

# The Endosafe<sup>®</sup>-PTS<sup>™</sup> Portable Test System

## USER'S GUIDE Version 7

 **charles river** | endotoxin and  
microbial detection

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# SAFETY FIRST

## WARNING

- DO NOT use an AC power adapter other than that which has been delivered with your system. Only plug the adapter into a socket which is grounded. Using a different adapter may cause fire leading to serious injury.
- DO NOT place PTS system or charge battery around any liquids or use in a location where it could get wet or splashed. Liquids could cause fire or electric shock.

## CAUTION

- DO NOT open the instrument and tamper with the interior components. It does not contain any parts that can be maintained, repaired, or replaced by the user. Doing so may cause fire or electric shock.
- DO NOT allow liquids to spill into the cartridge chamber. Doing so may damage interior components and may cause fire or electric shock.
- DO NOT use sharply pointed objects to operate the keyboard of your system.
- DO NOT unplug AC power cord or PC cable by pulling cord/cable directly. Doing so may damage cord and cause injury. Handle the AC adapter and Serial Port Connector directly to unplug.

**Read this User's Guide carefully before using the Endosafe<sup>®</sup> - PTS System. Understanding- the proper usage and operation is imperative for the safety of the User, as well as the protection of the Endosafe<sup>®</sup> - PTS System.**

## Endosafe® - PTS – System Overview

The Endosafe® - PTS (Portable Test System) is a rapid, point-of-use test system which is comprised of a test cartridge along with a hand-held spectrophotometer.

The Endosafe® - PTS Endotoxin test utilizes existing FDA-licensed LAL formulations. The PTS provides quantitative LAL test results in approximately 15 minutes (see Appendix A for testing procedures and test results).



The Endosafe® - PTS Rapid Micro Methods are cartridges designed to accelerate a wide range of quality control test methodologies. New assays are currently in development and will be available as we adapt them to the PTS format.

- The Rapid Micro Methods Gram ID assay is an alternative to conventional gram stain methods for identification of microorganisms in approximately 3 to 7 minutes (see Appendix B for testing procedure and test results).

All components required for testing samples with the PTS are listed below.

Product	Description	Catalog #	Quantity
Endosafe® - PTS kit Reader and integrated software Power supply Adapter cord (1) Mini pipettor (1) User's Guide	<i>Portable Test System</i>	PTS100	Each
Endosafe® - Licensed PTS Endotoxin Cartridge (10 cartridges per package)	0.1 EU/mL sensitivity 0.05 EU/mL sensitivity 0.01 EU/mL sensitivity 0.005 EU/mL sensitivity	PTS201F PTS2005F PTS2001F PTS20005F	10/pack
Endosafe® - Unlicensed PTS Endotoxin Cartridge (10 cartridges per package)	0.1 EU/mL sensitivity 0.05 EU/mL sensitivity 0.01 EU/mL sensitivity	PTS201 PTS2005 PTS2001	10/pack
Endosafe® - PTS Inhibition/Enhancement Cartridge (10 cartridges per package)	Inhibition/Enhancement Screen	PTS220	10/pack
Endosafe® - PTS Rapid Micro Methods Cartridge (10 cartridges per package)	Gram ID	LRMMGI100	10/pack
Endosafe® - PTS Glucan Cartridge (10 cartridges per package)	(1,3) – $\beta$ -D-Glucan	RMMGS1000	10/pack

Note: Multi-cartridge packs are also available.  
Visit online at [www.criver.com](http://www.criver.com) for additional product information.

### Endosafe® - PTS Reader Specifications

- Temperature control: 37° C  $\pm$  1° C
- Data interface: RS232 serial port
- Printer support: Thermal printer and dot matrix compatible
- Data storage: Maximum of one hundred (100) stored test results.

- Dimensions: 9.25" x 4.625" x 2.50" corresponding 235 mm (D) x 128 mm (W) x 65 mm (H)
- Power supply unit: 100-240 V, 50-60 Hertz
- Power supply on board: 12 V DC, 5A
- Battery life: 6 - 8 hours of operation post-charge
- Warm-up time: Approximately 5 -10 minutes from 20° C start
- Display: Two (2) lines of sixteen (16) characters each
- Environmental Conditions:
  - Operating Temperature 15° to 27 ° C
  - Humidity 5% to 95% noncondensing
  - Indoor and outdoor use
  - Altitude - unlimited
- Weight: 3 lbs. corresponding 1100 Gram (without power supply unit)

### Endosafe<sup>®</sup> - PTS Cartridge Specifications

- Reference package insert for storage requirements
- Endotoxin Sensitivity: 10-0.1 EU/mL range, 5-0.05 EU/mL range, 1-0.01 EU/mL range, 0.5-0.005 EU/mL range (see Appendix A)
- Rapid Micro Methods – Gram ID: Archived parameters for Gram-negative, Gram-positive and Yeast/Mold isolate identification (see Appendix B)
- Inhibition/Enhancement Screening (see Appendix C)
- Rapid Micro Methods – Glucan (see Appendix D)
- Acceptable temperature: 37° C ± 1° C

Sample requirement: 25 µL sample per channel

**NOTE:** Sample must be delivered to each sample port without contamination or cross contamination between samples.

## Endosafe<sup>®</sup> - PTS Accessory Products

<b>Product</b>	<b>Description</b>	<b>Code</b>
PC Cable	Molded cable for PTS Reader to PC	PTS108
AC Adaptor	AC Adaptor for the PTS Reader	PTS109
Seiko <sup>®</sup> DPU-414 Printer	Battery powered, rechargeable thermal unit	PTS300
Seiko Printer Paper	Thermal paper rolls for Seiko <sup>®</sup> DPU-414 Printer	PTS301
Seiko Printer Cable	Molded cable for PTS Reader to Seiko <sup>®</sup> DPU-414 Printer	PTS302
Epson TM-U220D Printer	AC powered non-thermal unit	PTS310
Epson Printer Cable	Molded cable for Epson TM-U220D Printer	PTS311
Epson Printer Ribbon	Ribbon for Epson TM-U220D Printer	PTS312
Epson Printer Paper	Paper rolls for Epson TM-U220D Printer	PTS313
Endosafe <sup>®</sup> - PTS mini pipettor	25 $\mu$ L disposable unit with $\pm$ 5% accuracy and $\pm$ 3% precision at full stroke	PTS400
Protective reader case	Solid plastic, with handle for instruments and supplies	PTS600
Eppendorf <sup>®*</sup> pipette tips	200 $\mu$ L, individually wrapped, validated to 0.005 EU/mL	D100

\*Eppendorf is a registered trademark of Brinkmann

Multiple patents pending.

## Endosafe<sup>®</sup> - PTS Service Programs

### **WARRANTY with PURCHASE**

Charles River Laboratories warrants the Endosafe<sup>®</sup> - PTS instrument will be delivered in a functional state and free from defect, and will meet stated specifications for a period of one (1) year. The warranty period will start on the date of shipment by Charles River Laboratories.

During the warranty period, Charles River Laboratories will repair the instrument at no charge to the client for parts and labor. If repairs are needed, Charles River Laboratories will provide the client a loaner instrument during the period the instrument is being repaired. The client shall be responsible for all freight charges associated with the returned instrument and the loaner instrument.

Opening the case or tampering with the interior components of the PTS Reader will invalidate warranty provisions.

Additional service contracts are available as follows:

<b>Service</b>	<b>Code</b>
Annual Calibration Certification	PTS500
Extended Warranty	PTS501
IQ,OQ,PQ	PTS502
On Demand Repairs	PTS503

### **ANNUAL CALIBRATION CERTIFICATION**

The PTS instrument factory calibration, which is certified at the time of initial shipment, is valid for one (1) year. Charles River Laboratories offers an annual re-calibration service. To request this service, the client must notify the Company sixty (60) days prior to the end of the initial calibration period to arrange for re-calibration service.

### **EXTENDED WARRANTY PROGRAM**

The Extended Warranty Program is available to the client during the 1<sup>st</sup> year from the date of purchase of the initial Warranty Period.

This service program includes:

- A. A diagnostic and performance check, including replacement or repair of parts as necessary to return the instrument to original performance specifications.
- B. Loading software improvements/upgrades introduced to the PTS design since last inspection.
- C. A complete instrument cleaning operation.
- D. Certification for the extension of the Warranty Period for another four (4) years.

Charles River Laboratories will arrange transfer for the PTS instrument to the Company's technical services laboratory, and provide the client a loaner instrument during the period the instrument is being serviced (See **Returned Goods Authorization Procedure** below). The client shall be responsible for all freight charges associated with the returned instrument and the loaner instrument.

## **ON DEMAND REPAIRS**

After the initial Warranty Period has ended, the client may request Charles River Laboratories to service or repair the PTS instrument without having the benefit of one of the above Service Agreements.

Charles River Laboratories will arrange transfer of the PTS instrument to the Company's technical services laboratory, and provide the client a loaner instrument during the period On Demand repairs are being made (See **Returned Goods Authorization Procedure** below). The client shall be responsible for all freight charges associated with the returned instrument and the loaner instrument.

## **RETURNED GOODS AUTHORIZATION PROCEDURE**

The client must obtain a Returned Goods Authorization Number from Charles River Laboratories before any items can be shipped to the Technical Services Department. All goods returned for repair, preventative maintenance, or calibration, whether under warranty or not, must be properly packed to avoid damage and clearly marked with the RGA number.

## **WARRANTY REGISTRATION**

A Warranty Registration Card is provided in this User's Guide, and is also available online at [www.criver.com](http://www.criver.com). Submitting the completed card will permit the Technical Services Department to more efficiently meet each client's needs.

All warranty and service options are subject to the Terms and Conditions and procedures specified in the Service Agreement. For answers to questions about any of these components for the Endosafe<sup>®</sup> - PTS or for additional product information, please contact Charles River Laboratories Technical Services Department:

United States:	1023 Wappoo Road, Suite 43-B Charleston, SC 29407 USA (800) 762-7016
Europe:	00 800 15 78 97 43

# Operating the Reader

## **BATTERY INFORMATION**

The PTS Reader can operate on its own battery power or with the supplied AC power adapter. The AC power adapter also serves as the battery charger for the PTS Reader. The batteries enable the user to operate the PTS Reader onsite without the use of a power cord. The rechargeable lithium-ion batteries are installed at the factory and should be replaced only by the factory. The following procedures are presented so the user can experience the maximum useful performance and life from the batteries.

The batteries should be fully charged (about 4 to 4.5 hours) before use. This will give approximately 6 to 8 hours of continuous usage. To charge the batteries, use only the AC power adapter supplied with the instrument.

NOTE: Insert the power cord into any grounded 3-prong outlet, and then insert the DC plug into the rear of the PTS Reader. The AC power cord adapter displays a green LED when the cord is securely plugged into a wall outlet. If this light does not appear, try a different socket or make sure the power cord is properly inserted into the outlet. Never use a charger that is damaged.

A desirable operating condition for the batteries is to be fully charged and then used to operate the PTS Reader on battery power until a low level of charge is reached – best if fully discharged. Then repeat the “full charge-full discharge” usage cycle. Leaving the PTS on continuously with the external charger connected is not recommended.

NOTE: If the PTS Reader is continuously connected to an external charger, the batteries will self-discharge approximately 10 to 15%, and then the charging circuit will activate and restore the charge. This will result in a shortened life span of the batteries.

When operating on batteries, eventually a “LOW BATTERY” message will be displayed indicating that only one (1) or two (2) more tests can be performed before the battery charge is too low to initiate and complete another test. The AC power adapter must then be connected to continue operation. Testing can be resumed as the batteries are in the process of being charged.

As the batteries approach their end of life (approximately 300 charge-discharge cycles), the number of tests that can be run on one (1) charge will diminish. The “Charge Battery” message will start to appear more often. The user will be alerted with the display and an audible beep every 5 minutes that there is a “Battery Issue – See User Manual”. The alerts will also occur on system start-up but will not occur during a test. If the alerts are not heeded, and the batteries eventually reach full discharge, the PTS Reader will shut down, but will resume operation within 1 minute once the AC power adapter has been connected. Although operational with end-of-life batteries, the PTS Reader will be vulnerable to power interruptions. In all instances, when the batteries approach end of life, the PTS Reader should be returned to the factory for battery replacement.

If the batteries are to remain unused for extended periods of time, it is recommended that they be stored at a charge level of 30 to 70%; maximizing the overall life of the battery.

## **KEYPAD OPERATION**

It is important to develop a thorough knowledge of the use of the PTS Reader keypad. Learning proper sequences for data entry will ensure your test procedures are successful, and that all necessary results are displayed at the conclusion of each test. The following overview of the PTS keypad operation covers all necessary functions and procedures for proper use of the PTS Reader during test operations.

### **A. ON/OFF**

ON – When using battery power, pressing the **MENU** key on the keypad will turn the instrument on.

OFF – Pressing the **MENU** key from the initial screen followed by the **5** key will turn the instrument off, conserving battery power.

**NOTE:** Press CANCEL to return to the initial screen.

### **B. MENU KEY**

1. Pressing the **Menu** key initiates the *Main Menu* display on the PTS Reader's information screen.
2. Once *Main Menu* is displayed on the screen, Use the **Menu** key repeatedly to scroll through the separate, numbered headers that are available on the *Main Menu*:

**#1 – Enter Test Inf** – The PTS Reader will prompt the user for all pertinent test information automatically when a cartridge is inserted. It is not necessary to *Enter Test Info* under this header.

**#2 - User Setup** – The majority of the options under this header are for factory use only. If selected, "Action Denied" will be displayed on the screen with an audible notification. The user has the capability of erasing all stored lot numbers under this heading.

**#3 - System Menu** – This header allows you to enter a variety of constants, such as:  
Time Menu, Date Menu, Languages, System Options, and setting the COM1 Baud rate.

**NOTE:** Selecting any sub-header that is for factory use only will display "Action Denied" on the screen with an audible notification.

**#4 - Print Menu** – This header allows you to set options to govern the data printing process for your test results, and includes settings for:  
Printing the Last Test, Print all tests by a given date, Printing All Tests stored on the PTS Reader (up to 100 max.), Print 40 Character Line, A Display of # of Tests stored on the reader, Performing a Printer Test, and Erasing All Records.

**NOTE:** Once Erase All Records has been selected and confirmed, all records will be erased and irretrievable. If necessary, download desired data to PC, Seiko<sup>®</sup> DPU-414 Printer, or Epson TM-U220D Printer to store prior to erasing all records (see pages 12-14).

**#5 – System OFF** – Selecting this *Main Menu* option will turn the PTS reader off.

**#6 – System Reset** – Selecting this *Main Menu* option will automatically reboot the test system.

**#7 – System Info** – This header of the *Main Menu* allows you to view system information, such as the serial number, and the system software version.

Becoming familiar with available options from each of the numbered headers of the *Main Menu*, allows you to proceed with greater speed and confidence as you perform your tests and specific data collection.

## C. EXAMPLE OF KEYPAD OPERATION

### Setting the Time on the PTS Reader:

1. Turn the instrument on by pressing the **MENU** key  
→ The PTS Reader displays *Insert Cartridge* after Systems Self Test
2. Press the **MENU** key  
→ The PTS Reader displays *Main Menu* and *1-Enter Test Inf*
3. Press **MENU** two (2) additional times for *3-System Menu*, and then press **3**  
→ The PTS Reader displays *System Menu* and *1- Display Date Time*
4. Press **3** to select the *Time Menu*
5. Use the **MENU** key to scroll through the options governing the time setting feature: **1** – *Set Time*, **2** – *12 Hour*, **3** – *24 Hour*
6. For each of the 3 *Time Menu* items, you can press the **ENTER** key to enter the appropriate information regarding the time settings and preferences you want the system to use
7. For example, if you press **ENTER** when the PTS Reader displays *1 – Set Time*, you will see the default time on the PTS Reader screen. A cursor will appear below the first number, which allows you to enter a new number in that position to format the correct time. Simply move the cursor left or right using the ◀ ▶ arrow keys, and press the numeral keys on the keypad to enter the correct time
8. Once you have entered the appropriate information, press the **ENTER** key  
→ The PTS Reader displays your entry and *Stored*, to indicate the data was stored successfully

**D. MENU SHORTCUTS FOR PTS READER KEYPAD**

The following Menu Shortcuts diagrams the Menu options and their headings and subheadings. Using the table, you can go directly to any of the available menu fields by pressing the MENU key and the appropriate menu item code number.

	MAIN MENU
M2	USER SETUP
M24	4-Erase Lot Numb
M25	5-Channel EU YES/NO
M3	3-System Menu
	SYSTEM MENU
M31	1- Displ DateTime
	TIME MENU
M331	1-Set Time
M332	2-12 Hour
M333	3-24 Hour
	DATE MENU
M321	1-Set Date
M322	2-MON/DAY/YEAR
M323	3-DAY/MON/YEAR
	PRINT MENU
M41	1-Print Last Tst
M42	2-Print All Tsts on given date
M43	3-Print All Tsts
M44	4-Print 40-Character format
M45	5-#Tests Stored:
M46	6-Printer Test
M47	7-Erase All Recs
M5	5-System OFF
M6	6-System Reset
M7	7-System Info

**E. CANCEL KEY**

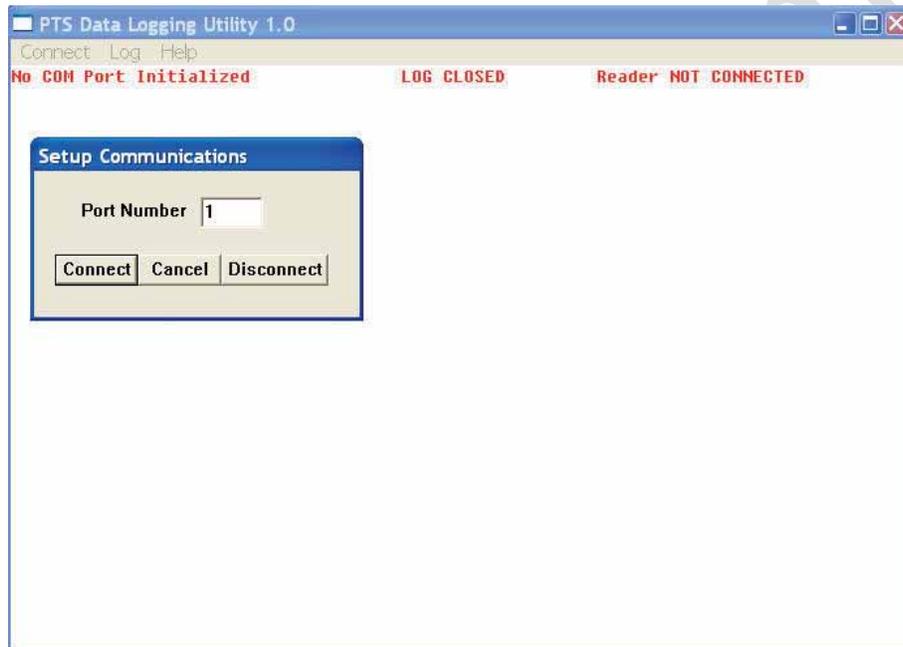
Pressing the **CANCEL** key at any time during data entry to the PTS Reader will return the display to the previous numbered header of the *Main Menu*.

If you continue to press the **CANCEL** key, the display will cycle over to the *Main Menu* display, and subsequently out of all menus, at which point the PTS Reader will display *Insert Cartridge*. At this point, if all necessary information has been entered to the PTS Reader for the test setup, testing can begin.

## Reader Output

### Downloading Output to PC using the PTS Logger Software

1. Insert the PTS Logger software CD into your PC and download to PC.
2. Connect Cable – Serial port connection to PC and RJ45 plug into back of PTS Reader (cable is provided with PTS System).
3. Select *Connect* then choose the com port your PTS Reader is connected to in the Setup communications window. Click on the Connect button to connect to PTS Reader.



4. Select *Log* then *Open/Close Log* to open the log.
5. Press the **MENU** key on the PTS Reader keypad.

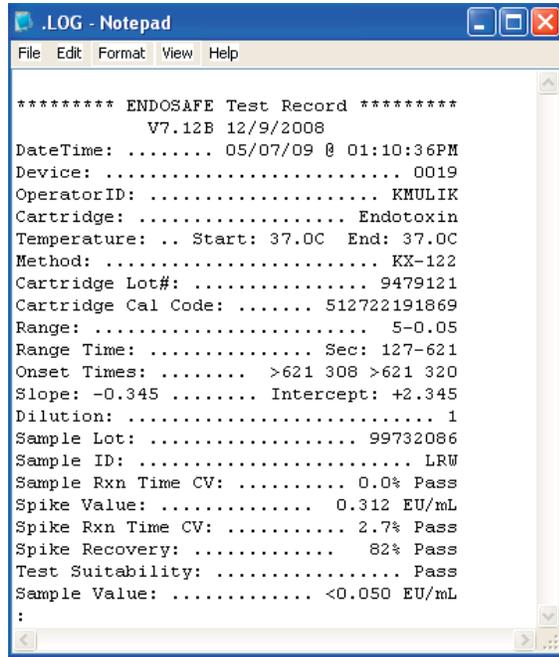
Select **4** for the *Print Menu*.

The options for downloading data to the PC are:

- 1-*Print Last Test*
- 2-*Print by Date*
- 3-*Print all Tests*

Selecting one (1) of the above three (3) choices to print will automatically download results to the PTS Logger software if connected as described above.

6. Select *Log* then *View* to view data in notepad format.



```

***** ENDOSAFE Test Record *****
V7.12B 12/9/2008
DateTime: ..... 05/07/09 @ 01:10:36PM
Device: ..... 0019
OperatorID: ..... KMULIK
Cartridge: ..... Endotoxin
Temperature: .. Start: 37.0C End: 37.0C
Method: ..... KX-122
Cartridge Lot#: ..... 9479121
Cartridge Cal Code: ..... 512722191869
Range: ..... 5-0.05
Range Time: ..... Sec: 127-621
Onset Times: ..... >621 308 >621 320
Slope: -0.345 ..... Intercept: +2.345
Dilution: ..... 1
Sample Lot: ..... 99732086
Sample ID: ..... LRW
Sample Rxn Time CV: ..... 0.0% Pass
Spike Value: ..... 0.312 EU/mL
Spike Rxn Time CV: ..... 2.7% Pass
Spike Recovery: ..... 82% Pass
Test Suitability: ..... Pass
Sample Value: ..... <0.050 EU/mL
:

```

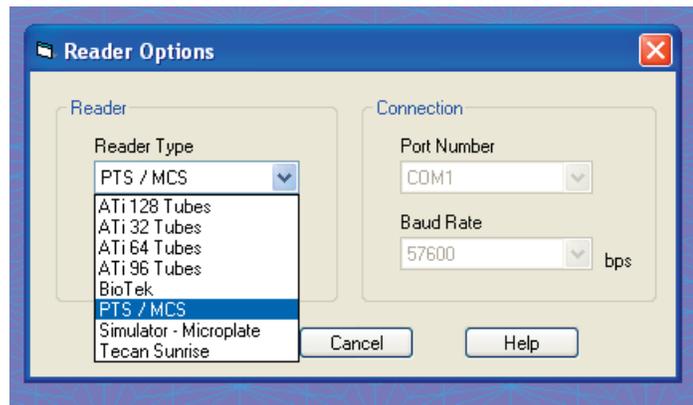
Note: The data will automatically be sent to an unnamed *Notepad* file within the PTS Logger folder. If this file remains in the PTS Logger folder, the next set of data will be added to the bottom of this file. It is recommended that you either rename the *Notepad* file and move it to another folder or copy the data into a *Word* file and delete the *notepad* file.

### Printing with the DPU-414 Seiko Thermal Printer or the Epson TM-U220D Printer

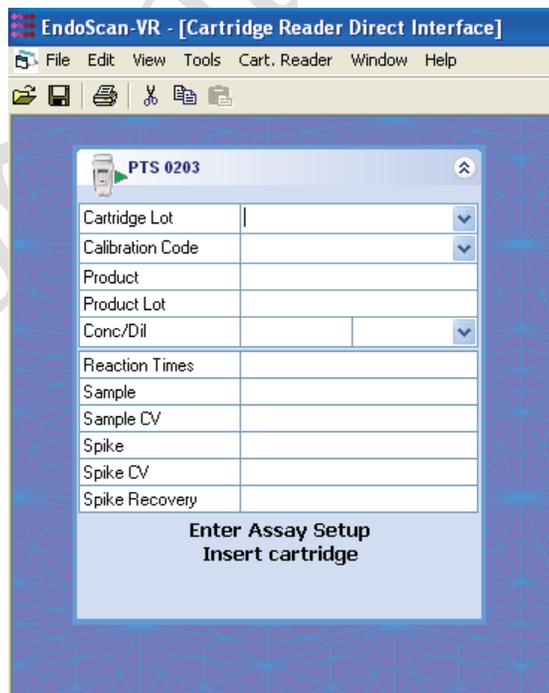
1. Setup printer according to owner's manual instructions.
2. Connect Cable – Serial port connection to Printer and RJ45 plug in back of the PTS Reader (Cable is provided with PTS System).
3. Press the **MENU** key on the PTS Reader keypad.
4. Select **4** for the *Print Menu*.  
The options for downloading data to the Printer are:  
*1-Print Last Test*  
*2-Print by Date*  
*3-Print all Tests*
5. Selecting one (1) of the above three (3) choices on the PTS Reader keypad will send results to the connected Printer.
6. If the user desires to also download data to a PC, follow instructions above for *Downloading Output to PC using the PTS Logger software*.

**Using EndoScan-V with Endosafe<sup>®</sup> - PTS for data acquisition.**

1. Insert the EndoScan-V CD into the CD drive.
2. Install EndoScan-V software.
3. Upon successful installation and registration of the software select PTS/MCS as the reader type from the reader options dialog box.



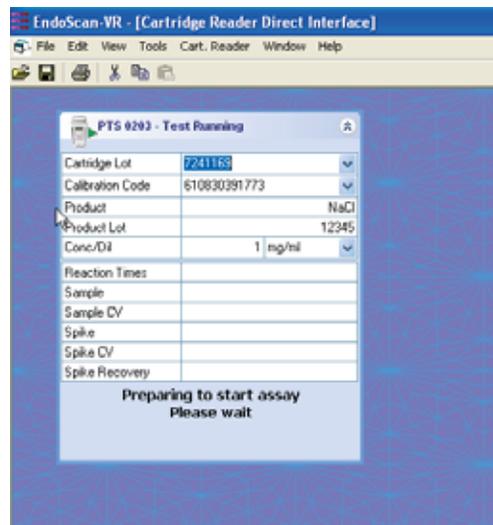
4. Once successfully connected to a PTS Reader the following screen will appear. While connected using EndoScan-V keyboard operations of the PTS are disabled.



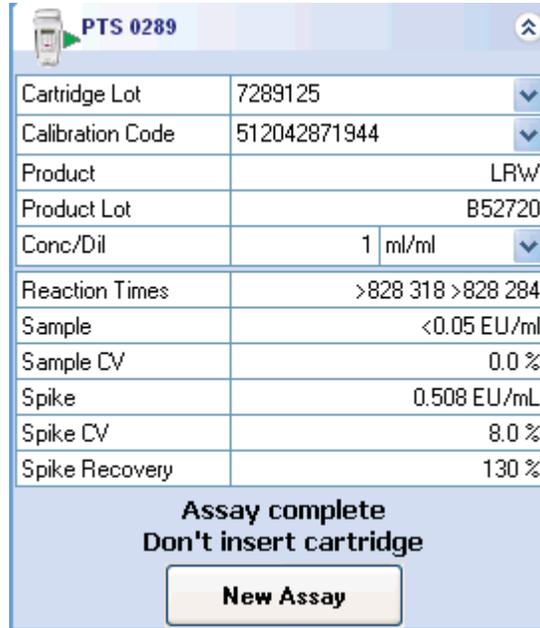
5. Enter the Cartridge lot number. The cartridge lot number will be stored for later use.
6. Enter the Calibration code. The Calibration code will be stored for later use.
7. Enter product information by either typing directly into the box or by dragging information from the product database into the dialog box.
8. Enter the dilution in the form of "1:x mL/mL" or "x units/mL" for concentration.
9. Insert the cartridge.



10. Select the Send Setup button to send information to the PTS Reader.
11. Once the Add sample and Click start message is displayed dispense 25  $\mu$ L into each well of the test cartridge and click start on the screen.
12. While in progress the screen will display messages showing the current progress.



13. Upon completion of the assay, a message will be displayed instructing the user to remove the cartridge and a screen similar to the one below containing data for the assay will be displayed.



PTS 0289	
Cartridge Lot	7289125
Calibration Code	512042871944
Product	LRW
Product Lot	B52720
Conc/Dil	1 ml/ml
Reaction Times	>828 318 >828 284
Sample	<0.05 EU/ml
Sample CV	0.0 %
Spike	0.508 EU/mL
Spike CV	8.0 %
Spike Recovery	130 %

**Assay complete**  
**Don't insert cartridge**

**New Assay**

14. Select the report option to print a report for this assay.
15. Select the save or save as option to save the assay as an EndoScan-V file if Autaname is not selected.
16. To return the PTS to keypad simply disconnect the serial cable from the rear of the PTS unit. The unit will perform a system self-check and return to keypad operations.

## Troubleshooting

Listed in the table below are various Error or Fault Messages and a description of the corresponding cause of the error or fault.

- One or more LONG audible tones will precede each error message.
- Any fault listed here will prevent the PTS Reader from running a test.
- Unless it is a hardware problem, the only way to clear an error message is to turn the PTS Reader OFF and back ON again.

<b>MESSAGE</b>	<b>DESCRIPTION</b>
"A2D SETUP"	Photo A/D set up did not complete
"TEMP TOO LOW"	Cartridge temperature is too low
"TEMP TOO HI"	Cartridge temperature is too high
"MOTOR NOT HOME"	Cannot run pump motor
"CLOCK FAULT"	Cannot read Real Time Clock
"Computing Error"	Divide by 0 or range error
"Charge Battery"	Batteries too weak to run tests
"Battery Fault"	Battery charging problem
"UNKNOWN"	Any unspecified system fault
"One or more test LEDs out of spec" "Abort Test CANCEL OR ENTER"	One or more of the LEDs does not have sufficient intensity to run the test properly
"Sample Not Seen" flashes during test	Sample was not detected in one or more of the optical cells

If any of these or other problems persists, contact Charles River Laboratories Technical Service:

United States: 1023 Wappoo Road, Suite 43-B  
Charleston, SC 29407  
USA  
(800) 762-7016

Europe: 00 800 15 78 97 43

Fax: (843) 766-7576  
E-Mail: endo-comments@crl.com

# Appendix A

## Endosafe<sup>®</sup> - PTS Endotoxin

### PERFORMING ROUTINE ENDOTOXIN TEST

A routine PTS LAL assay is conducted by following the simple prompts on the PTS instrument. The following represents a typical assay procedure:

#### 1. Instrument Operation

- Press the **MENU** key on the PTS keypad to turn instrument on (Menu 5 turns instrument off).
- The PTS Reader initiates a "SYSTEM SELF TEST" as it heats up to 37°C – this takes approximately 5 minutes.
- The PTS Reader displays "SELF TEST OK" and then "INSERT CARTRIDGE".

#### 2. Insert the Cartridge

Note: Allow the cartridge to come to room temperature in pouch before use.

Remove cartridge from pouch and insert with sample reservoirs facing up into slot at front of the PTS Reader.

Press cartridge firmly into slot.



#### 3. Enter Required Information

Once the cartridge has been firmly inserted into the PTS Reader, the PTS Reader prompts the user to enter the following information:

- **Enter OID** (Operator ID)
  - **Enter Lot #** (Cartridge Lot #)
  - **Enter Calibration Code** (If the Calibration Code for the particular lot # has already been entered, the PTS Reader does not prompt for the code again. (To Erase all stored lot #'s and corresponding calibration codes, select menu, 2, then 4 from the initial menu)
  - **Lot #** (Confirms cartridge lot number entered)
  - **Enter Sample Lot #**
  - **Enter Sample ID** (Selecting and scrolling with the menu key under the sample ID Header allows for fifty (50) samples to be entered and stored)
  - **Enter Dilution Factor**
- **Note:** All LAL Reagent Water (LRW) used to make product dilutions should be tested for the absence of detectable endotoxin.

While the above information is being entered into the PTS Reader, the cartridge is being pre-warmed.

#### 4. Dispense the Sample

Once all test information is entered, the PTS Reader displays:

- **ADD SAMPLE; PRESS ENTER**
- Pipette 25  $\mu$ L of sample into all four (4) sample reservoirs of the inserted cartridge and press **Enter** on the PTS Reader keypad.
- Pumps draw sample aliquots into the test channels, thereby initiating the test.
- Results will be obtained in approximately 15 minutes.



### ENDOTOXIN TEST RESULTS

1. When the test is complete, the PTS Reader gives an audible notification that the assay is finished.
2. At the conclusion of the test, the endotoxin measurement and the assay acceptance criteria are displayed on the screen.
3. The PTS Reader display alternates between the following results:
  - Sample EU/mL
  - Sample %CV
  - Spike EU/mL
  - Spike %CV
  - % Spike Recovery
  - Remove Cartridge

The PTS Reader continues to display the assay results until cartridge is removed.

## RETRIEVING RESULTS OPTIONS

1. You can download results directly to your PC and retrieve from the designated location file.
2. You can use the Seiko<sup>®</sup> DPU-414 Printer or the Epson TM-U220D Printer (available from Charles River Laboratories) to print the last test result, all results from a particular date, or up to a maximum of one hundred (100) stored test results.

```
***** ENDOSAFE Test Record *****
          V7.12B 12/9/2008
DateTime: ..... 05/07/09 @ 11:04:12AM
Device: ..... 0019
OperatorID: ..... KMULIK
Cartridge: ..... Endotoxin
Temperature: .. Start: 37.0C End: 37.0C
Method: ..... KX-122
Cartridge Lot#: ..... 9478126
Cartridge Cal Code: ..... 511534382938
Range: ..... 5-0.05
Range Time: ..... Sec: 115-743
Onset Times: ..... >743 294 >743 290
Slope: -0.405 ..... Intercept: +2.344
Dilution: ..... 1
Sample Lot: ..... 99732086
Sample ID: ..... LRW
Sample Rxn Time CV: ..... 0.0% Pass
Spike Value: ..... 0.451 EU/mL
Spike Rxn Time CV: ..... 1.0% Pass
Spike Recovery: ..... 92% Pass
Test Suitability: ..... Pass
Sample Value: ..... <0.050 EU/mL
:
```

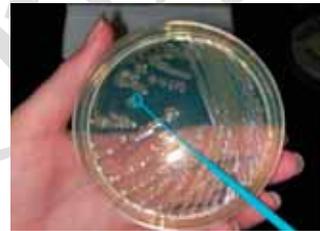
## Appendix B

### Endosafe<sup>®</sup> - PTS Rapid Micro Methods Gram ID

#### PERFORMING ROUTINE GRAM ID TEST

A routine Gram ID assay is conducted by preparing a bacterial suspension and following the simple prompts on the PTS Instrument. The following represents a typical assay procedure:

The PTS Gram ID offers two (2) assay report formats. One assay result format will report the presence of either Gram-negative microorganisms, Yeast/Mold or Gram-positive microorganisms in approximately 7 minutes. The second assay result format will report the presence of Gram-negative and Gram-positive in approximately 3 minutes (this format does not differentiate between Gram-positive and Yeast/Mold isolates). Reference the Certificate of Analysis for the calibration code to be used for each assay result format.



#### Sample Preparation:

From an isolated culture, carefully remove colonies from agar surface and suspend cells in approximately 2 mLs of LPS-free Saline or LRW and adjust to a 0.5 McFarland Equivalence Turbidity Standard.



Note: Do not use cotton tip swabs of any kind during sample preparation.

#### 1. Instrument Operation

- Press the **MENU** key on the PTS keypad to turn instrument on (Menu 5 turns instrument off).
- The PTS Reader initiates a "SYSTEM SELF TEST" as it heats up to 37°C – this takes approximately 5 minutes.
- The PTS Reader displays "SELF TEST OK" and the "INSERT CARTRIDGE".



#### 2. Insert the Cartridge

Remove cartridge from pouch and insert with sample reservoirs facing into slot at front of the PTS Reader. Press cartridge firmly into slot.

Note: If refrigerated, allow the cartridge to come to room temperature in pouch before use.

### 3. Enter Required Information

Once the cartridge has been firmly inserted into the PTS Reader, the PTS Reader prompts the user to enter the following information:

- **Enter OID** (Operator ID)
- **Enter Lot #** (Cartridge Lot #)  
*Note: If alternating between assay result formats, the user must delete all stored lot numbers in the PTS Reader before initiating a test. This is done by selecting Main Menu > #2 User Setup> #4 Erase Lot Numbers. Select Enter to erase all stored lot numbers*
- **Enter Calibration Code** (If the Calibration Code for the particular lot # has already been entered, the PTS Reader does not prompt for the code again. After deleting stored lot numbers in the PTS Reader, the user will be prompted to enter in the calibration code)
- **Lot #** (Confirms cartridge lot number entered)
- **Enter Sample #1 Lot #** (This prompt is available for all four (4) samples)
- **Enter Sample #1 ID** (Selecting and scrolling with the menu key under the sample ID Header allows for fifty (50) samples to be entered and stored)

While the above information is being entered into the PTS Reader, the cartridge is being pre-warmed.

### 4. Dispense the Sample

Once all test information is entered, the PTS Reader displays:

- **ADD SAMPLE; PRESS ENTER**
- Pipette 25µL of first sample into one (1) sample reservoir of the inserted cartridge. *Change pipette tip to avoid cross-contamination between each sample.* After all four (4) sample reservoirs are filled, press **Enter** on the PTS Reader keypad.
- Pumps draw sample aliquots into the test channels, thereby initiating the test.
- Results will be obtained in approximately 7 minutes for Gram-negative, Gram-positive and Yeast/Mold identification and 3 minutes for Gram-negative and Gram-positive identification.

## **GRAM ID TEST RESULTS**

1. When the test is complete, the PTS Reader gives an audible notification that the assay is finished.
2. At the conclusion of the test, the gram identification is displayed on the screen for each sample as Gram Negative, Gram Positive, Yeast / Mold.
3. The PTS Reader display alternates between the following results:
  - Sample #1
  - Sample #2
  - Sample #3
  - Sample #4
  - Remove Cartridge

The PTS Reader continues to display the assay results until the cartridge is removed.

## RETRIEVING RESULTS OPTIONS

1. You can download results directly to your PC and retrieve from the designated location file.
2. You can use the Seiko<sup>®</sup> DPU-414 Printer or the Epson TM-U220D Printer (available from Charles River Laboratories) to print the last test result, all results from a particular date, or up to a maximum of one hundred (100) stored test results.

Example of Gram-negative or Gram-positive assay result format report:

```
***** ENDOSAFE Test Record *****
          V7.12A 7/30/2008
DateTime: ..... 10/29/08 @ 12:02:26PM
Device: ..... 0560
OperatorID: ..... DN
Cartridge: ..... Gram ID
Temperature: .. Start: 37.0C End: 37.0C
Method: ..... GSX-401
Cartridge Lot#: ..... 8294900
Cartridge Cal Code: ..... 515015143077
Onset Times: ..... <150 <150 >151 >151
Sample #1 Lot: ..... EC0012
Sample #1 ID: ..... TB-1
Sample #2 Lot: ..... EC0013
Sample #2 ID: ..... TB-2
Sample #3 Lot: ..... BC0004
Sample #3 ID: ..... FL-1
Sample #4 Lot: ..... BC0005
Sample #4 ID: ..... GL-1
Sample #1: ..... Gram Negative
Sample #2: ..... Gram Negative
Sample #3: ..... Gram Positive
Sample #4: ..... Gram Positive
```

Example of Gram-negative, Yeast/Mold or Gram-positive assay result format report:

```
***** ENDOSAFE Test Record *****
          V7.12A 7/30/2008
DateTime: ..... 10/29/08 @ 11:45:32AM
Device: ..... 0560
OperatorID: ..... DN
Cartridge: ..... Gram ID
Temperature: .. Start: 37.0C End: 37.0C
Method: ..... GSX-401
Cartridge Lot#: ..... 8294900
Cartridge Cal Code: ..... 515040043099
Onset Times: ..... 344 360 352 380
Sample #1 Lot: ..... EC0001
Sample #1 ID: ..... FL-2
Sample #2 Lot: ..... CA0002
Sample #2 ID: ..... FL-2
Sample #3 Lot: ..... CA0003
Sample #3 ID: ..... TB-3
Sample #4 Lot: ..... BC0006
Sample #4 ID: ..... GL-2
Sample #1: ..... Gram Negative
Sample #2: ..... Yeast / Mold
Sample #3: ..... Yeast / Mold
Sample #4: ..... Gram Positive
```

## Appendix C

### Endosafe<sup>®</sup> - PTS Inhibition/Enhancement Screen

#### PERFORMING INHIBITION/ENHANCEMENT TEST

An Inhibition/Enhancement PTS LAL assay is conducted by following the simple prompts on the PTS instrument. Different dilutions of one (1) sample can be placed in each sample well to determine the non-interfering dilution or different samples can be placed in each well of one (1) test cartridge. The following represents a typical assay procedure:

#### 1. Instrument Operation

- Press the **MENU** key on the PTS keypad to turn instrument on (Menu 5 turns instrument off).
- The PTS Reader initiates a "SYSTEM SELF TEST" as it heats up to 37°C – this takes approximately 5 minutes.
- The PTS Reader displays "SELF TEST OK" and then "INSERT CARTRIDGE".

#### 2. Insert the Cartridge

Remove cartridge from pouch and insert with sample reservoirs facing up into slot at front of the PTS Reader.

Press cartridge firmly into slot.

Note: Allow the cartridge to come to room temperature in pouch before use.



#### 3. Enter Required Information

Once the cartridge has been firmly inserted into the PTS Reader, the PTS Reader prompts the user to enter the following information:

- **Enter OID** (Operator ID)
- **Enter Lot #** (Cartridge Lot #)
- **Enter Calibration Code** (If the Calibration Code for the particular lot # has already been entered, the reader does not prompt for the code again. (To Erase all stored lot #'s and corresponding calibration codes, select menu, 2, then 4 from the initial menu)
- **Lot #** (Confirms cartridge lot number entered)
- **Enter Sample 1 Lot #** (Sample 1 is designated as the well on the far left after cartridge is inserted into the PTS Reader)

- **Enter Sample 2 Lot #** (Sample 2 is the next well to the right of sample 1)
  - **Enter Sample 3 Lot #** (Sample 3 is the next well to the right of sample 2)
  - **Enter Sample 4 Lot #** (Sample 4 is the last well on the right)
  - **Enter Sample 1 ID** (Selecting and scrolling with the menu key under the sample ID Header allows for fifty (50) samples to be entered and stored)
  - **Enter Sample 2 ID**
  - **Enter Sample 3 ID**
  - **Enter Sample 4 ID**
  - **Enter Dilution #1 Factor**
  - **Enter Dilution #2 Factor**
  - **Enter Dilution #3 Factor**
  - **Enter Dilution #4 Factor**
- **Note:** All LAL Reagent Water (LRW) used to make product dilutions should be tested for the absence of detectable endotoxin.

While the above information is being entered into the PTS Reader, the cartridge is being pre-warmed.

#### 4. Dispense the Sample

Once all test information is entered, the PTS Reader displays:

- **ADD SAMPLE; PRESS ENTER**
- Pipette 25  $\mu$ L of sample into four (4) sample reservoirs of the inserted cartridge and press **Enter** on the PTS Reader keypad.
- Pumps draw sample aliquots into the test channels, thereby initiating the test.
- Results will be obtained in approximately 15 minutes.



## **INHIBITION/ENHANCEMENT TEST RESULTS**

1. When the test is complete, the PTS Reader gives an audible notification that the assay is finished.
2. At the conclusion of the test, the assay acceptance criteria are displayed on the screen.
3. The PTS Reader display alternates between the following results:
  - Spike #1 Recovery
  - Spike #2 Recovery
  - Spike #3 Recovery
  - Spike #4 Recovery

The PTS Reader continues to display the assay results until cartridge is removed. Once the assay is complete and the results are noted, remove the cartridge promptly from the PTS Reader.

**RETRIEVING RESULTS OPTIONS**

1. You can download results directly to your PC and retrieve from the designated location file.
2. You can use the Seiko<sup>®</sup> DPU-414 or the Epson TM-U220D Printer (available from Charles River Laboratories) to print the last test result, all results from a particular date, or up to a maximum of one hundred (100) stored test results.

```

***** ENDOSAFE Test Record *****
          V7.12B 12/9/2008
DateTime: ..... 05/07/09 @ 09:28:35AM
Device: ..... 0019
OperatorID: ..... KMULIK
Cartridge: ..... I/E Screen
Temperature: .. Start: 37.0C End: 37.0C
Method: ..... KX-410
Cartridge Lot#: ..... 9454812
Cartridge Cal Code: ..... 509025092498
Range: ..... 5-0.05
Range Time: ..... Sec: 90-650
Onset Times: ..... >650 530 294 272
Slope: -0.429 ..... Intercept: +2.254
Dilution #1: ..... 10
Sample #1 Lot: ..... 07106
Sample #1 ID: ..... ETHANOL
Dilution #2: ..... 50
Sample #2 Lot: ..... 07106
Sample #2 ID: ..... ETHANOL
Dilution #3: ..... 100
Sample #3 Lot: ..... 07106
Sample #3 ID: ..... ETHANOL
Dilution #4: ..... 500
Sample #4 Lot: ..... 07106
Sample #4 ID: ..... ETHANOL
Spike #1 Recovery: ..... < 11%
Spike #2 Recovery: ..... 18%
Spike #3 Recovery: ..... 72%
Spike #4 Recovery: ..... 86%
:

```

## Appendix D

### Endosafe<sup>®</sup> - PTS Rapid Micro Methods Glucan

#### PERFORMING ROUTINE GLUCAN TEST

The PTS Glucan assay is used for the detection of (1,3)- $\beta$ -D-Glucans. The Endosafe<sup>®</sup> -PTS Glucan assay is intended for research purposes only and is not to be used for diagnostic testing purposes.

A routine PTS Glucan assay is conducted by following the simple prompts on the PTS instrument. The following represents a typical assay procedure:

#### 1. Instrument Operation

- Press the **MENU** key on the PTS keypad to turn instrument on (Menu 5 turns instrument off)
- The reader initiates a "SYSTEM SELF TEST" as it heats up to 37°C – this takes approximately 5 minutes
- The reader displays "SELF TEST OK" and then "INSERT CARTRIDGE"

#### 2. Insert the Cartridge

Remove cartridge from pouch and insert with sample reservoirs facing up into slot at front of the PTS Reader.

Press cartridge firmly into slot.

Note: Allow the cartridge to come to room temperature in pouch before use.



#### 3. Enter Required Information

Once the cartridge has been firmly inserted into the reader, the reader prompts the user to enter the following information:

- **Enter OID** (Operator ID)
- **Enter Lot #** (Cartridge Lot #)
- **Enter Calibration Code** (If the Calibration Code for the particular lot # has already been entered, the reader does not prompt for the code again. (To Erase all stored lot #'s and corresponding calibration codes, select menu, 2, then 4 from the initial menu)
- **Lot #** (Confirms cartridge lot number entered)
- **Enter Sample Lot #**

- **Enter Sample ID** (Selecting and scrolling with the menu key under the sample ID Header allows for fifty (50) samples to be entered and stored)
- **Enter Dilution Factor**
- **Note:** All LAL Reagent Water (LRW) used to make product dilutions should be tested for the absence of detectable endotoxin and glucan.

While the above information is being entered into the reader, the cartridge is being pre-warmed.

#### 1. Dispense the sample

Once all test information is entered, the reader displays:

- **ADD SAMPLE; PRESS ENTER**
- Pipette 25  $\mu$ L of sample into four (4) sample reservoirs of the inserted cartridge and press **Enter** on the reader keypad
- Pumps draw sample aliquots into the test channels, thereby initiating the test
- Results will be obtained in approximately 30 minutes.



### GLUCAN TEST RESULTS

1. When the test is complete, the PTS Reader gives an audible notification that the assay is finished.
2. At the conclusion of the test, the glucan measurement and the assay acceptance criteria are displayed on the screen.
3. The reader display alternates between the following results:
  - Sample pg/mL Value
  - Sample %CV
  - Spike pg/mL Value
  - Spike %CV
  - % Spike Recovery
  - Remove Cartridge

The reader continues to display the assay results until cartridge is removed. Once the assay is complete and the results are noted, remove the cartridge promptly from the reader.

**RETRIEVING RESULTS OPTIONS**

1. You can download results directly to your PC and retrieve from the designated location file.
2. You can use the Seiko<sup>®</sup> DPU-414 or the Epson TM-U220D Printer (available from Charles River Laboratories) to print the last test result, all results from a particular date, or up to a maximum of one hundred (100) stored test results.

**Example of Glucan Test Report:**

```

***** ENDOSAFE Test Record *****
          V7.12B 12/9/2008
DateTime: ..... 04/21/09 @ 08:59:40AM
Device: ..... 0633
OperatorID: ..... DN
Cartridge: ..... PTS Glucan
Temperature: .. Start: 37.0C End: 37.0C
Method: ..... KX-122
Cartridge Lot#: ..... 9107441
Cartridge Cal Code: ..... 901630102934
Range: ..... 1000-10.00
Range Time: ..... Sec: 16-701
Onset Times: ..... >701 098 >701 102
Slope: -0.821 ..... Intercept: +3.667
Dilution: ..... 1
Sample Lot: ..... 21042009
Sample ID: ..... RD0901
Sample Rxn Time CV: ..... 0.0% Pass
Spike Value: ..... 97.2 pg/mL
Spike Rxn Time CV: ..... 2.8% Pass
Spike Recovery: ..... 99% Pass
Test Suitability: ..... Pass
Sample Value: ..... <10.0 pg/mL
:

```

## Appendix E

Abbreviations used in this User's Guide:

PTS	Portable Test System
LAL	Limulus Amebocyte Lysate
FDA	Food and Drug Administration
EU	Endotoxin Unit
LRW	LAL Reagent Water

Information Only

## Appendix F

### Decontamination Procedures

Warning: Do not immerse the Endosafe<sup>®</sup> – PTS instrument, spray it with liquid, or use a “wet” cloth. Do not allow the cleaning solution to run into the interior of the Endosafe<sup>®</sup> – PTS instrument. If this happens, contact Charles River Laboratories Technical Service Department.

Do not soak the keypad, this will cause damage.

Important! Turn off and unplug the Endosafe<sup>®</sup> – PTS instrument for all decontamination and cleaning operations.

1. Turn off and unplug the Endosafe<sup>®</sup> – PTS instrument.
2. Moisten a cloth with a mild detergent solution. Do not soak the cloth. Wipe down all surfaces of the Endosafe<sup>®</sup> – PTS instrument.
3. Use a clean dry cloth to dry all wet surfaces.