

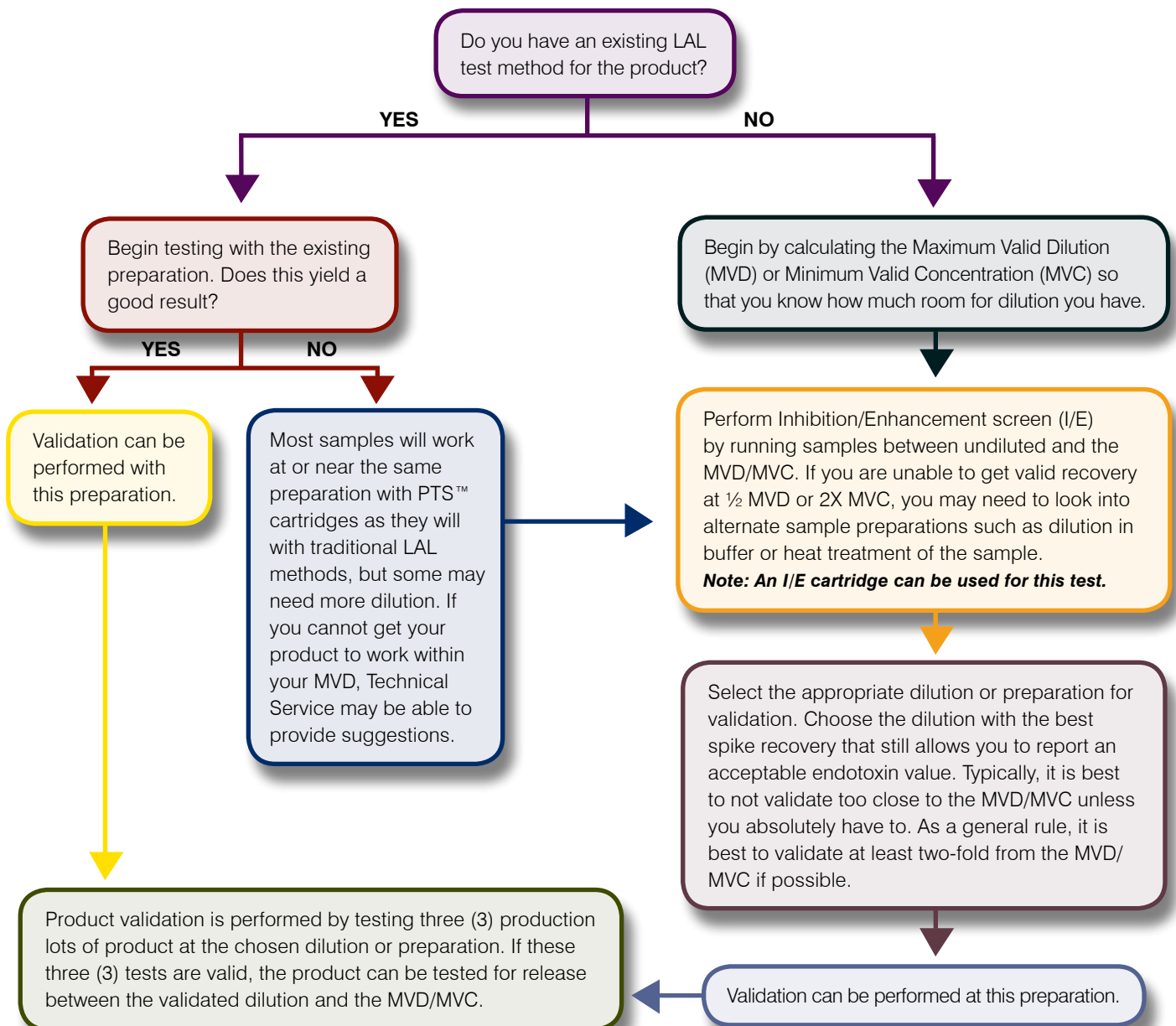
Endosafe[®]-PTS[™] Quick Start Guide

Getting Started with PTS[™]

In a regulated environment, there are three (3) steps to using the Portable Test System (PTS[™]) for product release:

1. The unit should be qualified. Charles River Laboratories has an IQ, OQ, PQ document available for purchase (PTS502).
2. Standard Operating Procedures outlining testing using the system should be in place. Charles River Laboratories can provide a sample Standard Operating Procedure.
3. Product validation should be completed.

Product Validation Steps



Using the PTS™

Performing Routine Tests

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 five 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 the slot at the front of the PTS™ reader.
- Press cartridge firmly into the slot.

*Note: PTS™ cartridge should be stored at 2-25°C. Allow the cartridge to come to room temperature in pouch before opening.**



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 number).
- Enter Calibration Code – Each lot of cartridges will have a unique calibration code. If the calibration code for the particular lot number has already been entered, the PTS™ reader does not prompt for the code again. To erase all stored lot numbers and corresponding calibration codes, select MENU 2 and 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.



4. Dispense the Sample

Once all test information is entered, the PTS™ reader displays:

- ADD SAMPLE; PRESS ENTER.
- Pipette 25 µL 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 if sample has no detectable endotoxin.

** Cartridges should come to room temperature in approximately 10-15 minutes if stored refrigerated at 2-8°C.*

Retrieving Results

From Epson or Seiko printer:

1. Connect Cable – Serial port connection to printer and RJ45 plug in back of the PTS™ reader (cable is provided with PTS™ system).
2. Press the MENU key on the PTS™ reader keypad.
3. 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
4. Selecting one (1) of the above three (3) choices on the PTS™ reader keypad will send results to the printer.

Results can also be retrieved in a secure electronic format through optional EndoScan-V™ software and PC. Refer to the PTS™ User's Guide for instructions.

Interpretation of Results

Sample EU/mL:

Endotoxin value of the sample with dilution factor taken into account.

Sample RT CV:

Coefficient of variation for the sample channel reaction times; Must be <25% for a valid test result.

Spike RT CV:

Coefficient of variation for the spike channel reaction times; Must be <25% for a valid test result.

Spike Recovery:

Percentage of the positive product control or spike that was recovered; Must be between 50 and 200% for a valid test result.

Challenging the PTS™

One of the more common questions from new PTS™ customers is: "Why is my solution not giving the expected value with the PTS™ system?" and usually this is because the system is being incorrectly challenged, using Control Standard Endotoxin (CSE). CSE and other non-primary standards cannot be used for endotoxin verification on the PTS™. In order to use CSE, a manufacturer must standardize CSE against the Reference Standard Endotoxin (RSE) on a lot-specific basis to obtain an EU/ng ratio for that lot combination. We perform all testing on the PTS™ cartridges using the RSE, which is the USP/FDA standard. RSE must be used to obtain appropriate values because there has been no RSE/CSE standardization performed for PTS™ cartridges as it has with LAL/CSE combinations.

Battery Information

The PTS™ comes with an internal battery to make the system truly portable, but often the unit is used in a single location in the lab, where it can be used on AC power at all times. Constantly being connected to a power source will shorten the life of the battery. To extend the life of the battery, it should be discharged fully at least once every two-three weeks. The unit will not start a test unless there is enough battery power to complete the assay, so there is no need to worry about a test being aborted due to a low battery. More detailed information on this subject is available in the user's guide.

Accessory Products for the PTS™ *

PTS™ Cartridges

Cartridges come in a variety of sensitivities and packaging configurations, as well as FDA-licensed and unlicensed. Licensed cartridges should be used for official release of product, and unlicensed cartridges are good for research & development.

PTS™ Inhibition and Enhancement Cartridges

Inhibition/Enhancement cartridges allow four (4) samples or four (4) dilutions of a sample to be tested on one (1) cartridge to determine the presence of inhibition or enhancement. These cartridges do not detect endotoxin in the sample and only report a spike recovery value, so samples evaluated on I/E cartridges should be free of detectable endotoxin.

LAL Reagent Water (LRW)

LRW is water that is free of detectable endotoxin and non-interfering to the assay. Charles River Laboratories offers LRW in a variety of sizes.

Dilution Tubes

Tubes for sample dilution should be free of detectable endotoxin. Charles River Laboratories offers a variety of sizes of borosilicate tubes for dilution.

Buffers

Charles River Laboratories offers several buffers for sample adjustment to account for pH, divalent cation reduction, and glucan-related interference. Contact Technical Service for advice on buffer use.

Pipettes

Charles River Laboratories offers glass depyrogenated, serological pipettes in a variety of sizes. Pipettes used for sample dilution should be free of detectable endotoxin and non-interfering to the assay.

25 µL Pipettor

A mini, disposable pipettor is supplied with the PTS™ system; however, we recommend a calibrated fixed-volume pipettor for regular use. 200 µL tips are also available.

** Not Included. See catalog for pricing and product codes.*