**In this issue:**
LAL-5000 with *Pyros*™
New Canadian Agent

# LAL UPDATE®

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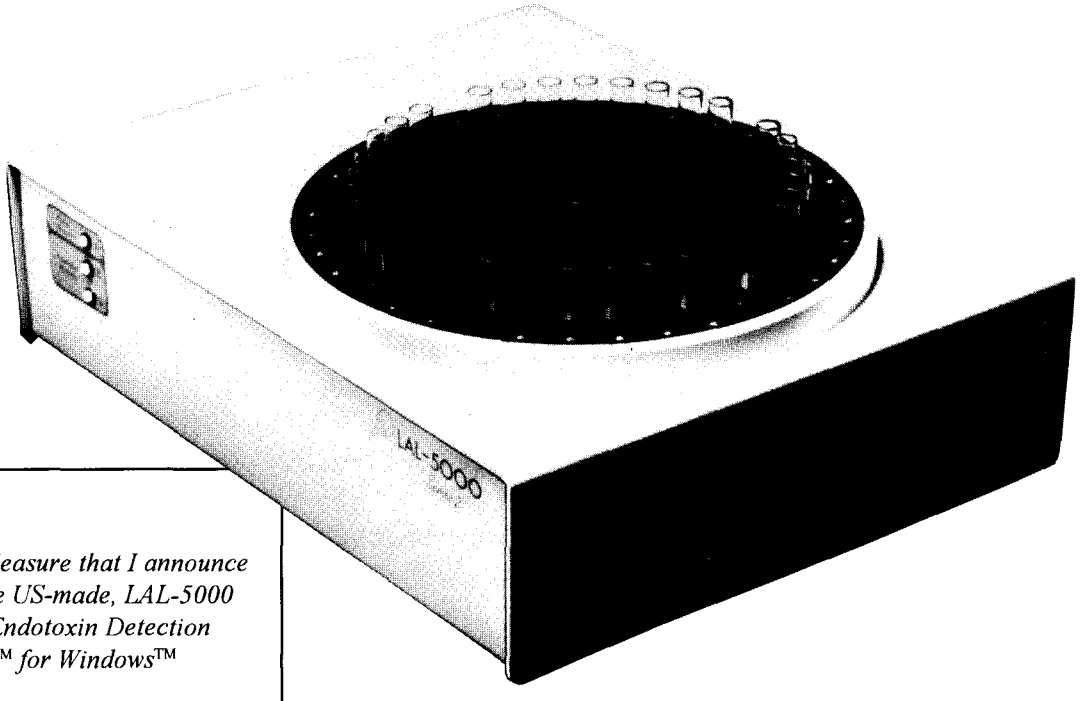
# LAL-5000 *Series 2* Automatic Endotoxin Detection System with *Pyros* ™ Software




*Dear LAL User,*

*It is with great pleasure that I announce the availability of the US-made, LAL-5000 Series 2 Automatic Endotoxin Detection System with Pyros™ for Windows™ software.*

*Ten years have passed since the introduction of the first dedicated instrument for LAL testing. In November 1984, at the PDA annual meeting in Philadelphia and in the LAL UPDATE®, Vol. 3 No.2, the introduction of the LAL-4000 was announced. It is fitting that the new system will be seen first at the PDA annual meeting in Philadelphia, November 3-5, 1994 in our 20th anniversary year.*

*Sincerely,*

*Thomas J. Novitsky, Ph.D.*
*Editor*

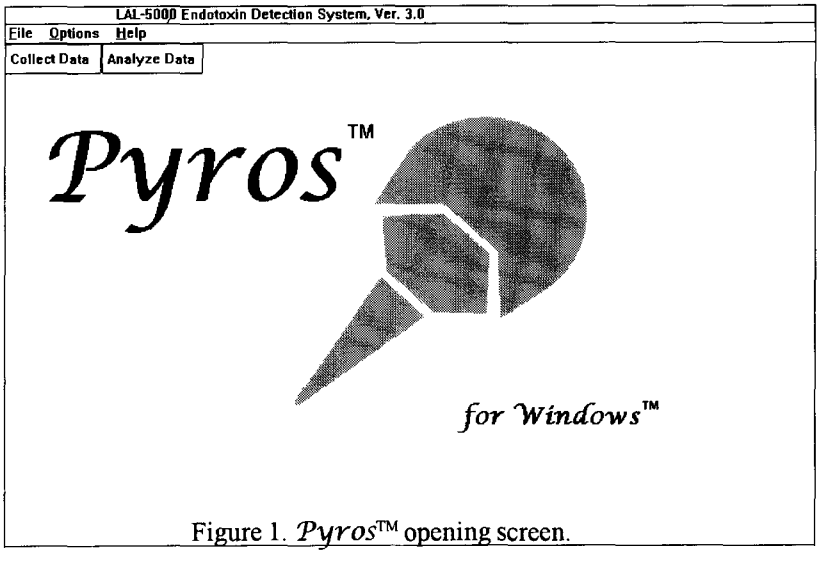



Figure 1. *Pyros*™ opening screen.

The new LAL 5000 system features the *Series 2* instrument and *Pyros*™ software. Manufacture of the LAL-5000 *Series 2* has been transferred from Europe to the United States. The instrument is the same as before and parts are interchangeable with other *Series 2* instruments. The software, however, is completely new.

*Pyros* is a Windows™ program with quite a different look and feel. In fact, it embodies a completely different philosophy. Whereas the DOS-based LAL-5000 (and LAL-4000) software was essentially linear and forced the user to go from step to step in a predetermined fashion, *Pyros* gives the user a wide range of options that do not have to be taken in a particular order. The program is very flexible. It incorporates a host of new features and is easy to use.

### An Overview of *Pyros*

After clicking on the *Pyros* icon at Windows™ Program Manager, the opening screen is displayed. If the password access security option has been activated, you will be required to enter your password to run the program.

The main features of the opening screen (Fig. 1) are the **Collect Data** and **Analyze Data** buttons. There is also a typical Windows menu bar that enables you to perform file functions, access security and default setting options and use the Help utility.

Usually, you will either click on **Collect Data** to set up and run a test, or on **Analyze Data** to look at the data for a completed test.

The main screen for **Collect Data** is a list of well numbers that will display information that you specify for each well and results as soon as they are available. Click on the appropriate buttons for fast and easy test setup, or use a previously stored test format as with Version 2 of the LAL-5000 program. Unlike Version 2, *Pyros* lets you set up a test and then close the file so you can come back to collect data later. Major new features include the ability to see real time data plots (Fig. 2) and results as soon as they are available.

*Pyros* also allows real time editing during data collection. If additional samples need to be inserted after a test has begun, descriptors can be added and tubes can be inserted into the LAL-5000. This kind of flexibility is impossible for a plate reader because the plate is inside the incubation chamber and wells are not individually timed.

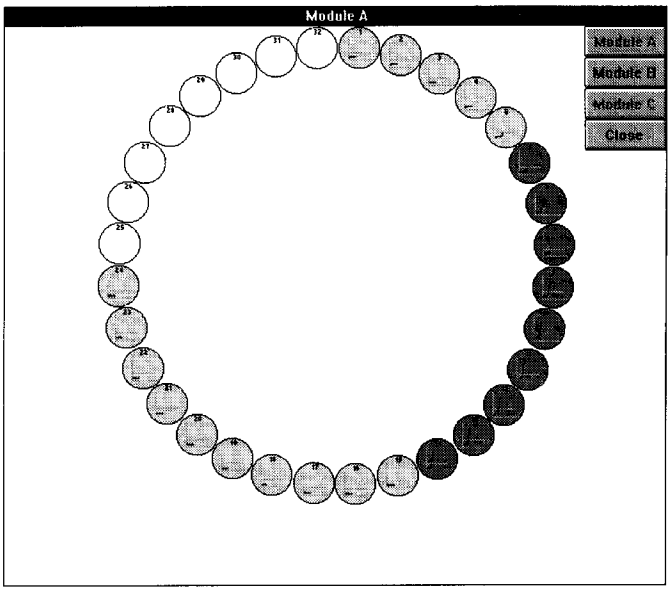


Figure 2. Graphic display of test status during data collection.

At the end of a test, *Pyros* will analyze the data file and print results. Files can be reviewed at any time by clicking on the **Analyze Data** button on the opening screen. The main screen for this module is similar to that for **Collect Data** and shows results for individual wells. Buttons across the top of the screen provide a wide range of options.

The **Std. Curve** function allows analysis using different standard curves. **Graphics** enables you to view the data plots (Fig. 3) and standard curves. An important new feature is **Results,** which gives summaries and reports of the results (Fig. 4).

*Pyros* has a potency determination feature. Simply run a test of the RSE and the appropriate CSE and the program will calculate the potency of the CSE. Another added feature that had been frequently requested is the option of saving a file containing the results and the ability to export the results to other applications.

The principle features of the LAL-5000 software Version 2 are retained, including autoanalysis, archived standard curves and stored test formats.

### Details of the Major Features

#### Security

A system administrator can set up the program so that a password must be entered before a user can get into the program to either collect or

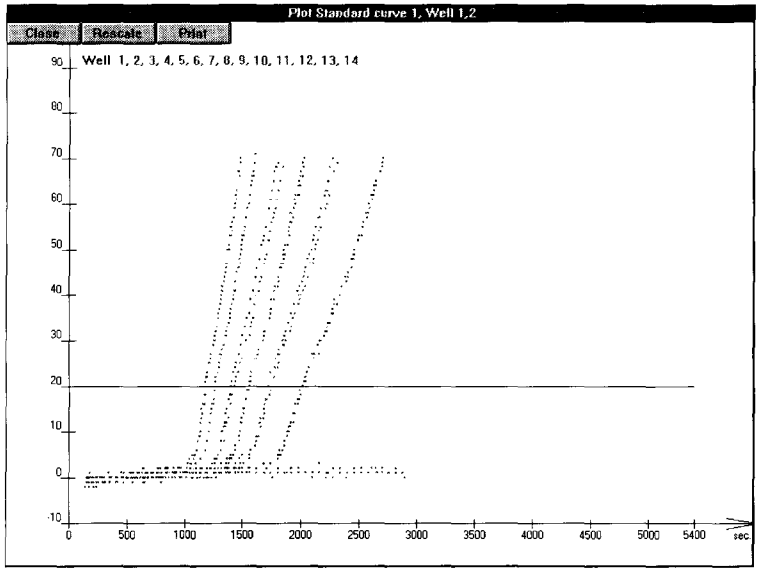



Figure 3. Plot of data in Data Analysis.

analyze data. The default parameters can also be locked so that users cannot change the test parameters unless the administrator unlocks them.

**Test Setup**

Specifying the descriptors for the wells is easy. First click on **Neg. Ctl.** and specify the number of negative controls required. Then click on the **Std. Curve** button. Enter the highest standard concentration, the number of dilutions, the dilution factor, the number of replicates and the first well. The program will then fill in the descriptors for the appropriate wells.

Similarly for a **Sample**, specify the number of dilutions, the dilution factor, the initial concentration and the spike concentration. You can also specify the endotoxin limit and initial concentration of the sample so that the program can determine the MVD and whether or not the endotoxin limit has been exceeded. Then click **OK**. The program does the rest. Alternatively, you can use a test format that you have stored for routine tests with a similar setup.

Editing the test setup is also simple and can be done either before or after data collection has started. New sample descriptors can be added while a test is running to accommodate additional samples.

**Real Time Data Plots**

You can view test data as it is collected on a graphic representation of the instrument with the circle of wells while a test is running (Fig.2). The data is plotted for each well in the appropriate position on the display. Click on any of the 32 small plots for a full screen display of an individual plot. When the onset time is reached for a particular well, the background color of the circle changes from yellow to green for an "at-a-glance" indication of test status.

**Real Time Display of Results**

You can switch between the graphic display of results and the numeric data. The numeric display consists of the main screen table with the well descriptors and time and current OD for each well. When sufficient data has been collected to construct a standard curve, endotoxin concentrations are calculated and displayed for each sample as soon as an onset time has been reached.

**Continuous Data Backup**

Raw data, transmitted by the LAL-5000, are continuously stored in a data file on the computer's hard drive. Should a test be interrupted by a power failure, this file can be used to reconstruct the data file up to the point at which the test was interrupted. Access to the raw data file is also useful for system validation.

**Calculation of Results**

Three results summaries are available that give details of the

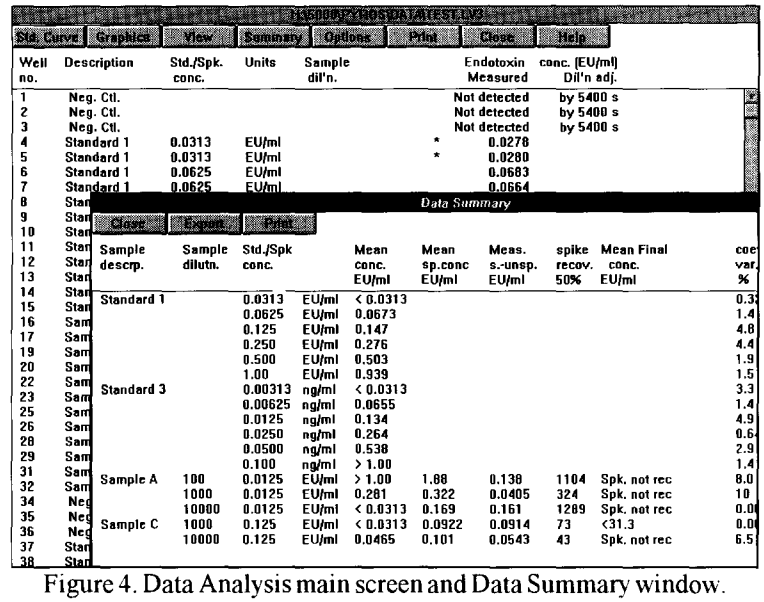



Figure 4. Data Analysis main screen and Data Summary window.

calculation of means and spike recovery. The data summary (Fig. 4) gives the means of all replicates and determines spike recoveries and coefficients of variation. A sample summary gives the results for all the samples in the test with their endotoxin limits and can provide a pass/fail decision based on the endotoxin limit. The single sample summary provides a single page report for a selected sample giving all the pertinent test data and comments.

**Data Export**

The results for individual wells or the summaries of results can be saved as a text (ASCII) file. They can then be incorporated into word processor documents, into spread sheets or databases or a LIMS (Laboratory Information Management System) for trending data, or electronic storage of reports.

**Help**

On-line help is available by clicking on Help almost anywhere in the program.

**Conclusion**

The LAL-5000 *Series 2* Automatic Endotoxin Detection System with *Pyros*™ software make a powerful combination. The most sensitive LAL test available is coupled with *Pyros*, a sophisticated software package that advances automated LAL testing and provides a high degree of flexibility while being remarkably easy to use.

**ACC Appoints New Canadian Agent**

Associates of Cape Cod, Inc. is pleased to announce the appointment of **Betatek Inc.** (Markham, Ontario) as sales agents for Canada. Betatek was formed to serve the testing needs of the Canadian pharmaceutical marketplace and is dedicated to providing superior customer service to the growing number of LAL users.

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