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Products & Services Catalog

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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, 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 see www.acciusa.com.

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

Methodology & Applications

Introduction

Limulus Amebocyte Lysate (LAL) tests detect and quantify bacterial endotoxins derived from the outer wall membrane of gram-negative bacteria. The critical component of the LAL reagents used in endotoxin tests is derived from blood cells (amebocytes) of the horseshoe crab, *Limulus polyphemus*. It contains the proteins of the blood clotting mechanism, which is triggered primarily by endotoxins and also by (1→3)-β-D-Glucan. LAL reagents are primarily used to test for endotoxins in injectable pharmaceuticals, biological products, medical devices and renal dialysis centers. Endotoxin tests are described in the Bacterial Endotoxins Test chapter in the United States Pharmacopeia (Chapter <85>) and in the equivalent chapters in the European Pharmacopoeia (Chapter 2.6.14) and the Japanese Pharmacopoeia (General Tests, No. 4.01). Modified LAL reagents can be used for specific detection of (1→3)-β-D-Glucans.

Testing Methods

There are three principal Bacterial Endotoxins Test methods: the chromogenic, turbidimetric and gel-clot methods. The first two may be grouped together as photometric methods as they require an optical reader.

Chromogenic Method

The LAL 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 microplate reader.

- Requires a Pyros Kinetix Flex tube reader or microplate reader (an incubating reader is required for the kinetic methods)
- Maximum sensitivity to 0.001 EU/mL, highest sensitivity available in the LAL industry when using ACC's Pyrochrome® reagent
- Electronically stored data
- Incubation time varies depending on the standard curve range
- High sensitivity allows for greater dilution to overcome interference
- The option of a diazo-coupled endpoint method (read at 540–550 nm) is available, which is useful for samples that absorb at 405 nm

Turbidimetric Method

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.

- Requires either the Pyros Kinetix® Flex, Pyros Kinetix® tube reader systems or an incubating microplate reader
- Maximum sensitivity to 0.001 EU/mL, highest sensitivity available in the LAL industry when using ACC's Pyrotell®-T reagent
- Electronically stored data
- Incubation time varies depending on the standard curve range
- High sensitivity allows for greater dilution to overcome interference

Gel-clot Method

The formation of a gel-clot indicates the presence of endotoxin in a sample. The method is performed in small test tubes and is read manually by inverting the test tubes.

- Requires non-circulating water bath or dry bath incubator
- Manually read test
- Reagents of differing sensitivity available: 0.25, 0.125, 0.06 and 0.03 EU/mL
- May be less sensitive to interference than other LAL methods
- Is the "referee method" for the great majority of products in the United States, European and Japanese Pharmacopoeia

Selecting a Method

Consider the following when deciding which Bacterial Endotoxins Test method to use:

- What are the regulatory requirements, if any?
- What type of product or sample is to be tested?
- What test sensitivity is required?
(What is the endotoxin limit specification for the sample?)
- Is electronic storage of data desired?

Both chromogenic and turbidimetric methods offer the greatest sensitivity, allowing detection of low endotoxin concentrations and greater dilutions of sample, which is important for overcoming interference. For users with a non-incubating optical reader, an endpoint chromogenic test may be the best choice. As with other photometric methods, the software will store data electronically. The gel-clot method may be the method of choice for opaque samples, suspensions or colored samples, though dilution of the sample may enable use of the photometric methods.

Overview of Testing Procedures

The following section summarizes the procedures/steps to be taken to perform routine product release testing of a sample in a regulated environment. In an unregulated environment, or when testing for informational purposes only, follow the procedures described under Product Characterization.

Qualification of Reagent, Technician and Laboratory

The reagent must be tested to ensure that it is performing to specification, technicians must be qualified to perform the test and the absence of significant day to day or inter-technician variability in the laboratory should be documented. This requires tests using endotoxin standards only, not samples.

Product Characterization

Samples should be characterized for endotoxin contamination and/or potential interference. Characterization is not a regulatory requirement, but is important to develop a test method that can be validated to demonstrate the absence of interference. It is typically performed by testing a series of dilutions of sample without and with a Positive Product Control (PPC), which consists of sample plus a known amount of added endotoxin. The purpose of the PPC is to indicate that added endotoxin is appropriately detected and that the sample does not interfere with the test. From the results of characterization testing, a product dilution (and possibly product treatment) is selected for validation of the test (see below). The endotoxin limit for the product must be detectable at the dilution selected.

Test for Interfering Factors (Validation)

The test for interfering factors is performed to validate the test for the particular sample type. It is accomplished by demonstrating, with three lots of product, that endotoxin added to the sample in PPCs can be readily detected within required limits.

Routine Testing

Routine testing is conducted at the validated dilution and includes a parallel PPC to control for interference. Tests also include negative controls and appropriate standards. A minimum of three units per lot of drug product should be tested, with the samples taken from the beginning, the middle and the end of the production run. For medical devices, aqueous extracts of up to ten units are tested, usually after pooling.

Summary

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 the website. Our Contract Test Service (see page 16) 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 Associates of Cape Cod, Inc.

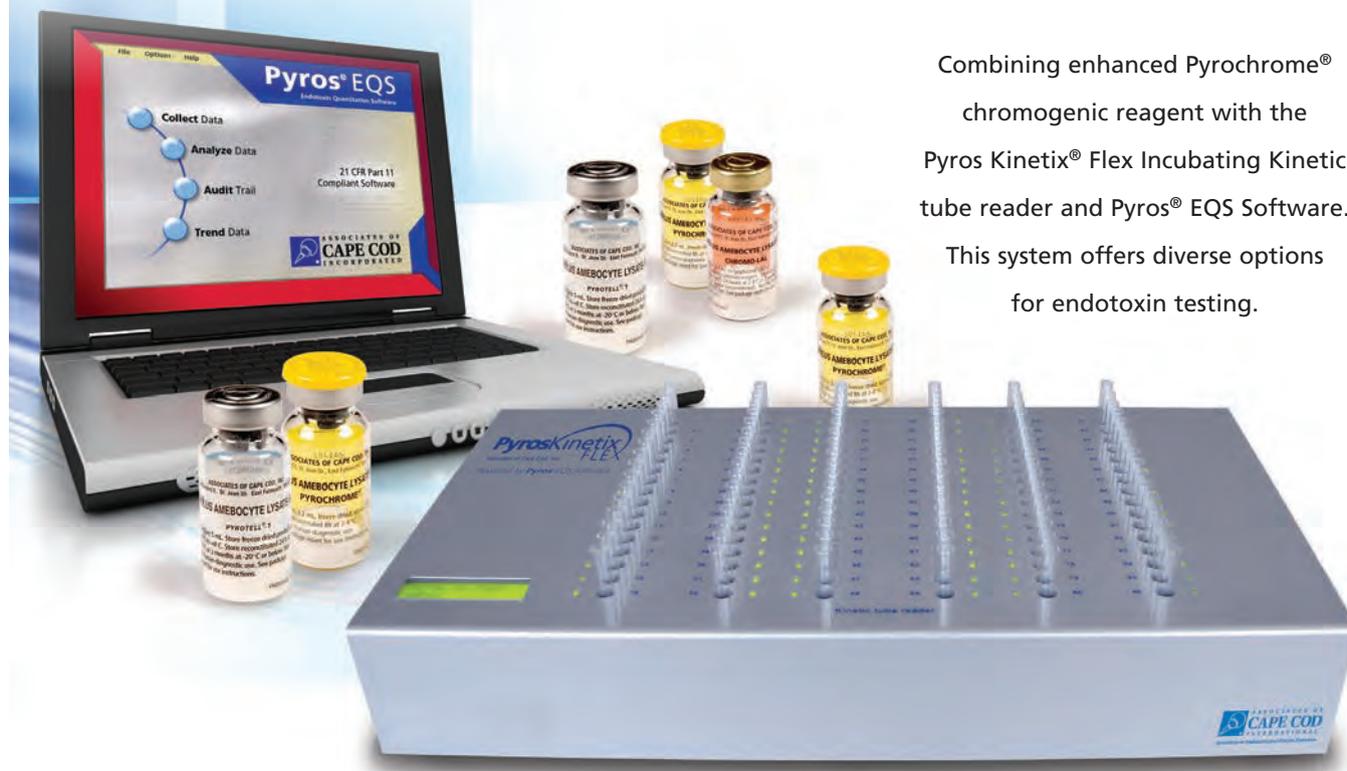
For details on endotoxin testing in the United States (USA), users should consult the current revision of the United States Pharmacopoeia (USP), chapter <85>, "Bacterial Endotoxins Test".

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Chromogenic Endotoxin Detection System



Combining enhanced Pyrochrome® chromogenic reagent with the Pyros Kinetix® Flex Incubating Kinetic tube reader and Pyros® EQS Software. This system offers diverse options for endotoxin testing.

Pyros Kinetix® Flex (Details on page 12) Incubating Kinetic Tube Reader

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

The Pyros Kinetix Flex tube reader is available in three configurations: 32, 64 or 96 eight mm wells. Two 32 well units may be connected to double testing capacity. Each well has a detector that identifies changes in the optical density of a sample. In addition, each well is independently timed, allowing the operator to add more samples while a run is in progress.

Pyros® EQS (Details on page 13) Endotoxin Quantitation Software

Pyros EQS is intuitive, easy-to-use software that is designed specifically for endotoxin testing 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. The software 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 new summarized Pass/Fail Report.

Pyrochrome® (Details on page 4) Kinetic Chromogenic Endotoxin Testing

Pyrochrome is a versatile quantitative reagent that is used to perform 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 chapter. Pyrochrome is offered with either Pyrochrome Buffer or for endotoxin-specific testing, with Glucashield® Buffer. Pyrochrome can be used with the new Pyros Kinetix® Flex tube reader at a 1:1 and an economical 4:1 sample to LAL ratio.

Pyrochrome 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.

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

For more information please visit our website at www.acciusa.com or contact Customer Service at (508) 540-3444.

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Pyrochrome® Kinetic Chromogenic Endotoxin Testing



General Product Description

Pyrochrome is a versatile quantitative reagent that is used to perform kinetic or endpoint assays. It is a sensitive and flexible reagent that can be used for testing in compliance with the USP, EP and JP bacterial endotoxins test chapter. Pyrochrome is offered with either Pyrochrome Buffer or for endotoxin-specific testing, with Glucashield® Buffer. Pyrochrome can be used with the new 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 endotoxin tests, 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 sensitivity for chromogenic assays is determined by the lowest standard concentration on the standard curve used for the assay. 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).

Performing the Test

The Pyrochrome – sample mixture is incubated in an optical reader at 37±1°C and read at wavelengths depending on the instrumentation and user choice. For diazo method, this mixture is read in a microplate reader at 540–550 nm. The time of incubation is dependent on the lowest standard concentration in the standard curve. Software is used to construct the standard curve and calculate the endotoxin concentrations.

Reconstitution

Pyrochrome lysate is reconstituted with an optimized Pyrochrome reconstitution buffer (C1500-5). Pyrochrome can also be reconstituted with Glucashield buffer, a (1→3)-β-D-Glucan inhibiting buffer, to render the assay endotoxin specific (CG1500-5).

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.

Accessory Products

1. LAL Reagent Water, available in multiple package sizes, see page 14
2. Control Standard Endotoxin 10 ng/vial, *E. coli* O113:H10 (EC010-5)
3. Glucashield Buffer, (1→3)-β-D-Glucan Inhibiting Buffer (GB051-5)
4. Pyrotubes® - 13 x 100 mm borosilicate glass dilution tubes (TB013-5)
5. Pyroplate® - 96-well microplate (CA961)
6. 250 µL Pipette tips (PPT25)
7. 1000 µL Pipette tips (PPT10)
8. Pyros Kinetix® Flex tube reader and EQS Software, see pages 12 and 13
9. Pyrotubes®, for use with Pyros Kinetix® Flex (TK100-10)

Pyrochrome®

#C1500-5 ----- 5 pack (300 Test)

#C1500-25 ----- 25 pack (1500 Test)

#CD060 ----- 60 Test
(with Diazo-reagents)

#CG1500-5 ----- 5 pack (300 Test)

#CG1500-25 ----- 25 pack (1500 Test)
(with Glucashield Buffer)

Chromo-LAL

Kinetic Chromogenic Endotoxin Testing

General Product Description

Chromo-LAL is lyophilized with substrate reagent and buffers. It is optimized for the kinetic chromogenic LAL 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 LAL 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

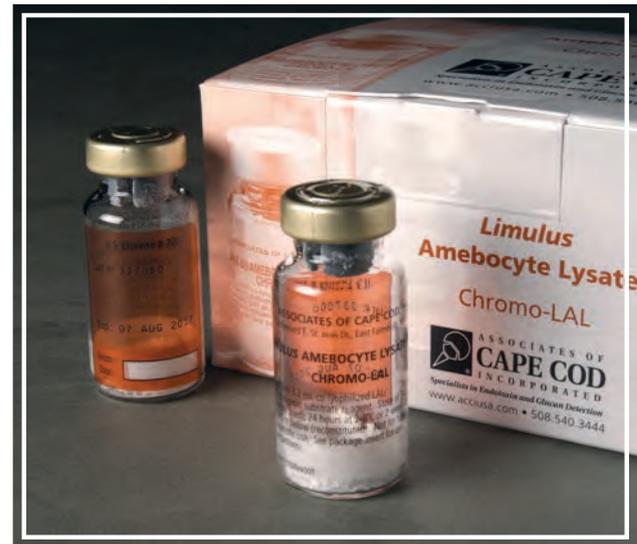
Chromo-LAL lysate is reconstituted with LAL Reagent Water (LRW). It can also be reconstituted with Glucashield® buffer, a (1→3)-β-D-Glucan inhibiting buffer, to render the assay endotoxin specific.

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.



Accessory Products

1. LAL Reagent Water, available in multiple package sizes, see page 14
2. Control Standard Endotoxin, *E. coli* O113:H10, 0.5 µg/vial (E0005-1)
3. Glucashield Buffer, (1→3)-β-D-Glucan Inhibiting Buffer (GB051-5)
4. Pyrotubes®, 13 x 100 mm borosilicate glass dilution tubes (TB013-5)
5. Pyroplate®, 96-well microplate (CA961)
6. 250 µL Pipette tips (PPT25)
7. 1000 µL Pipette tips (PPT10)

Chromo-LAL 3.2 mL/vial (approx. 30 tests/vial)

#C0031-5 ----- 5 pack (150 tests)

For more information please visit our website at www.acciusa.com or contact Customer Service at (508) 540-3444.

Pyrotell®-T Turbidimetric Endotoxin Testing



General Product Description

Pyrotell-T is used to quantify endotoxin in kinetic turbidimetric tests. Pyrotell-T 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 gives a highly economic, flexible and sensitive LAL assay.

It 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.

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 LAL Ratio

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

Performing the Test

The Pyrotell-T sample mixture is incubated in an optical reader at 37±1°C and read at wavelengths 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 construct the standard curve and calculate the endotoxin concentrations.

Reconstitution

Pyrotell-T may be reconstituted with 5 mL of LAL Reagent Water (LRW) (or equivalent), Pyrosol® buffer, or Glucashield® buffer, depending on the demands of the sample being tested. Pyrosol buffer provides 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 LAL 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 at www.acciusa.com.

Accessory Products

1. LAL Reagent Water, available in multiple package sizes, see page 14
2. Control Standard Endotoxin, *E. coli* O113:H10, 0.5 µg/vial (E0005-1)
3. Glucashield Buffer, (1→3)-β-D-Glucan Inhibiting Buffer (GB051-5)
4. Pyrosol LAL Reconstitution Buffer (BC051-5)
5. Pyrotubes®, 8 x 75 mm borosilicate glass test tubes (TK100-10)
6. Pyrotubes, 13 x 100 mm borosilicate dilution tubes (TB013-5)
7. Pyroplate®, 96-well microplate (CA961)
8. 250 µL Pipette tips (PPT25)
9. 1000 µL Pipette tips (PPT10)
10. Pyros Kinetix® Flex tube reader and EQS Software, see pages 12 and 13

Pyrotell®-T Multi-Test 5 mL/vial (approx.50 tests/vial)

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

For more information please visit our website at www.acciusa.com or contact Customer Service at (508) 540-3444.

Pyrotell® Gel-clot Endotoxin Testing



General Product Description

Pyrotell was the first LAL reagent licensed by the US FDA. It is easy to use and is available in both economical Multi-Test Vials (MTVs) and convenient Single Test Vials (STVs). Pyrotell is a robust reagent, producing firm, easily read clots and is resilient to interfering substances. The gel-clot test does not require sophisticated equipment and software and is the simplest LAL test to implement.

Sensitivity

Pyrotell is available in a variety of sensitivities: 0.03 EU/mL; 0.06 EU/mL; 0.125 EU/mL; and 0.25 EU/mL.

Sample to LAL Ratio

Reconstituted Pyrotell reagent is used at a ratio of 1:1 and a volume of 100 µL/test.

Performing the Test

For 2 mL and 5 mL MTV, 100 µL of lysate is mixed with 100 µL of sample in a reaction tube. For STV, 200 µL of sample is added to the vial, which serves as a reaction tube. Test tubes are incubated at 37±1°C for 60 minutes ± 2 minutes. A positive test is indicated if the clot remains solid after the inversion of the test tube.

Reconstitution

Pyrotell MTV may be reconstituted with LAL Reagent Water (LRW), Pyrosol® buffer or Glucashield® buffer, a (1→3)-β-D-Glucan inhibiting buffer, to render the assay endotoxin specific. Pyrotell STV is reconstituted by the sample being tested.

Stability

Once reconstituted, Pyrotell MTV is stable for 24 hours, if stored at 2–8°C. Pyrotell MTV may be frozen once and will retain activity for as long as 3 months if stored at or below -20°C. STVs are used immediately upon addition of the sample.

Packaging

Pyrotell is available in 2 mL or 5 mL MTV and STV sizes. STV's are sold in 5x10 vial packs. Certificates of Analysis, specific to the Pyrotell and CSE lot, can be obtained from ACC or online at www.acciusa.com. It is recommended for use with 0.5 µg/vial Control Standard Endotoxin (E0005-1).

Accessory Products

1. LAL Reagent Water, available in multiple package sizes, see page 14
2. Control Standard Endotoxin, *E. coli* O113:H10, 0.5 µg/vial (E0005-1)
3. Glucashield Buffer, (1→3)-β-D-Glucan Inhibiting Buffer (GB051-5)
4. Pyrosol Buffer with pH indicator (BR051-5)
5. Pyrosol LAL Reconstitution Buffer (BC051-5)
6. Pyrotubes®, 10 x 75 mm soda lime glass test tubes (TS050-10)
7. Pyrotubes, 12 x 75 mm borosilicate dilution tubes (TB240-5)
8. Pyrotubes, 13 x 100 mm borosilicate dilution tubes (TB013-5)
9. 250 µL Pipette tips (PPT25)
10. 1000 µL Pipette tips (PPT10)

Multi-Test Vial (MTV), 5 mL/vial (approx. 50 tests/vial)

#G5003-5	-----	0.03 EU/mL (5 pack)
#G5003-25	-----	0.03 EU/mL (25 pack)
#G5006-5	-----	0.06 EU/mL (5 pack)
#G5006-25	-----	0.06 EU/mL (25 pack)
#G5125-5	-----	0.125 EU/mL (5 pack)
#G5125-25	-----	0.125 EU/mL (25 pack)
#G5250-5	-----	0.25 EU/mL (5 pack)
#G5250-25	-----	0.25 EU/mL (25 pack)
#GP5003-5	-----	0.03 EU/mL vial*
*must be used with Pyrosol and purchased in multiples of 5.		

Multi-Test Vial (MTV), 2 mL/vial (approx. 20 tests/vial)

#G2003-5	-----	0.03 EU/mL (5 pack)
#G2006-5	-----	0.06 EU/mL (5 pack)
#G2125-5	-----	0.125 EU/mL (5 pack)
#G2250-5	-----	0.25 EU/mL (5 pack)

Single Test Vial (STV), 0.2 mL/vial, 5-10 vial packs

#GS003-5	-----	0.03 EU/mL
#GS006-5	-----	0.06 EU/mL
#GS125-5	-----	0.125 EU/mL
#GS250-5	-----	0.25 EU/mL

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PYROSATE®

RAPID ENDOTOXIN DETECTION KIT



NOW FDA Licensed

New Sensitivities Of
0.03, 0.125 and 0.25 EU/mL

Final Product Release

Easy-To-Use Method

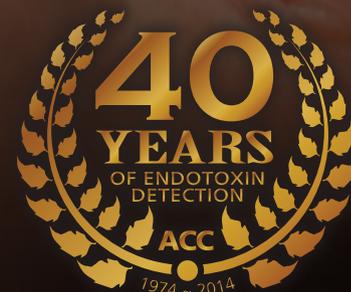
Rapid Test Results

Bacterial Endotoxin Testing
USP Chapter <85> Compliant



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Pyrosate® Kit Rapid Endotoxin Detection



General Product Description

The Pyrosate kit is developed as an easy-to-use LAL gel-clot test. The assay does not require special training or laboratory supplies. The step-by-step illustrated instructions allow the user to perform assays within minutes. The Pyrosate kit provides rapid results and is especially convenient for research, testing water and dialysate.

Sensitivity

The Pyrosate kit is available in sensitivities of 0.25 EU/mL, 0.125 EU/mL and 0.03 EU/mL. The test may be as short as 30 minutes, depending on the sensitivity.

Performing the Test

The Pyrosate kit is a rapid gel-clot test that contains a 2λ* endotoxin tube (PPC) matched to the sample (SPL) tube for each sensitivity. This feature is unique to the Pyrosate assay. The endotoxin tube (PPC) assures that the sample does not interfere with the test, ruling out false negatives. Pyrosate is formulated to eliminate false positives due to (1→3)-β-D-Glucans. This endotoxin specific reagent does not require additional blocking buffers.

Reconstitution

Pyrosate is reconstituted directly with the sample by adding 0.5 mL to the sample tube (SPL). After approximately 60 seconds of gentle mixing, 0.25 mL is transferred to the endotoxin tube (PPC). The lot-specific incubation time at 37±1°C is given on the Certificate of Compliance.

*λ (lambda) is the lowest concentration of endotoxin to cause a positive test result under standard conditions.

Stability

Pyrosate is stable at room temperature and does not require refrigeration for shipping or storage.

Product Applications

- Hemodialysis
- Water and Water Systems
- Filter Industry
- Research
- Final Product

Product Benefits

- Shorter Assay Time
- Endotoxin Specific
- No Dilutions Required
- No Refrigeration Required
- Matched Positive Product Control

Packaging

The Pyrosate kit is available in a 10 test kit and a 30 test bulk package for each sensitivity. Each kit contains sample test tubes (SPL) and endotoxin test tubes (Positive Product Control-PPC). A Certificate of Analysis, specific to the Pyrosate and CSE lot, can be obtained from ACC or online at www.acciusa.com.

Pyrosate® Kits

- #PSD030-10 ----- Pyrosate 0.03 EU/mL 10-Test Kit includes sample test tubes, positive product control test tubes, and disposable pipettes
- #PSD030-30 ----- Pyrosate 0.03 EU/mL 30-Test Bulk Package includes sample test tubes and positive product control test tubes only
- #PSD125-10 ----- Pyrosate 0.125 EU/mL 10-Test Kit includes sample test tubes, positive product control test tubes, and disposable pipettes
- #PSD125-30 ----- Pyrosate 0.125 EU/mL 30-Test Bulk Package includes sample test tubes and positive product control test tubes only
- #PSD250-10 ----- Pyrosate 0.25 EU/mL 10-Test Kit includes sample test tubes, positive product control test tubes, and disposable pipettes
- #PSD250-30 ----- Pyrosate 0.25 EU/mL 30-Test Bulk Package includes sample test tubes and positive product control test tubes only
- #PPT50 - - - - Disposable 50/pack transfer pipettes for Pyrosate kits

Control Standard Endotoxin (CSE)



General Product Description

Control Standard Endotoxin (CSE) is a widely used standard for endotoxin testing. It is a purified extract from *E. coli* O113:H10, the same strain used for the United States Pharmacopeia and the European Pharmacopeia Reference Standard Endotoxin (RSE).

CSE is an economic alternative to the RSE. CSEs are standardized against the RSE as indicated on the Certificate of Analysis, so that results can be reported in Endotoxin Units (EU) and International Units (IU). CSE can be used for all routine LAL testing. A 10 ng/vial CSE is made specifically for use with our Pyrochrome® chromogenic reagent.

Depyrogenation Controls

In addition to their use as standards for controlling LAL tests, the 0.5 µg and 125 µg CSEs can be used for validation of depyrogenation processes. They may be used directly, without reconstitution, as depyrogenation indicators (recommended for 0.5 µg) or can be reconstituted and endotoxin added to challenge articles (recommended for 125 µg).

Performing the Test

CSE is used to make standard curves and controls when performing the LAL assay. The concentrations used are dependent on the type of assay and for photometric methods (chromogenic and turbidimetric), the detection range required.

Reconstitution

CSE is reconstituted with LAL Reagent Water (LRW). Please refer to the Certificate of Analysis when using CSE. A Certificate of Analysis for each CSE-LAL lot combination can be obtained from ACC or online at www.acciusa.com.

Stability

Once reconstituted, CSE stored at 2–8°C is stable for maximum storage time for the different CSE preparations as listed below:

10 ng/vial	-----	7 days
0.5 µg/vial	-----	4 weeks
125 µg/vial	-----	3 months

CSE should not be frozen.

Product Benefits

- CSE is a premium, stable preparation of endotoxin that can be used in all LAL testing
- CSE E0005-1 and E0125-1 can be used for depyrogenation studies
- Certificates of Analysis for each CSE-LAL lot pairing gives a potency that is specific to the unique lot combination
- CSE can be reconstituted to achieve specific endotoxin concentrations

Control Standard Endotoxin, *Escherichia coli* O113:H10

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

For more information please visit our website at www.acciusa.com or contact Customer Service at (508) 540-3444.

GlucateLL® Kit (1→3)-β-D-Glucan Detection

General Product Description

The GlucateLL kit is specific for detection of (1→3)-β-D-Glucan. The assay is based upon a modification of the *Limulus* Amebocyte Lysate (LAL) pathway. GlucateLL reagent is processed to eliminate Factor C, and is therefore specific for (1→3)-β-D-Glucan. The reagent does not react with other polysaccharides, including beta-glucans with different glycosidic linkages. GlucateLL is a chromogenic reagent that may be used to perform either kinetic or endpoint assays in microplate readers.

Sensitivity

The sensitivity for GlucateLL assay is determined by the lowest standard concentration on the standard curve used for the assay. The maximum sensitivity for GlucateLL is 3.125 pg/mL when used with a microplate reader.

Sample to GlucateLL Ratio

Kinetic Assay: Reconstituted GlucateLL reagent is used at a ratio of 1:4 and a volume of 100 µL/well (55 tests/vial).

Endpoint Assay: Reconstituted GlucateLL reagent is used at a ratio of 1:1 and a volume of 50 µL/well (55 tests/vial).

Performing the Test

Kinetic Assay: The GlucateLL/sample mixture is incubated at 37±1°C in a microplate reader. Software is used to construct the standard curve and calculate glucan concentrations.

Endpoint Diazo Assay: The GlucateLL/sample mixture is incubated at 37±1°C in a microplate heating block for the recommended time period. 50 µL each of the three diazo reagents are then added to the mixture. Software is used to construct the standard curve and calculate glucan concentrations.

Reconstitution

GlucateLL reagent can be reconstituted differently depending on the assay you use. For endpoint assays, use 2.8 mL of only Pyrosol reconstitution buffer. For kinetic assays, combine 2.8 mL each of Pyrosol and Reagent Grade Water.

Stability

Store all reagents at 2–8°C in the dark. Once reconstituted, GlucateLL reagent should be stored at 2–8°C and used within 2 hours. Alternatively, reconstituted GlucateLL reagent can be frozen at -20°C for 20 days, thawed once and used. The diazo reagents should be used the day they are prepared.



Product Applications

- Analyzing final products for (1→3)-β-D-Glucan
- Investigating LAL Out of Specification results
- Qualifying raw materials
- Monitoring cellulosic filter extractables
- Monitoring fungal fermentation processes
- Analyzing fermentation and cell culture media
- Monitoring airborne glucan burden

Packaging

The GlucateLL kit is available as either an endpoint or kinetic chromogenic assay for use in microplates. The kit contains the GlucateLL reagent, a (1→3)-β-D-Glucan standard, buffer, glucan-free water, glucan-free microplates and diazo reagents (endpoint kit only).

Accessory Products

1. 250 µL Pipette tips (PPT25)
2. 1000 µL Pipette tips (PPT10)
3. Pyrotubes®, 13 x 100 mm borosilicate glass dilution tubes (TB013-5)

GlucateLL® Kit

#GT002	-----	Kinetic assays; 110 tests
#GT003	-----	-With diazo reagents for endpoint assays; 55 tests
#GT004	-----	Kinetic assays; 55 tests

PyrosKinetix[®] FLEX

Associates of Cape Cod, Inc.

Incubating Kinetic Tube Reader



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

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. In addition, each well is independently timed, allowing the operator to add more samples while a run is in progress.

Pyros Kinetix Flex Features

- Precise Temperature Control—incubator temperature is held to 37°C ± 0.5°C
- Solid State Design—low maintenance
- Two wavelength settings
- Uses Low Cost Depyrogenated Disposables

Advantages

- **Broad Sensitivity Range:** No other system is more sensitive; As high as 0.001 EU/mL with Pyrotell[®]-T or Pyrochrome[®] lysate
- **Increased Efficiency:** The ability for end-users to add samples to an existing run 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
- **Independently timed wells:** Allows for more samples to be added to a continuous run

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Instrumentation & Software

#PKF32 - - - - - 32 well Pyros Kinetix Flex*
Incubating Kinetic Tube Reader

#PKF64 - - - - - 64 well Pyros Kinetix Flex*
Incubating Kinetic Tube Reader

#PKF96 - - - - - 96 well Pyros Kinetix Flex*
Incubating Kinetic Tube Reader

*Each PK Flex system comes with Pyros EQS 21 CFR Part 11 Compliant Software (PEQS11), Pyros EQS Validation Protocol Package (PEQS11-VAL-PKF) and corresponding tube racks.

#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)

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

#TK100-10 - - - Pyrotube[®] 8 x 75 mm borosilicate glass 50 tube/pack

System Specifications

Capacity - - - - - 32, 64 or 96 reaction test tubes

Power Requirement - - - - - 100 to 240 VAC @ 50 / 60 Hz
(requires 2 Amp 5 x 20 mm fuse – spare fuse supplied)

Light Source - - - - - LED

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

& Weight 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.

Extended Warranty

#WPKX32 - - - - - Pyros Kinetix[®] Flex 32 well format

#WPKX32-D - - - - - Pyros Kinetix[®] Flex 32 well format (distributor)

#WPKX64 - - - - - Pyros Kinetix[®] Flex 64 well format

#WPKX64-D - - - - - Pyros Kinetix[®] Flex 64 well format (distributor)

#WPKX96 - - - - - Pyros Kinetix[®] Flex 96 well format

#WPKX96-D - - - - - Pyros Kinetix[®] Flex 96 well format (distributor)

Service and Calibration

#CAL04 - - - - - On-Site MicroPlate Reader Calibration

#CAL06 - - - - - Pyros Kinetix Flex Calibration at ACC facility

#CAL07 - - - - - On-Site Pyros Kinetix Flex Calibration

#CALRU - - - - - Rush On-Site Calibration

Pyros® EQS Endotoxin Quantitation Software



Pyros EQS is intuitive, easy-to-use software that is designed specifically for endotoxin testing 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. The software 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 new summarized Pass/Fail Report. Pyros EQS is LIMS compatible through multiple export options.

Software Validation Protocols

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.

Pyros EQS Software

- #PEQS11 - - - - - Pyros EQS Software with Manual (21 CFR Part 11 Compliant)
- #PEQS - - - - - Pyros EQS Software with Manual (without part 11 compliance features)
- #PEQS11-VAL-PKF - - - - - Pyros EQS Validation Protocol Pkg. (for Pyros Kinetix Flex)
- #PEQS-OS - - - - - On-site Pyros EQS service

*Cost for Pyros EQS software includes first year annual Oracle license fee.

For more information please visit our website at www.acciusa.com or contact Customer Service at (508) 540-3444.

Incubating Microplate Readers



ACC's versatile quantitative reagents work with incubating microplate readers, and can be used to achieve maximum sensitivity in endotoxin and glucan detection using kinetic chromogenic or kinetic turbidimetric methods. The limit of detection is dependent on the protocol and reagent employed.

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 Associates of Cape Cod's endotoxin specific assay protocols.

Software Validation Protocols

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 protocol files in Microsoft® Word format allows users to edit the documents to meet their company's specific validation requirements.

- #Gen5 - - - - - Gen5 Secure Software. Compliant, Microplate Software; Data collection and analysis.
- #5320500 - - Gen5 Installation Qualification Pkg. Packages include thorough procedures to allow a user to perform installation.

†Trademark of Bio-Tek Instruments, Inc.

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Disposable Products

Pyroclear®

Pyroclear brand products are the first disposables in the industry that are certified to be free of interfering endotoxin and (1→3)-β-D-Glucan contamination. Pyroclear products include depyrogenated test tubes, 96-well microplates, pipette tips and LAL Reagent water. These products are designed to reduce Out of Specification (OOS) investigations due to contaminated consumables.



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 ----- 100 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
- #TS050-10 --- 10 x 75 mm soda lime glass for gel-clot method
50 tubes/pack, 10 packs/carton
- #TB050-5 --- 10 x 75 mm borosilicate glass for turbidimetric method
50 tubes/pack, 5 packs/carton
- #TB240-5 --- 12 x 75 mm borosilicate glass (for dilutions only)
40 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

Precision Pipette Tips

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

Reconstitution Buffers

Pyrosol® LAL Reconstitution Buffer

Pyrosol is an FDA licensed buffer for reconstituting Pyrotell® Multi-Test Vial or Pyrotell®-T reagents. It is used for testing electrolytes, strongly buffered solutions (especially bicarbonate buffers), and solutions for which it is difficult to adjust pH into the required range. Pyrosol buffer is also available with a pH indicator for gel-clot applications.

- #BR051-5 --- Pyrosol Buffer with pH indicator (gel-clot method only)
5.5 mL/vial (5 pack)
- #BR051-25 --- Pyrosol Buffer with pH indicator (gel-clot method only)
5.5 mL/vial (25 pack)
- #BC051-5 ----- Pyrosol Buffer without pH indicator
5.5 mL/vial (5 pack)
- #BC051-25 ----- Pyrosol Buffer without pH indicator
5.5 mL/vial (25 pack)
- #BC554-1 ----- Pyrosol Buffer without pH indicator
55 mL/vial

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)





Introduction

Associates of Cape Cod,® Inc. Contract Test Service (CTS) laboratory specializes in testing for endotoxin and glucan contamination and has the most extensive experience of any endotoxin testing laboratory in the world. CTS performs all methods of the LAL assay: gel-clot, chromogenic, and turbidimetric.

CTS is GMP compliant and ISO registered. CTS is licensed by the DEA as a laboratory capable of handling all controlled drug substances except those included in Schedule I. Endotoxin testing can be performed in accordance with FDA, USP, EP and/or JP, depending on the specifications of the client.

In addition to routine testing, CTS has extensive expertise and the ability to:

- Customize endotoxin testing to individual client needs
- Troubleshoot difficult samples
- Develop and/or transfer LAL test methods
- Design and produce custom depyrogenation controls for oven validations
- Perform Low Endotoxin Recovery (LER) studies/protocols

Examples of samples with which CTS has experience:

- Pharmaceutical Drugs, including Class II controlled substances, compounded pharmaceuticals and anti-cancer drugs
- Medical Devices
- Dialysate
- Water
- Air Quality Samples
- Filters
- Veterinary Products
- Cosmetics
- Food Products
- Vaccines
- Tobacco Products
- Machine Oils
- Raw Materials

CTS offers fast processing for routine samples, accurate and reliable test results along with full confidentiality. After sample test results are reviewed, a written report is sent to the client. The client also receives an electronic copy of the report as a PDF.

CTS Qualifications

- GMP Compliant Laboratory
- ISO 13485:2003 Registered
- FDA Inspected
- DEA Licensed

Test Methods

- **Chromogenic** - Color formation is used to quantitate endotoxin (maximum sensitivity 0.001 EU/mL) and glucans
- **Turbidimetric** - The most sensitive turbidimetric endotoxin test available in the industry (maximum sensitivity 0.001 EU/mL)
- **Gel-clot** - The original LAL assay and the method of reference in most reference manuals (maximum sensitivity 0.03 EU/mL)
- **GlucateLL** - Glucan testing to quantitate the amount of (1→3)-β-D-Glucans in samples.

Test Types

- **Characterization Test** - This test is used to quantify the amount of endotoxin or glucan present in a test sample. A series of dilutions are made in order to find a valid testing dilution which can be used to calculate the endotoxin or glucan concentration of a sample.
- **Validation (USP/EP test for interfering factors)** - This test is used to demonstrate that the product does not interfere with the LAL assay. This test is performed at a dilution not exceeding the Maximum Valid Dilution (MVD) for that product. The MVD is a function of the endotoxin limit for the product. Validation is required for all finished products that are parenteral or intrathecal and for non-pyrogenic medical devices. The test method should be validated using three lots of the finished product before the Release Test is used to release product. The procedure is also used to demonstrate that the assay is valid when used to test raw or in-process materials.
- **Release Test** - This test is used to release finished products once the assay has been validated. The test is run at the same dilution used in the Validation. The Release Test is also used to release raw materials, in-process materials, and other non-finished goods.

Drug & Medical Device Testing

Product Testing

Testing for endotoxin is performed at many steps in the manufacture of drugs and medical devices. Endotoxin testing is required for the release of finished product (see Validation of End Product Tests and Release Testing). Testing for endotoxins is also frequently performed to assess raw materials, in-process materials, vendors, as well as for projects and components in research and development. Endotoxin testing is often a component of investigations into product quality issues.

CTS works with clients to perform testing rapidly and assists customer quality departments in identifying endotoxin sources, and troubleshooting product and production issues. CTS can help with integrating endotoxin testing into the quality system at the client's facility.

Raw Materials Testing

Raw materials can be tested as part of a traditional QC program or Process Analytical Technology (PAT). Identifying the amount of endotoxin in raw materials helps highlight process modifications that can improve the final product. Matching results from raw materials and final product can yield the contribution of each raw material to the endotoxin content of the final product and facilitate improvements in quality during production. Some raw materials should have endotoxin limits established and confirmed to determine if a batch can be accepted from a vendor.

Validation of End-Product Tests

Production lots of the final product should be subject to validation (test for interfering factors) before the test may be used to release final product. The validation assay is also used in QC programs to accept raw materials into production. Validation testing can be performed in accordance with USP, EP, and/or JP, depending on the specifications of the client.

Release Testing

The Release Test is performed according to a validated method and is used to release finished product. The test can also be performed for release of raw/in-process materials. Release testing can be performed in accordance with USP, EP, and/or JP, depending on the specifications of the client.

Sending Samples

A Sample Submission form must be completed and accompany each sample sent for testing. Sample Submission forms can be obtained from our website at www.acciusa.com/cts or by calling CTS (U.S. office (888) 232-5889 or U.K. office (44) 151-547-7444).

Custom Services

CTS offers a variety of services that are customized to meet each client's individual requirements.

Method Development

Some samples or devices interfere with the BET tests and a method must be developed in order to be able to perform a valid test for endotoxin. CTS will determine how best to prepare the sample for testing. We can also perform testing to validate any sample, pre-treatment, and the test method.

Method Transfer

Many companies have sufficient testing volume to justify performing the assay in-house. For these customers, Associates of Cape Cod, Inc. supplies a complete line of the highest quality LAL reagents. CTS supports this line by working with companies to develop and optimize methods to test their products. CTS also helps customers convert from one methodology to another, e.g., from testing by the gel-clot method to chromogenic or turbidimetric assays. The methods developed by CTS are then transferred to the client for use by their own QC laboratories. Your company gets the assurance that the method will work well with your products.

Custom Depyrogenation Controls

CTS will make custom depyrogenation controls using the same items normally processed in your oven and provide a Certificate of Analysis for the articles. The controls are then used to demonstrate at least a three-log reduction by your oven cycle. CTS can also test items post-depyrogenation to verify your oven cycle performance.



Contact Information

U.S. Office

Contract Test Service at Associates of Cape Cod, Inc.
124 Bernard E. Saint Jean Drive
East Falmouth, MA 02536-4445

Tel: (888) 232-5889 or (508) 540-3444

Fax: (508) 540-2019

E-mail: testservice@acciusa.com

Hours of Operation

Monday through Friday, 8:00 a.m. to 5:00 p.m. EST

U.K. Office

Our UK office also operates a Contract Test Service laboratory for endotoxin and glucan testing. For information on services provided and laboratory qualifications please contact the UK office directly at (44) 151-547-7444 or by email at info@acciuk.co.uk

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Fax: (44) 151-547-7400

E-mail: info@acciuk.co.uk

Hours of Operation

Monday through Friday, 9:00 a.m. to 5:00 p.m. GMT

Services Offered

Characterization Test

Gel Clot Method

Initial Test (a series of dilutions) -----	GSAM
Rush test-48 hour study initiation -----	GSAM-R
STAT test-24 hour study initiation -----	GSAM-S
Endotoxin-specific gel test -----	ESGEL
Rush test-48 hour study initiation -----	ESGEL-R
STAT test-24 hour study initiation -----	ESGEL-S
Repeat tests, as needed -----	GREP
Rush test-48 hour study initiation -----	GREP-R
STAT test-24 hour study initiation -----	GREP-S

Turbidimetric Method

Initial Test (a series of dilutions) -----	TSAM
Rush test-48 hour study initiation -----	TSAM-R
STAT test-24 hour study initiation -----	TSAM-S
Endotoxin-specific turbidimetric test -----	ESTURB
Rush test-48 hour study initiation -----	ESTURB-R
STAT test-24 hour study initiation -----	ESTURB-S
Repeat tests, as needed -----	TREP
Rush test-48 hour study initiation -----	TREP-R
STAT test-24 hour study initiation -----	TREP-S

Chromogenic Method

Initial Test (a series of dilutions) -----	CSAM
Rush test-48 hour study initiation -----	CSAM-R
STAT test-24 hour study initiation -----	CSAM-S
Endotoxin-specific chromogenic test -----	ESCHRM
Rush test-48 hour study initiation -----	ESCHRM-R
STAT test-24 hour study initiation -----	ESCHRM-S
Repeat tests, as needed -----	CREP
Rush test-48 hour study initiation -----	CREP-R
STAT test-24 hour study initiation -----	CREP-S

GlucateLL® Method

GlucateLL® (1→3)-β-D-glucan specific test -----	GLUC (research use only)
Rush test-48 hour study initiation -----	GLUC-R
STAT test-24 hour study initiation -----	GLUC-S
GlucateLL re-tests, as needed -----	GLUR
Rush test-48 hour study initiation -----	GLUR-R
STAT test-24 hour study initiation -----	GLUR-S

Validation (USP/EP Test for Interfering Factors)

Characterization of samples must be done prior to validation testing

Gel-clot method	-----	GVAL
Rush test-48 hour study initiation	-----	GVAL-R
STAT test-24 hour study initiation	-----	GVAL-S
Turbidimetric method	-----	TVAL
Rush test-48 hour study initiation	-----	TVAL-R
STAT test-24 hour study initiation	-----	TVAL-S
Chromogenic method	-----	CVAL
Rush test-48 hour study initiation	-----	CVAL-R
STAT test-24 hour study initiation	-----	CVAL-S
Endotoxin-specific gel-clot method	-----	EGVAL
Rush test-48 hour study initiation	-----	EGVAL-R
STAT test-24 hour study initiation	-----	EGVAL-S
Endotoxin-specific turbidimetric method	-----	ETVAL
Rush test-48 hour study initiation	-----	ETVAL-R
STAT test-24 hour study initiation	-----	ETVAL-S
Endotoxin-specific chromogenic method	-----	ECVAL
Rush test-48 hour study initiation	-----	ECVAL-R
STAT test-24 hour study initiation	-----	ECVAL-S

Release Testing

Product must first pass the Test for Interfering Factors.

Gel-clot method	-----	GREL
Rush test - 48 hour study initiation	-----	GREL-R
STAT test - 24 hour study initiation	-----	GREL-S
Turbidimetric method	-----	TREL
Rush test - 48 hour study initiation	-----	TREL-R
STAT test - 24 hour study initiation	-----	TREL-S
Chromogenic method	-----	CREL
Rush test - 48 hour study initiation	-----	CREL-R
STAT test - 24 hour study initiation	-----	CREL-S
Endotoxin-specific gel-clot method	-----	EGREL
Rush test - 48 hour study initiation	-----	EGREL-R
STAT test - 24 hour study initiation	-----	EGREL-S
Endotoxin-specific turbidimetric method	-----	ETREL
Rush test - 48 hour study initiation	-----	ETREL-R
STAT test - 24 hour study initiation	-----	ETREL-S
Endotoxin-specific chromogenic method	-----	ECREL
Rush test - 48 hour study initiation	-----	ECREL-R
STAT test - 24 hour study initiation	-----	ECREL-S

Custom Services

Oven depyrogenation validation	-----	COVN
Methods transfer (in-lab technician training)	-----	CMTN
Technician qualification (in-lab, one-on-one training)	----	CTQN
SOP writing of developed method	-----	CSOP

Additional Services

Special shipping (samples sent to alternate location)	---	RTRND
Additional sample prep/extraction/ unusual treatment or handling	-----	PREP
Rush test - 48 hour study initiation	-----	PREP-R
STAT test - 24 hour study initiation	-----	PREP-S



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Bacterial Endotoxin Testing

Support Services

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 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 to discuss their issues.

On-Site Consulting Services

ACC staff are available to visit client sites to assist investigations and trouble-shooting. These visits often address Bacterial Endotoxin Testing (BET) procedures, in addition to identifying sources of contamination in test laboratories and manufacturing processes.

#CSOS01 ----- Please call for quotation

Endotoxin Testing Workshop

Associates of Cape Cod offers training courses on all aspects of endotoxin testing. Courses are conducted at our facility in East Falmouth, MA and other locations worldwide.

We offer a comprehensive workshop that covers methodology, background and in-depth courses, as well as hands-on laboratory experience.

Methodology Background

This course is designed to introduce BET methodologies to technicians and managers who are new to endotoxin testing. Topics include:

- Endotoxins—What they are, where they come from, and why they are important
- LAL—An overview of the LAL/endotoxin reaction, with emphasis on sources of interference
- Detailed instruction of the test methods, including a discussion of laboratory set-up, materials, and aseptic techniques
- Sample handling and preparation
- Practical approaches to sample characterization and overcoming interference
- Technician and laboratory certification and validation of the BET

Hands-On Laboratory

The laboratory courses for photometric and gel-clot methods are designed to give the attendee hands-on experience conducting endotoxin tests. Participants perform tests and learn to read and interpret results. Familiarity with general laboratory techniques (especially pipetting) is essential.



In-Depth Topics

This course provides the experienced technician with a more detailed understanding of how a BET program can be applied to quality control. Topics include:

- Techniques for testing non-aqueous or highly interfering substances
- (1→3)-β-D-Glucan: contamination, recognition and investigation
- Medical device sample preparation and validation of extraction protocols
- Regulatory considerations

Customized Workshop

ACC can customize a 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 Thechnical Service at (508) 540-3444 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

#WKSP03 ----- 3 Day Workshop up to 5 Attendees

Course Schedule and Fees

For course dates and fees, please check our website at www.acciusa.com. The Endotoxin Testing Workshop schedule can be accessed from the LAL Products section or from the Calendar section of the ACC website. To receive additional information, our annual course schedule, or to register for a course, contact the appropriate office below.

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United Kingdom: Tel: (44) 151-547-7444 • info@acciu.co.uk

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BEST QC Microbiology Training

Bioburden, Endotoxin, Sterility Testing

Innovative educational programs designed specifically for you.

BEST programs focus on three critical in-process and product release quality control tests:

- **Bioburden**
- **Endotoxin**
- **Sterility Testing**

QC Microbiology Training

BEST is a 3 day innovative educational program designed specifically for you and your laboratory staff. This program will focus on both in-process and product release quality control, including Bioburden, Endotoxin and Sterility Testing. It will provide an overview of relevant methods in each area, however basic technical laboratory skills are assumed as a prerequisite for participation. The course will consist of class presentations and demonstrations of laboratory applications.

Program Material Outline

DAY 1

Bioburden Testing

Dependable Tests Based on Membrane Filtration

Bioburden testing is critical for monitoring water quality and raw materials and for ensuring that manufacturing processes remain in microbiological control. During the first day of the training, you will learn about:

- Advantages and limitations of membrane filtration
- How to choose the right membrane for your application
- The regulations governing Bioburden testing
- How to develop a sampling plan for Bioburden testing
- How to qualify and validate a method
- How to set alert and action limits
- How to interpret Bioburden test results
- How to troubleshoot membrane filtration issues
- Rapid methods for Bioburden testing
- Hands-on session using a manifold and Milliflex Plus Pump

DAY 2

Endotoxin Testing

BET Methodology and Background

The Bacterial Endotoxin Test (BET) is used for the detection and quantitation of endotoxins from Gram-negative bacteria. Reagents are primarily used to test for endotoxins in injectable pharmaceuticals, biological products, and medical devices. They are also used in renal dialysis centers and a wide range of other applications. During the second day of training, you will learn:

- What are endotoxin and BET reagents
- The regulations governing bacterial endotoxin testing
- The methodology for bacterial endotoxin testing
- How to qualify a chosen BET method
- How to validate samples and how to test them routinely
- How to analyze and interpret data
- How to address sample interference
- Hands-on session - Pyros Kinetix® Flex tube reader and Pyros® EQS software

DAY 3

Sterility Testing

A Complete Solution for Reliable Results

Sterility Testing is considered the most essential QC Microbiological test for releasing sterile final product. This test is heavily regulated and harmonized across most of the globe. During the third day of training, you will learn about:

- The history of Sterility Testing
- The global harmonized regulations overview
- Environmental Monitoring requirements for Sterility Testing
- Deep Dive into USP <71>
- Advantages and Limitations of Direct Inoculation Sterility Testing
- Advantages and Limitations of Open Funnel Sterility Testing
- Advantages and Limitations of Closed System Sterility Testing
- Overview of Sterility Testing Media and Rinse Fluids
- Most Common Sterility Questions
- Hands-on session - Steritest Equinox

For more information go online to: www.acciusa.com/acc/bestqctraining.html

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GROW WITH US

**40 years of Endotoxin
Innovation, Technical Expertise
and Customer Support.**

**Grown from a commitment to
quality, compliance and excellence.
Reach new heights with us.**



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