EQS and validation doc)
#PKF32-PKG	Pyros Kinetix® Flex 32-well (includes instrument, Pyros® eXpress and validation doc)
#PKF64-PKG	Pyros Kinetix® Flex 64-well (includes instrument, Pyros® eXpress and validation doc)
#PKF96-PKG	Pyros Kinetix® Flex 96-well (includes instrument, Pyros® eXpress and validation doc)

Microplate Reader

#PPS04	ELx808 IU™ Incubating Microplate Reader, (software sold separately)
#ELXP	Elx808 IU™ Universal Test Plate
#CALPR	On-site Preventative Maintenance and Performance Verification Service

Pyros® eXpress

Endotoxin and Glucan Analysis Software

#PEXS	Pyros® eXpress Software Package (USB media, 1 Workgroup License[1], 1 Reader License[2] and Software Support[3])
#PEXS-RL[2]	Pyros® eXpress Software Reader License
#PEXS-WL[1]	Pyros® eXpress Software Workgroup License
#PEXS-VAL-DOCS	Pyros® eXpress Software Validation Protocols (Pyros Kinetix® Flex and Biotek ELx808 IU™)
#PEXS-SUP[3]	Pyros® eXpress Software Annual Support (annual support)
#PEXS-ADVS[4]	Pyros® eXpress Software Remote Advanced Support[4]
PEXS-VAL	Pyros® eXpress Software On-site Validation for Pyros Kinetix® Flex and ELx808 IU™
PEXS-OS	On-site Pyros® eXpress Software Support (plus travel expense)

1. Workgroup License: License allows software to be loaded on all computers connected to one Pyros® eXpress network database.
2. Reader License: Allows for one reader/instrument to be connected; standalone or as part of the network database.
3. Software Support can be provided through ACC's Field Service, Technical Services and/or the Software Support Group and is provided for a period of 1 year from time of software purchase. Software support includes upgrades, patches and basic assistance with software setup. This does not include advanced or onsite support, however advanced and onsite support is available through our remote advanced and onsite support service offerings (refer to pricelist for options and pricing). Examples of basic support include, but are not limited to: Assistance setting up products, accessories and templates; running validation and endotoxin tests, trending data; software configuration of the Pyros® eXpress UI; and pre-installation and installation questions covered within the scope as defined in the software manual.
4. Advanced Support includes those support needs that are beyond scope of basic support as described above. It may require a fee for service (including travel costs). Please refer to our price list or speak with your Account Manager or Field Service Support representative for pricing information. Examples of Advanced Support include, but are not limited to: database setup, maintenance and troubleshooting, network, security and firewall troubleshooting, report customization, and import or export setup with external systems such as environmental monitoring systems or laboratory information management systems.

ORDERING INFO AND SALES OFFICES



Ordering Information
Customer service representatives are available to assist you with orders, pricing requests and Certificates of Analysis.

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, and Name (as it appears on the card).

Additional Information
ACC reserves the right to institute, modify or discontinue credit limits provided to customers at any time for any or no reason.

The use of credit cards for payment may incur a fee, please see our website for ACC's policy on credit card usage at www.acciusa.com/pdfs/acctc.pdf

Outside the U.S.
Please contact your local office for information regarding method of payment. For a list of your country specific distributors please visit www.acciusa.com.

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

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All Products and Services listed herein are offered exclusively under Associates of Cape Cod, Inc.'s Terms and Conditions of Sale which can be found at www.acciusa.com/pdfs/acctc.pdf

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INCORPORATED

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