



# GEL-CLOT ENDOTOXIN DETECTION TESTING

# The Original Gel-Clot Assay

## Pyrotell®

Gel-Clot LAL Reagent

ACC's Pyrotell® was the first BET 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 resistant to interfering substances. The gel-clot test does not require sophisticated equipment and software and is the simplest BET 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 BET Ratio

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

### Performing the Test

For 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 BET 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 5 mL (approx. 50 tests/vial) MTV and STV sizes. STVs are sold in 5x10 vial packs. Certificates of Analysis, specific to the Pyrotell® and CSE lot, can be obtained from ACC or online at [acciusa.com](http://acciusa.com). It is recommended for use with 0.5 µg/vial Control Standard Endotoxin (E0005-1). See page 28 for product vial test quantities.

## PYROTELL® SINGLE TEST VIALS



## PYROTELL® MULTI-TEST VIALS



# Pyrosate®

Rapid Endotoxin Detection Kit

The Pyrosate® kit is an easy-to-use, FDA-licensed BET gel-clot test allowing for BET-compliant endotoxin testing. The assay does not require special training or laboratory supplies and 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  $2\lambda^*$  endotoxin tube (PPC) matched to the sample tube (SPL) 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)- $\beta$ -D-glucan. 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  $37\pm 1^\circ\text{C}$  is given on the Certificate of Compliance.

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



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



# Gel-Clot Testing Ordering Information

## Pyrotell®

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

#G5003-5	0.03 EU/mL (250 test 5 pack)
#G5003-25	0.03 EU/mL (1250 test 25 pack)
#G5006-5	0.06 EU/mL (250 test 5 pack)
#G5006-25	0.06 EU/mL (1250 test 25 pack)
#G5125-5	0.125 EU/mL (250 test 5 pack)
#G5125-25	0.125 EU/mL (1250 test 25 pack)
#G5250-5	0.25 EU/mL (250 test 5 pack)
#G5250-25	0.25 EU/mL (1250 test 25 pack)

### Single Test Vial (STV), 0.2 mL/vial

#GS003-5	0.03 EU/mL (five 10 vial packs)
#GS006-5	0.06 EU/mL (five 10 vial packs)
#GS125-5	0.125 EU/mL (five 10 vial packs)
#GS250-5	0.25 EU/mL (five 10 vial packs)

## Endotoxin Standards

For use in standard preparation and for depyrogenation control vials.

#E0005-1	0.5 µg/vial (1 vial)
#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) <i>(for use with Pyrochrome® kits)</i>

## Pyrosol® LAL Reconstitution Buffer

#BR051-5	Pyrosol® Buffer with pH indicator (gel-clot only), 5.5 mL/vial (5 pack)
#BR051-25	Pyrosol® Buffer with pH indicator (gel-clot 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 (1 pack)

## Glucashield® 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)

## Pyrosate® Kit

Includes sample test tubes and positive product control test tubes. Disposable transfer pipettes (PPT50) sold separately.

#PSD030-10	Pyrosate® 0.03 EU/mL (10 Test Kit)
#PSD030-30	Pyrosate® 0.03 EU/mL (30 Test Kit)
#PSD125-10	Pyrosate® 0.125 EU/mL (10 Test Kit)
#PSD125-30	Pyrosate® 0.125 EU/mL (30 Test Kit)
#PSD250-10	Pyrosate® 0.25 EU/mL (10 Test Kit)
#PSD250-30	Pyrosate® 0.25 EU/mL (30 Test Kit)

## Accessory Products\*

### LAL Reagent Water (LRW)

LRW is intended for reconstitution of BET reagents, CSE, and to dilute samples and standards for BET 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
#WP050C	50 mL/plastic bottle, 30 bottles/pack
#WP100C	100 mL/plastic bottle, 30 bottles/pack
#WP500C	500 mL/plastic bottle, 12 bottles/pack
#WP1000C	1L/plastic bottle, 12 bottles/pack

### Pyrotubes®

#TK100-10	8 x 75 mm borosilicate glass for Pyros Kinetix®, 50 tubes/pack, 10 packs/carton
#TS050-10	10 x 75 mm soda lime glass for gel-clot method, 52 tubes/pack, 10 packs/carton
#TB050-5	10 x 75 mm borosilicate glass for turbidimetric method, 52 tubes/pack, 5 packs/carton
#TB013-5	13 x 100 mm borosilicate glass, 18 tubes/pack, 5 packs
#TB16C	16 x 90 mm depyrogenation tubes with aluminum caps, 65/pack
#WP1000C	1L/plastic bottle, 12 bottles/pack

### Pipette Tips

#PPT25	250 µL tips, 96 tips/box, 10 boxes/pack
#PPT10	1000 µL tips, 96 tips/box, 8 boxes/pack
#PPT50	Disposable Transfer Pipettes 50/pack <i>(for use with Pyrosate® kits)</i>

\*Availability of ancillary products varies depending upon the local office.



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BR002906