

# **Accessory Products**

# **Disposable Products**

## Pyroclear<sup>®</sup>

Pyroclear® brand products are the first disposables in the industry that are certified to be free of interfering endotoxin and (1→3)-β-Dglucan 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 BET reagents and 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

# Pvrotubes<sup>®</sup>

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#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, 52 tubes/pack, 10 packs/carton
#TB050-5	10 x 75 mm borosilicate glass for turbidimetric method, 52 tubes/pack, 5 packs/carton
#TB240-5	12 x 75 mm borosilicate glass (for dilutions only), 42 tubes/pack, 5 packs/carton
#TB013-5	13 x 100 mm borosilicate glass, 18 tubes/pack, 5 packs
#TB16C	16 x 90 mm depyrogenation tubes with aluminum caps, 65/pack

## Pyroplates<sup>®</sup>

#CA961-10	96-well microplate, 10 pack
#CA961-50	96-well microplate, 50 pack

## **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 when 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 (1 pack)

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

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

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



# Control Standard Endotoxin (CSE)

Control Standard Endotoxin (CSE) is a standard for endotoxin testing. It is a purified extract from E. coli O113:H10, the same strain used for the US 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 BET testing. A 10 ng/vial CSE is made specifically for use with our Pyrochrome® chromogenic reagent.

#### **Performing the Test**

CSE is used to make standard curves and controls when performing the BET 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 acciusa.com.

#### **Depyrogenation Controls**

In addition to their use as standards for controlling BET 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).

# **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 stable preparation of endotoxin that can be used in all BET 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**

SOCIATES OF CAPE COD

rol Standard Endotoxin (

scherichia coli 0113:HI

ASSOCIATES OF CAPE COD, INC E. Saint. Jean Dr , East Falmouth, Tol Standard Endotoxin (CSE

tscherichia coli 0113:H10

ng freeze-dried endotoxin. Store at 210

with LAL reagent water (LRW) and distant tificate of Analysis for LAL lot-specific

on volume. Not intended for use in her

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)









# **CORPORATE HEADQUARTERS**

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