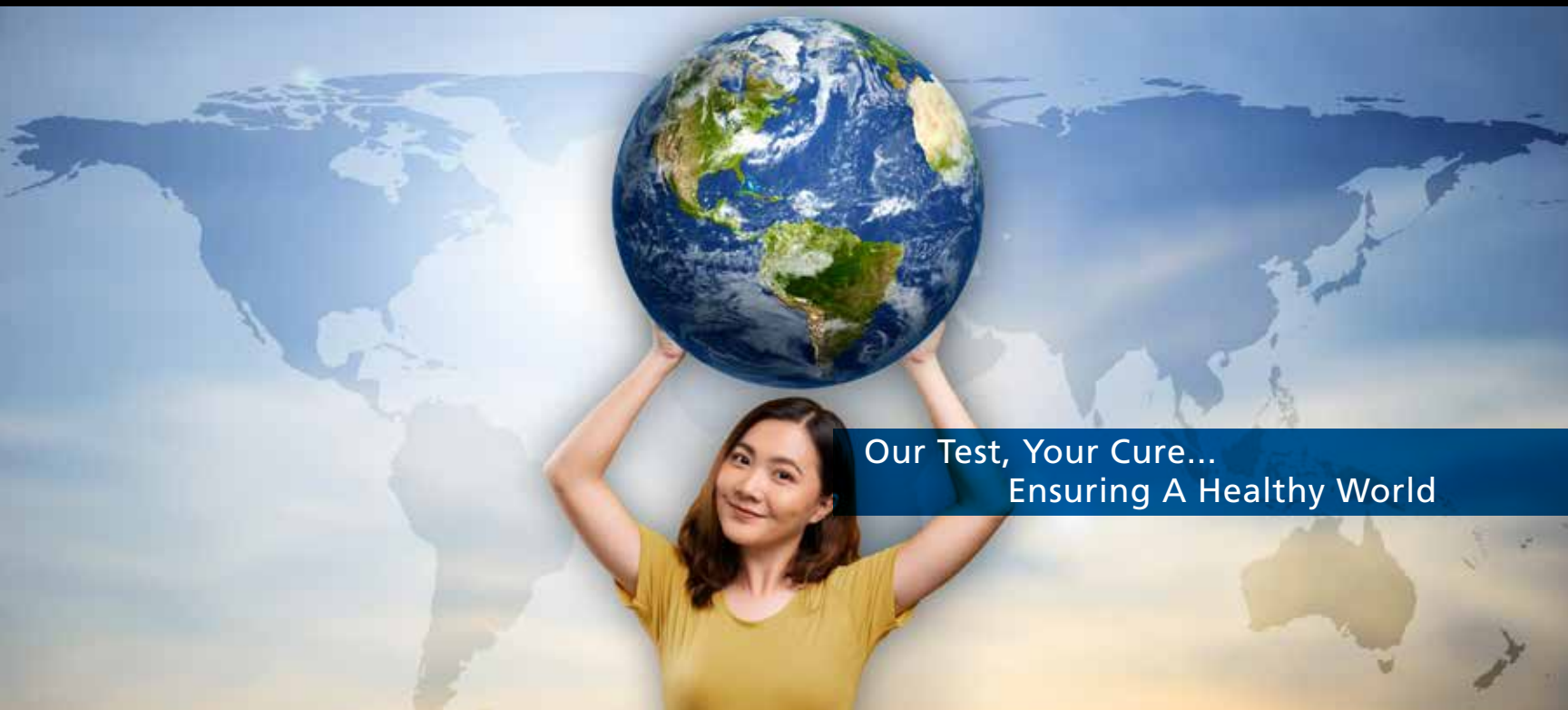




KINETIC ENDOTOXIN DETECTION SYSTEMS



Our Test, Your Cure...
Ensuring A Healthy World

Your Endotoxin Experts!

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

Another First!



*rCR, Brought To You By The BET Pioneers
Associates of Cape Cod, Inc.*



A History Of Firsts!

First To Introduce An Animal Free, Recombinant LAL Reagent

First Large Scale IVF Program To Introduce Horseshoe Crabs Into The Wild

First To Receive FDA License For All Three BET Test Methods

First BET Company Licensed By FDA



KINETIC CHROMOGENIC METHOD RECOMBINANT REAGENT

PyroSmart NextGen® Recombinant Cascade Reagent (rCR)



PyroSmart NextGen® recombinant Cascade Reagent (rCR) marks the introduction of a new sustainable recombinant LAL reagent technology for Bacterial Endotoxin Testing (BET). Utilizing the same LAL cascade as traditional LAL reagents, while eliminating the potential for (1→3)-β-D-Glucans cross reactivity, PyroSmart NextGen® delivers all of the quality and consistency of results you have come to expect from ACC LAL reagents.

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

Product Sensitivity

The sensitivity for recombinant chromogenic assays is determined by the lowest standard concentration on the standard curve used for the assay. The maximum sensitivity of PyroSmart NextGen® is 0.005 EU/mL when run in an incubating microplate reader (or 0.001 EU/mL when run in Pyros Kinetix® Flex tube reader).

Sample to Lysate Ratio

PyroSmart NextGen® is used at with an economical volume of 50 µL of reagent per well yielding 50 tests/vial:

- Microplate reader: 1:1 ratio using 50 µL of test sample : 50 µL of reagent

Test Performance

The PyroSmart NextGen® reaction mixture is incubated at 37±1°C and read in a microplate reader equipped with a 405–410 nm filter. The time of incubation is dependent on the lowest standard concentration in the standard curve, with 0.005 EU/mL achievable in 2500 seconds in a microplate reader. Software is used to construct the standard curve and calculate the endotoxin concentrations.

Product Stability

PyroSmart NextGen® is a lyophilized product with an excellent shelf life of 3 years from the date of manufacture.

Product Reconstitution

PyroSmart NextGen® is provided as co-lyophilized with the chromogenic substrate and as such it is ready-to-use following a simple reconstitution (using 2.8 mL of the supplied reconstitution buffer).

Product Packaging

PyroSmart NextGen® reagent is provided as a pack of 2 vials of reagent and 2 vials of reconstitution buffer. This is sufficient for a total of 110 wells (55 wells per vial).

Multi-Test

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

- #PNG050-2 Each kit contains
- 2 x PyroSmart NextGen® Reagent
 - 2 x Reconstitution Buffer

KINETIC CHROMOGENIC METHOD RECOMBINANT REAGENT

PyroSmart NextGen® is a sustainable recombinant Cascade Reagent (rCR) that delivers the same reliable results as your conventional LAL reagent and offers these additional advantages:

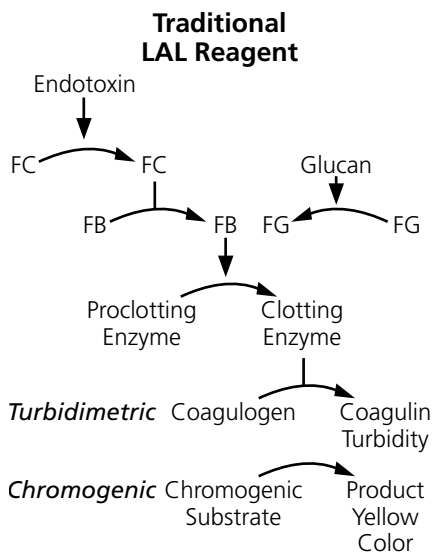
- No Animal Content – Horseshoe Crab Blood Free
- Same Cascade
- No Cross Reactivity With 1,3-b-D-glucans
- Same Instrument
- Same Preparation Steps
- Meets Your Sustainability Objectives

Keep Your Method. Make An Impact.

ACC's PyroSmart NextGen® uses the same cascade as traditional LAL reagents by manufacturing the Factors responsible for the cascade using recombinant processes. As a result, our new recombinant reagent's mechanism of action will deliver results consistent with traditional LAL reagents. It offers the added advantage of eliminating 1,3-b-D-glucans cross reactivity from the LAL cascade, since there is no Factor G in the final reagent.

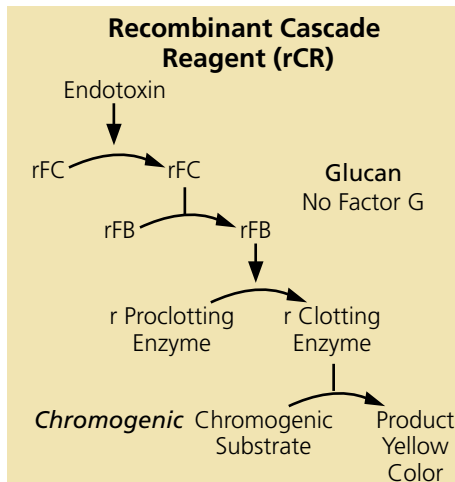
ACC developed PyroSmart NextGen® to provide a sustainable alternative to traditional naturally sourced LAL reagents, while maintaining your lab procedures, methods, instrumentation and most importantly your results.

The Importance of Mechanism of Action Recombinant Cascade Reagent (rCR)



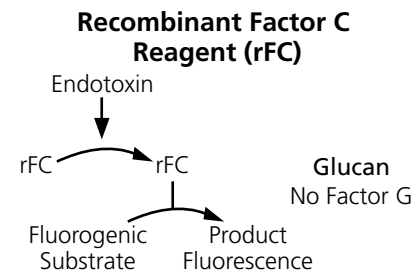
Traditional LAL reagent

In the presence of endotoxin, Factor C becomes an activated moiety which in turn activates Factor B and Proclotting Enzyme; ultimately resulting in the proteolytic cleavage of a substrate (either coagulogen in gel clot and turbidimetric assays or a colorless chromogenic substrate in chromogenic assays). The cascade mechanism thus amplifies the response of Factor C and leads to an exceptional sensitivity for this biological assay, with kinetic output being preferable. In the presence of 1,3-β-D-glucans, Factor G becomes an activated moiety which also activates Proclotting Enzyme and thus resulting in the same signal as that triggered by endotoxins through Factor C. This has been often observed as glucan-derived enhancement or false positive results.



Recombinant Cascade Reagent (rCR)

As with naturally sourced LAL reagents, in the presence of endotoxin, recombinant Factor C becomes an activated moiety which in turn activates recombinant Factor B and recombinant Proclotting Enzyme; ultimately resulting in the proteolytic cleavage of a colorless chromogenic substrate formulated with PyroSmart NextGen®. By relying on the same cascade mechanism, the response of recombinant Factor C is amplified the same way as by LAL reagents and thus the same sensitivity is achieved using this kinetic assay. Due to absence of Factor G, PyroSmart NextGen® will not react with any 1,3-β-D-glucans and therefore will prevent glucan-derived enhancement and false positive results.



Recombinant Factor C (rFC) – Competition

Launched almost two decades ago, rFC reagents rely **only** on a recombinant form of Factor C. Due to the absence of the cascade as the amplification mechanism, rFC reagents are paired with a fluorescence method instead. However, this constitutes a different measured entity, different instrumentation, and different preparation steps with a limited output (endpoint assay only). Therefore the uptake and implementation of this method has been rather limited.

Amplification

The Benefits Are Clear

LAL Reagent Comparison Table	Conventional LAL Reagent	ACC's PyroSmart NextGen® (rCR) Reagent	Competitor (rFC) Reagent
Year Technology Introduced	1977	2021	2003
Kinetic Assay	Kinetic	✓ Kinetic	✗ No. Endpoint only
Assay Setup	Single step reconstitution	✓ Single step reconstitution	✗ No. rFC requires three reagents in a 1:4:5 ratio and a 10 min. pre-incubation step
Same Standard Plate Reader	Incubating plate or tube reader at 405 nm	✓ Yes. Incubating plate or tube reader at 405 nm	✗ No. Fluorescent reader required
Derived From <i>Limulus</i> Amebocyte Lysate (LAL)	LAL	✓ Yes. rCR is recombinant LAL	✗ No. Based on <i>Carcinoscorpius</i> or <i>Tachypleus</i> Amebocyte Lysate (CAL/TAL)
Multi-step Cascade Pathway	Yes	✓ Yes	✗ No
Endotoxin Specific	No	✓ Endotoxin Specific	✓ Endotoxin Specific
Sustainable Reagent (animal free)	No	✓ Horseshoe Crab Blood Free	✓ Horseshoe Crab Blood Free

Converting to PyroSmart NextGen® Is Easy

Switching to this sustainable alternative is easy because PyroSmart NextGen® follows the same cascade pathway as traditional reagents.

But don't take our word for it – evaluate PyroSmart NextGen® yourself on your existing absorbance readers. Follow our user-friendly Evaluation Protocol to determine if PyroSmart NextGen® works in your laboratory and on your samples. Our experts will assist you every step of the way.

Keep Your Method. Make An Impact.

- Same Instrument
- Same Preparation Steps
- Same Method

The future of sustainable LAL testing has arrived with ACC's PyroSmart NextGen® recombinant LAL reagent. The new testing technology that delivers the best of traditional methods, combined with the benefits of sustainable recombinant Cascade Reagents (rCR). The future of LAL testing is bright!



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.

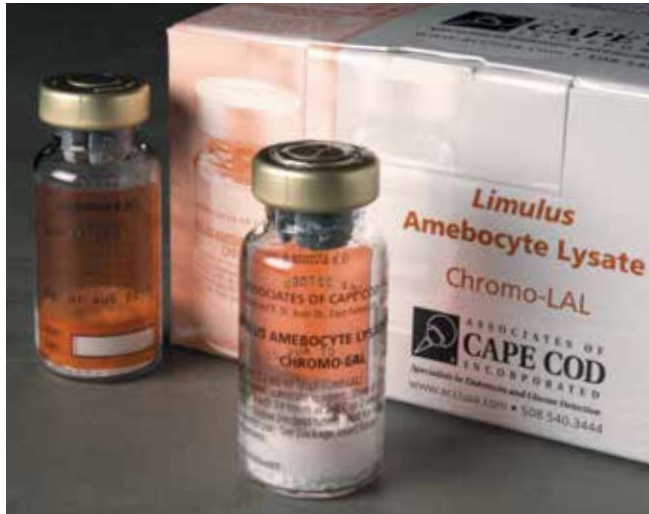
Pyrochrome® Chromogenic Test Kit

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 μ L/well (30 tests/vial).

Performing the Test

The Chromo-LAL/sample mixture is incubated at $37 \pm 1^\circ\text{C}$ 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 Gluca-shield[®] buffer, a (1 \rightarrow 3)- β -D-Glucan inhibiting buffer, to render the assay endotoxin specific.

Stability

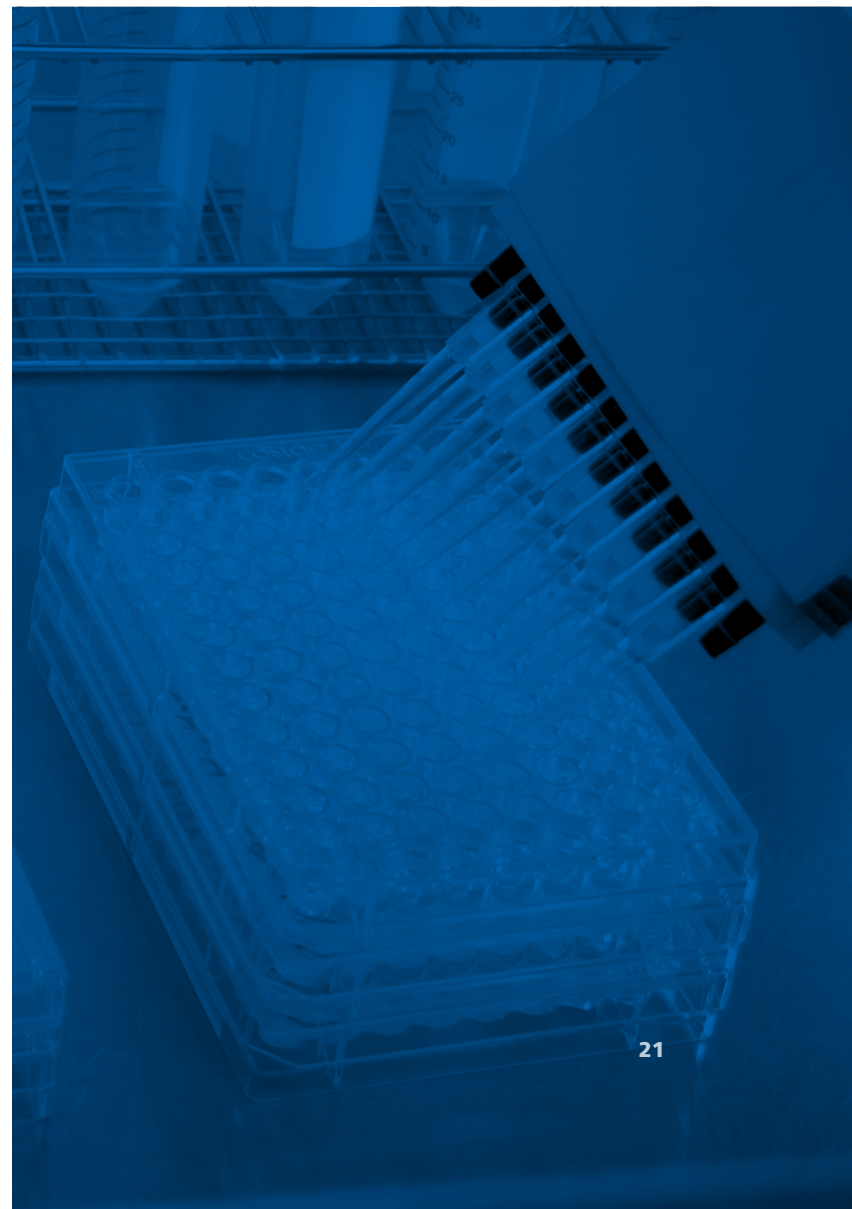
Once reconstituted, Chromo-LAL is stable for 24 hours if stored at 2–8°C. Chromo-LAL may be frozen once and will retain activity for 2 weeks if stored at or below -20°C.

Packaging

Each vial contains reagent for approximately 30 tests. It is recommended for use with 0.5 μ g/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

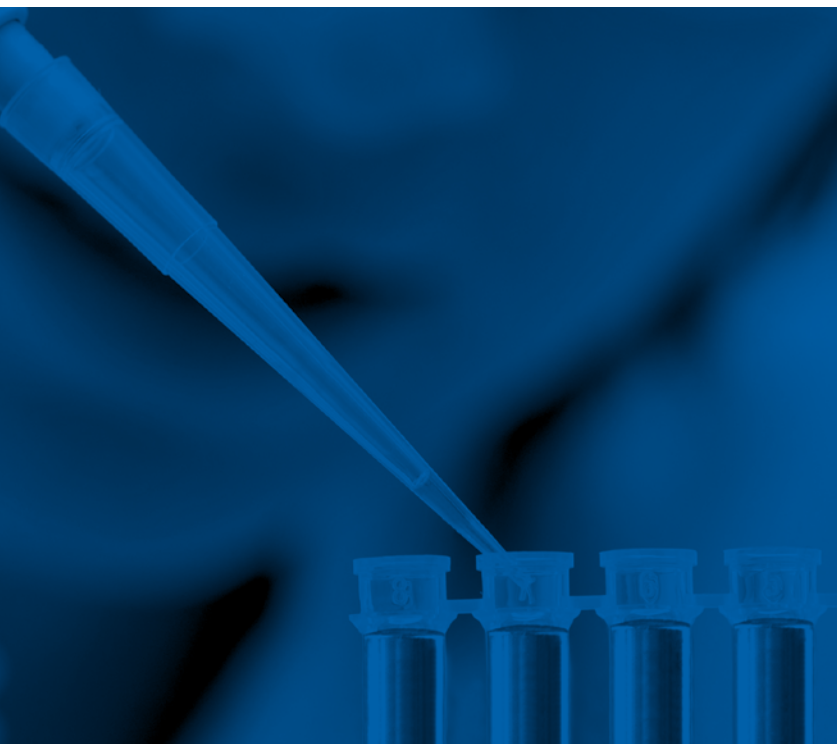
#PKF96 - 9.25" x 18" x 3.125" / 15 lbs 14.5 oz

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

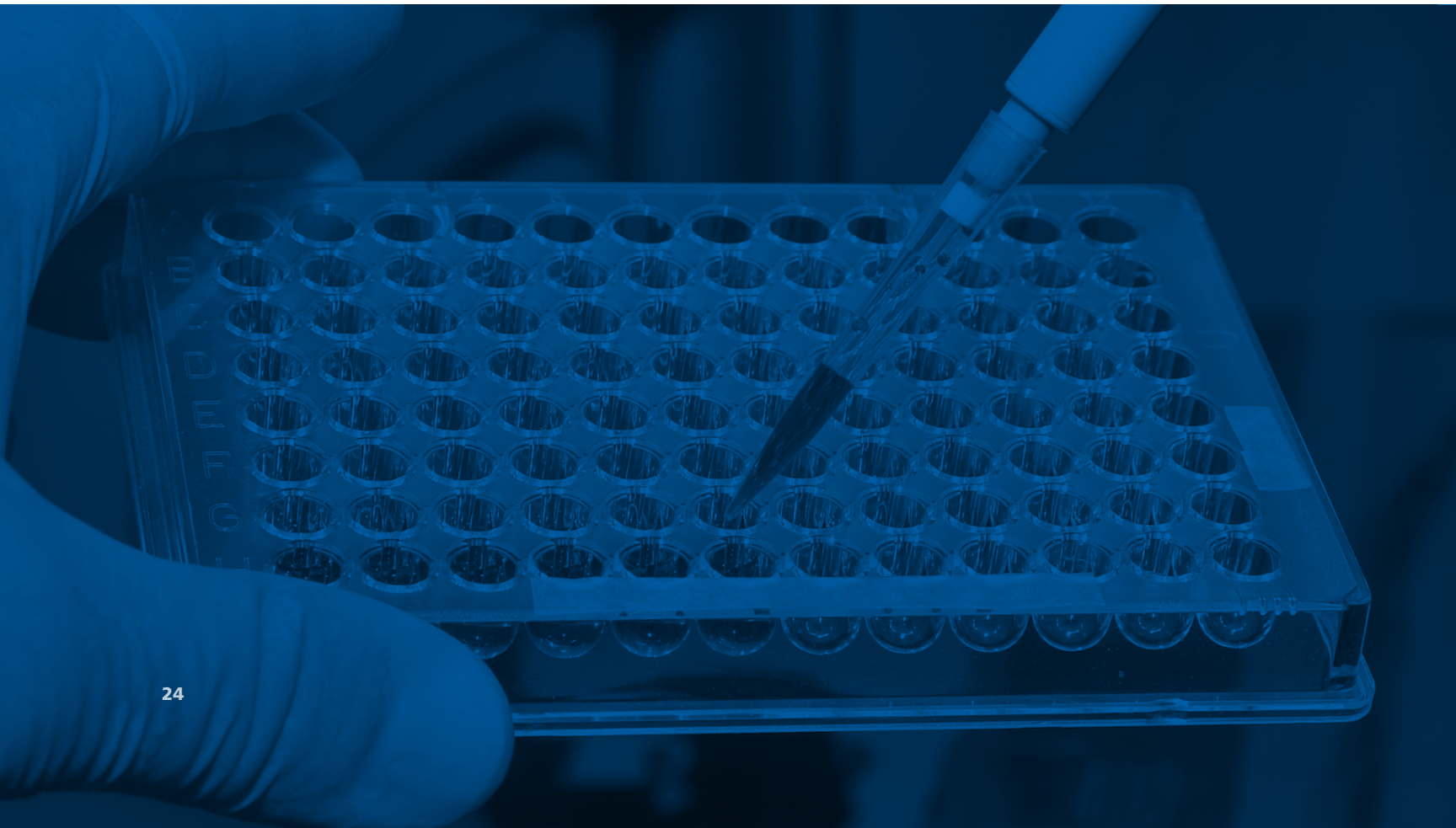
measure in intervals as short as 6 seconds. A 4-Zone™ Temperature Control system and unique heated track/carrier design provide for minimal evaporation and edge effect. The instrument incorporates a staggered optical design to eliminate channel-to-channel cross talk.

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

ACC recommends that customers confirm their expected product support window directly with the instrument manufacturer, Agilent Technologies.

**Trademark of BioTek Instruments, Inc.*



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:

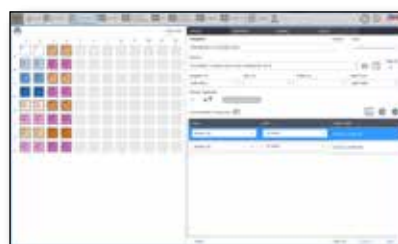
- Lysate/CSE matching to only allow the use of previously qualified reagents
- Optional Technician Qualification Requirements
- Supply/Equipment Expiry Safeguards



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 License¹, 1 Reader
License² and Software Support³)

#PEXS-RL² Pyros® eXpress Software Reader License

#PEXS-WL¹ Pyros® eXpress Software Workgroup
License

#PEXS-VAL-DOCS Pyros® eXpress Software Validation
Protocols (Pyros Kinetix® Flex and
Biotek ELx808 IU™)

#PEXS-SUP³ Pyros® eXpress Software Annual Support
(annual support)

#PEXS-ADVS⁴ Pyros® eXpress Software Remote
Advanced Support⁴

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 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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www.acciusa.de

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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a Seikagaku Group Company