

The Endosafe[®] – MCS[™] Multi-Cartridge System

USER'S GUIDE




charles river | endotoxin and
microbial detection

1023 Wappoo Road • Suite 43-B, Charleston, SC 29407
Phone: 843.766.7575 • Fax: 843.766.7576
www.criver.com • endo-comments@crl.com

Table of Contents

Safety Guidelines	1
Endosafe[®] - MCS System Overview	
Reader Specifications	3
Cartridge Specifications.....	4
Accessory Products.....	4
Environmental Requirements.	5
Installation.....	5
Controls and Signals.	5
Endosafe[®] - MCS Service Programs	
Warranty with Purchase.....	8
On Demand Repairs.....	9
Returned Goods Authorization Procedure.....	9
Warranty Registration.....	9
Using EndoScan-V with Endosafe [®] -MCS for data acquisition.....	10
Troubleshooting	13

Appendixes

Appendix A

Performing Routine Endotoxin Test.....	A1
Endotoxin Test Results	A2
Retrieving Results Options	A2

Appendix B

Performing Routine Gram ID Test	B1
Gram ID Test Results	B3
Retrieving Results Options	B3

Appendix C

Performing Inhibition/Enhancement Test	C1
Test Results.....	C3

Appendix D

Performing Routine Glucan Test.....	D1
Glucan Test Results	D2
Retrieving Results Options	D2

Appendix E

Abbreviations Used.....	E1
-------------------------	----

Appendix F

Decontamination Procedures.....	F1
---------------------------------	----

SAFETY FIRST

WARNING

- DO NOT use an AC power cord other than that which has been delivered with your system. Only plug the cord into a socket which is grounded. Using a different cord may cause fire leading to serious injury.
- DO NOT place MCS system around any liquids or use in a location where it could get wet or splashed. Liquids could cause fire or electric shock.
- IF the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.

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 unplug AC power cord or PC cable by pulling cord/cable directly. Doing so may damage cord and cause injury. Handle the AC power cord and Serial Port Connector directly to unplug.

Read this User's Guide carefully before using the Endosafe[®] - MCS System. Understanding- the proper usage and operation is imperative for the safety of the User, as well as the protection of the Endosafe[®] - MCS System.

Endosafe[®] - MCS – System Overview

The Endosafe[®] - MCS (Multi-Cartridge System) is a rapid test system which is comprised of a test cartridge along with a spectrophotometer.

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

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

Product	Description	Catalog #	Quantity
Endosafe [®] - MCS kit Reader and Integrated software Integrated power supply Power cable User's Guide	<i>Multi-Cartridge Multi-Cartridge System</i>	MCS100	Each
Endosafe [®] - Licensed Cartridge Pack (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	1/pack
Endosafe [®] - Unlicensed Cartridge Pack (10 cartridges per package)	0.1 EU/mL sensitivity 0.05 EU/mL sensitivity 0.01 EU/mL sensitivity	PTS201 PTS2005 PTS2001	1/pack
Endosafe [®] - PTS Inhibition/Enhancement Screening Cartridge Pack (10 cartridges per package)	Inhibition/Enhancement Screening	PTS220	1/pack
Endosafe [®] - PTS RMM Gram ID Cartridge (10 cartridges per package)	Gram ID	LRMMGI100	1/pack
Endosafe [®] - PTS RMM Glucan Cartridge (10 cartridges per package)	(1→3)-β-D-Glucan	RMMGS1000	1/pack

Endosafe[®] - MCS Reader Specifications

- Temperature control: 37° C ± 1° C
- Data interface: USB port
- Printer support: Windows supported printer
- Data storage: Files are stored on PC
- Dimensions: 375mm (D) x 370mm (W) x 105mm (H)
- Power supply unit: 100-230VAC, 50/60Hz, 1.75 A max.
- Power supply on board: 12 V DC, 5A
- Fuse: 2x T2.5A/L 250V, 5x20mm
- Warm-up time: Approximately 5-10 minutes from 20° C start
- Display: Computer Monitor
- Environmental Conditions:
 - Operating Temperature 15° to 27° C
 - Humidity 5% to 80% noncondensing
 - Indoor use
 - Altitude : normal environmental conditions
- Weight: 8.3 kg

Endosafe[®] - MCS 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 \pm 1° C

Sample requirement: 25 μ L sample per channel

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

Endosafe[®] - PTS Accessory Products

Product	Description	Code
PC Cable	Standard USB cable, Type A and Type B	PTS108
Endosafe [®] - MCS mini pipettor	25 μ L disposable unit with \pm 5% accuracy and \pm 3% precision at full stroke	PTS400
Eppendorf ^{®*} pipette tips	200 μ L, individually wrapped, validated to 0.005 EU/mL	D100

*Eppendorf is a registered trademark of Brinkmann

Multiple patents pending.

Endosafe[®] - MCS Reader Environmental Requirements

Surface: flat, level surface, vibration free

Surroundings: free from dust, solvents and acidics vapours, and out of direct sunlight

Operating Temperature: 15° to 27° C

Humidity: 5% to 80% noncondensing

Endosafe[®] - MCS Reader Installation

The MCS reader comes as a ready to use device, so no further installations on the hardware are necessary.

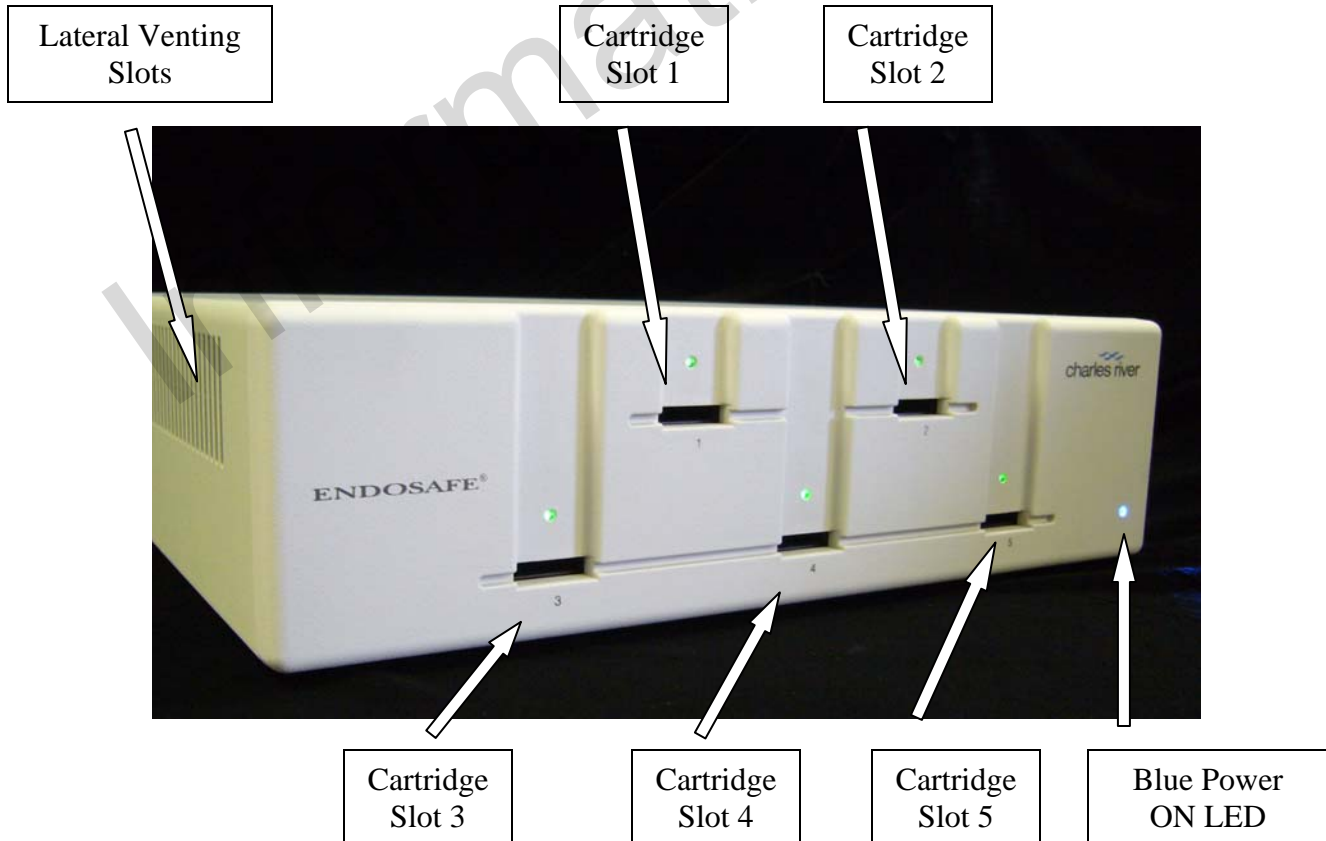
Simply connect the MCS reader to the computer with the provided USB cable. The Type B connector goes to the reader and the Type A connector to the PC.

Provide the MCS reader with power by connecting the provided power cable to the entry module of the reader and the grounded mains outlet. **DO NOT USE UNGROUNDED POWER OUTLETS.**

During operation of the MCS reader the lateral venting slots must not be blocked. Also the cooling fan in the back of the MCS reader must not be blocked at any time. Please ensure a 50 mm safety clearance on the left, right and back side of the instrument.

Endosafe[®] - MCS Reader Controls and Signals

Front/Side view:



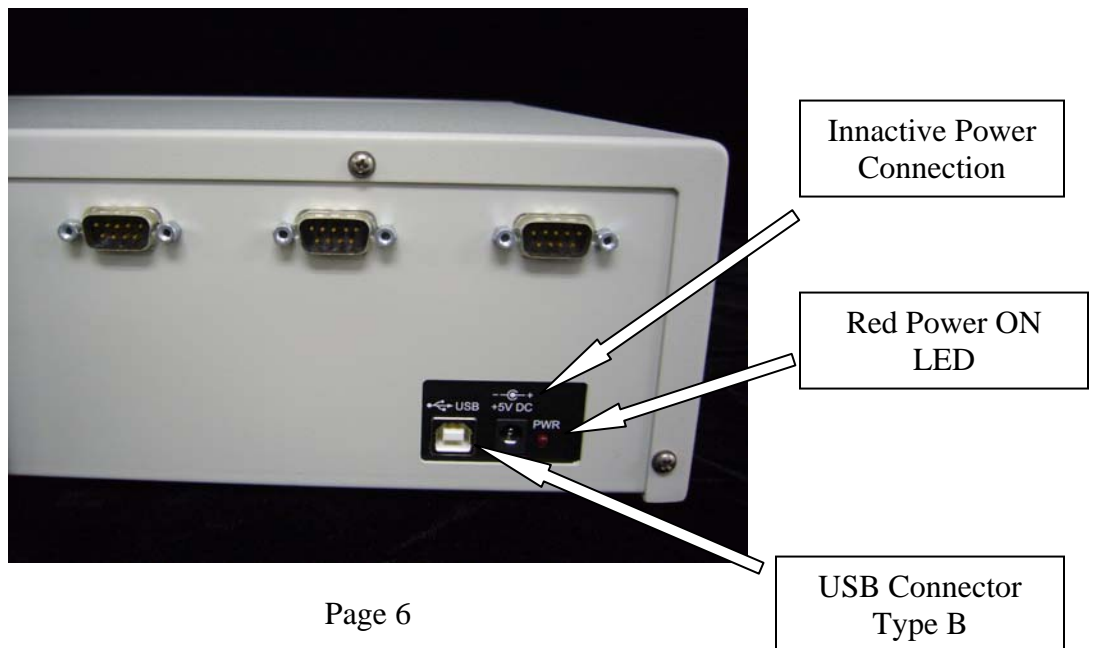
Side view:



Back left view:



Back right view:



After the warm-up time you will notice a short beep for each of the five (5) cartridge slots to indicate that the temperature has reached 37 degrees Celsius. The MCS reader is then ready to be operated through EndoScan-V. Cartridges can now be used according to our cartridge package inserts.

Please hold the cartridges as shown below. Touch only the "handle" end of the cartridge (curved edges) to place the cartridge into the reader.



Insert cartridge firmly into the slot at the front of the reader with the sample reservoirs facing up.



Endosafe[®] - MCS Service Programs

WARRANTY with PURCHASE

Charles River Laboratories warrants the Endosafe[®] - MCS 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 reader will invalidate warranty provisions.

Additional service contracts are available as follows:

Service	Code
Performance Qualification (PQ) Service	TS502
IQ,OQ,PQ Package	MCS502
On Demand Repairs	MCS503

ON DEMAND REPAIRS

After the initial Warranty Period has ended, the client may request Charles River Laboratories to service or repair the MCS. Charles River Laboratories will arrange transfer of the MCS 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

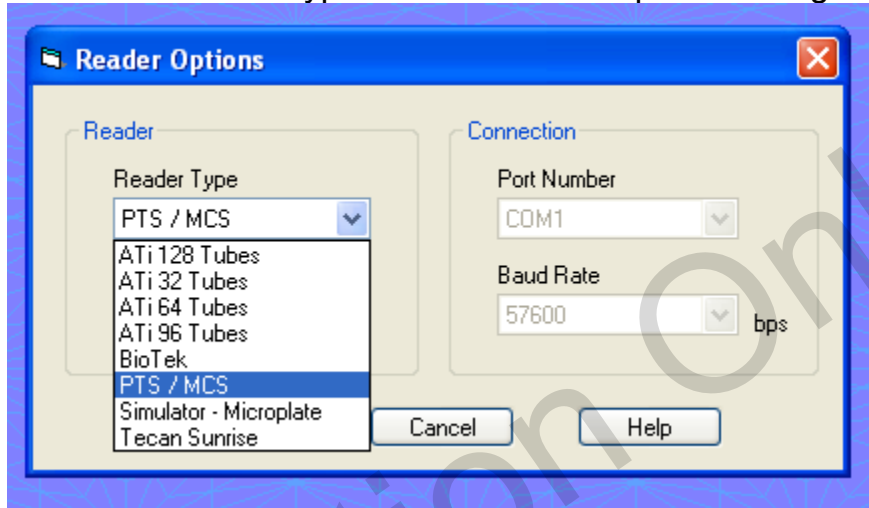
A Warranty Registration Card is provided in this User's Guide, and is also available online at www.criver.com. Submitting the completed card will permit the Technical Services Department to more efficiently meet each client's needs. All warranty and service options are subject to the Terms and Conditions and procedures specified in the Service Agreement. For answers to questions about any of these components for the Endosafe[®] - MCS 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 4

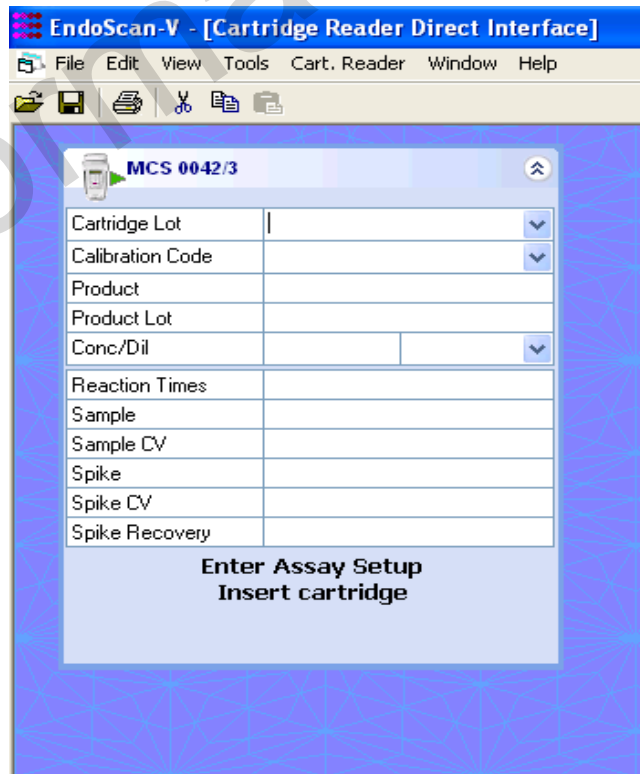
Operating the Reader

Using EndoScan-V with Endosafe[®]-MCS 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 MCS Reader the following screen will appear. This will show all available bays for each instrument connected.



5. Select Tools/Options/Calculations and change CV Limit Products and CV Limits Standards to 25. Change Spike recovery range to 50 to 200
6. Enter the Cartridge lot number. The Cartridge lot number will be stored for later use.
7. Enter the Calibration code. The Calibration code will be stored for later use.
8. Enter product information by either typing directly into the box or by dragging information from the product database into the dialog box.
9. Enter the concentration or dilution.
10. Insert the cartridge into the bay.
11. Select the Send Setup button to send information to the MCS Reader.

MCS 1412/1	
Cartridge Lot	7108155
Calibration Code	512727564808
Product	LRW
Product Lot	B52720
Conc/Dil	1 ml/ml
Reaction Times	
Sample	
Sample CV	
Spike	
Spike CV	
Spike Recovery	

Enter Assay Setup

Send Setup

12. Once the Add sample and Click start message is displayed dispense 25 μ L into each well of the test cartridge.
13. Repeat steps 5 through 12 for each "bay" that will be used.
14. While in progress the screen will display messages showing the current status.

Cartridge Lot	7108155
Calibration Code	512727564808
Product	LRW
Product Lot	B52720
Conc/Dil	1 ml/ml
Reaction Times	
Sample	
Sample CV	
Spike	
Spike CV	
Spike Recovery	

**Preparing to start assay
Please wait**

15. 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.

Cartridge Lot	7341167
Calibration Code	112436855083
Product	LRW
Product Lot	B52720
Conc/Dil	1 ml/ml
Reaction Times	>768 302 >768 288
Sample	<0.01 EU/ml
Sample CV	0.0 %
Spike	0.102 EU/mL
Spike CV	3.4 %
Spike Recovery	73 %

**Assay complete
Don't insert cartridge**

New Assay

16. Select the report option to print a report for this assay.
 17. Select the save or save as option to save the assay as an EndoScan-V file.
 18. The screen will display a message asking to save an individual assay or all assays that have been completed.
 19. Select the desired method.
 20. Assay is now saved as an EndoScan-V file.

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 reader from running a test.
- Unless it is a hardware problem, the only way to clear an error message is to turn the reader OFF and back ON again.

MESSAGE	DESCRIPTION
"A2D SETUP"	Photo A/D setup 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
"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 or (843) 766-7575

Europe: 00 800 15 78 97 43

Fax: (843) 766-7576

E-Mail: endo-comments@crl.com

Appendix A

Endosafe[®] - MCS Endotoxin

PERFORMING ROUTINE TEST

A routine MCS LAL assay is conducted by following the setup procedure. The following represents a typical assay procedure:

1. Instrument Operation

- Open the EndoScan-V software
- Verify the screen contains a panel for each bay of the instrument

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 one of the slots at front of the MCS Reader

Press cartridge firmly into slot

3. Enter Required Information

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

- **Enter Cartridge Lot #**
- **Enter Calibration Code** (If the Calibration Code for the particular lot # has already been entered, the software automatically inputs this information until the lot numbers and calibration codes are erased by the user).
- **Enter Product** (Enter a sample ID or drag and drop information from the database).
- **Enter Product Lot#**
- **Enter Dilution Factor or Concentration**
- **Select the Send Setup box on the screen to transfer the product information to the MCS Reader.**
- **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 reader, the cartridge is being pre-warmed.

4. Dispense the Sample

Once all test information is entered, the software displays:

- **Add Sample and click Start**
- Pipette 25 μ L of sample into all four (4) sample reservoirs of the inserted cartridge and select the start assay button on the panel.
- Pumps draw sample aliquots into the test channels, thereby initiating the test
- Results will be obtained in approximately 15 minutes

TEST RESULTS

1. When the test is complete, the results will be displayed on screen.

The software continues to display the assay results until the new assay button is selected.

RETRIEVING RESULTS OPTIONS

1. Select Report from the file menu or the printer icon from the toolbar. The assay results will be shown in a report format.
2. Results may be printed to any Windows compatible printer.

Appendix B

Endosafe[®] - MCS 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 EndoScan-V software. The following represents a typical assay procedure:

The MCS 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

- Open the EndoScan-V software
- Verify the screen contains a panel for each bay of the instrument

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 one of the slots at front of the MCS Reader

Press cartridge firmly into slot



3. Enter Required Information

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

- **Enter Cartridge Lot #**
- **Enter Calibration Code** (If the Calibration Code for the particular lot # has already been entered, the software automatically inputs this information until the lot numbers and calibration codes are erased by the user).
- **Enter Product** (Enter a sample ID or drag and drop information from the database. Repeat procedure 3 times and separate sample IDs by a semi-colon).
- **Enter Product Lot#** (Separate product Lots# by a semi-colon).
- **Enter Dilution Factor**
- **Select the Send Setup box on the screen to transfer the product information to the MCS Reader.**
- **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 reader, the cartridge is being pre-warmed.

4. Dispense the Sample

Once all test information is entered, the software displays:

- **Add Sample and click Start**
- Pipette 25 μ L of sample into all four (4) sample reservoirs of the inserted cartridge and select the start assay button on the panel.
- 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 results will be displayed on bay screen as "+", "-" and "Y/M".
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.

The software continues to display the assay results until the new assay button is selected.

RETRIEVING RESULTS OPTIONS

1. Select Report from the file menu or the printer icon from the toolbar. The assay results will be shown in a report format.
2. Results may be printed to any Windows compatible printer.

Appendix C

Endosafe[®] - MCS Inhibition/Enhancement Screen

PERFORMING INHIBITION/ENHANCEMENT TEST

An Inhibition/Enhancement MCS LAL assay is conducted by following the simple setup procedures. 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

- Open the EndoScan-V software
- Verify the screen contain a panel for each bay of the instrument

2. Insert the Cartridge

Remove cartridge from pouch and insert with sample reservoirs facing up into one (1) of the bays at front of the MCS 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, enter the following information into the software:

- **Enter Lot #** (Cartridge Lot #)
- **Enter Calibration Code** (If the Calibration Code for the particular lot # has already been entered, the software automatically inputs this information until the lot numbers and calibration codes are erased by the user.)
- **Enter Product** (If testing different products then enter the product information for each channel separated by a semi-colon. Sample 1 is designated as the well on the far left after cartridge is inserted into the reader. If testing the same product in all four (4) channels then it is only necessary to enter the product once.)

- **Enter Product Lot #** (If testing different lots of product then enter lot # separated by a semi colon. If testing the same lot # in all four (4) channels then it is only necessary to enter the lot # once.)
- **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 Conc/Dilution** (If testing different concentrations or dilutions then enter each concentration/dilution separated by a semi colon. For example, enter 1; 10; 100; 1000 if testing these dilutions. Select the unit of measure using the arrow down button.)
- **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 reader, the cartridge is being pre-warmed.

4. Dispense the sample

Once all test information is entered, the software displays:

- **ADD SAMPLE and click Start**
- Pipette 25 μ L of sample into four (4) sample reservoirs of the inserted cartridge and press **the start button**. (Be sure to change tips between each dilution or sample)
- Pumps draw sample aliquots into the test channels, thereby initiating the test
- Results will be obtained in approximately 15 minutes

TEST RESULTS

1. When the test is complete, the MCS 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 software displays the following results:
 - Spike #1 Recovery
 - Spike #2 Recovery
 - Spike #3 Recovery
 - Spike #4 Recovery

When the test is complete the results will be displayed on the screen. The software continues to display the assay results until the new assay button is selected.

Appendix D

Endosafe[®] - MCS Rapid Micro Methods Glucan

PERFORMING ROUTINE GLUCAN TEST

The PTS Glucan assay is used for the detection of (1,3)- β -D-Glucans. The Endosafe[®] - MCS Glucan assay is intended for research purposes only and is not to be used for diagnostic testing purposes.

A routine MCS Glucan assay is conducted by following the simple prompts on the EndoScan-V software. The following represents a typical assay procedure:

1. Instrument Operation

- Open the EndoScan-V software
- Verify the screen contains a panel for each bay of the instrument

2. Insert the Cartridge

Remove cartridge from pouch and insert with sample reservoirs facing up into slot at front of the MCS 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 software prompts the user to enter the following information:

- **Enter Lot #** (Cartridge Lot #)
- **Enter Calibration Code** (If the Calibration Code for the particular lot # has already been entered, the software automatically inputs this information until the lot numbers and calibration codes are erased by the user).
- **Enter Product** (Enter a sample ID or drag and drop information from the database).
- **Enter Product Lot#**
- **Enter Dilution Factor or Concentration** (Manually type "pg/mL" for the unit of measure)
- **Select the Send Setup Box on the screen to transfer the product information to the MCS Reader.**

- **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.

2. Dispense the sample

Once all test information is entered, the reader displays:

- **ADD SAMPLE and click Start**
- Pipette 25 μ L of sample into four (4) sample reservoirs of the inserted cartridge and select the start assay button on the panel.
- 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 MCS Reader gives an audible notification that the assay is finished and the results will be displayed on the screen.

The software continues to display the assay results until the new assay button is selected.

RETRIEVING RESULTS OPTIONS

1. Select Report from the file menu or the printer icon from the toolbar. The assay results will be shown in a report format.
2. Results may be printed to any Windows compatible printer.

Appendix E

Abbreviations used in this User's Guide:

MCS	Multi-Cartridge Multi-Cartridge System
LAL	Limulus Amebocyte Lysate
FDA	Food and Drug Administration
EU	Endotoxin Unit
LRW	LAL Reagent Water
Bay	Slot on the face of the MCS corresponding to an individual testing device

Information Only

Appendix F

Decontamination Procedures

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

Important! Turn off and unplug the instrument for all decontamination and cleaning operations.

1. Turn off and unplug instrument.
2. Moisten a cloth with a mild detergent solution. Do not soak the cloth. Wipe down all surfaces of the instrument.
3. Use a clean dry cloth to dry all wet surfaces.

Information Only