LAL Update®

ASSOCIATES OF CAPE COD, INCORPORATED

May 2008 • Volume 24, No.2

Letter From the President

Dear LAL User:

Spring has come to our corner of Massachusetts. It is always a little later here than on the mainland because of the cooling effect of the surrounding ocean, but the osprey have returned and the herring have travelled up the streams to spawn. For Associates of Cape Cod, this means that the horseshoe crab season is here. The crabs have emerged from the sea floor and are moving in shallow waters, and we have started our sustainable crab collection and return process.

This spring we are pleased to inform you of two important developments. First, we are proud to announce the release of Pyros® EQS [Endotoxin Quantification Software] for use with our Pyros Kinetix® tube reader, the most sensitive endotoxin detection system on the market today. The main article of this issue of this LAL Update highlights the new and enhanced features of this exciting new product.

Second, we are very pleased to report the completion of CE marking of our Fungitell® in vitro diagnostic medical device product. Fungitell® is a powerful LAL based clinical tool to aid physicians in the diagnosis of invasive fungal infections. While the essentials of the Fungitell® kit are unchanged, the CE marked product features revised labeling with instructions for use in the kit in five languages and 17 languages available on our website www.acciusa.com.

ACC continues to push forward into new areas of product development in order to better serve your endotoxin and glucan detection needs.

Sincerely,

A.J. Meuse, Ph.D.
President and CEO

New From Associates of Cape Cod:
Pyros® EQS Software

By: Malcolm A. Finkelman, Ph.D.

Introduction

ACC is very pleased to announce the release of Pyros® EQS, the newest generation of ACC's tube reader software. Pyros® EQS has been specifically designed for endotoxin analysis using the Pyros Kinetix® instrument. It is configured for installation in environments ranging from a single station test lab to a complex multi-user network in large pharmaceutical or medical device facilities. Across that spectrum, it supports accurate endotoxin analysis in full compliance with the regulatory demands of Good Manufacturing Processes (GMP) and 21 CFR Part 11. While the new application was written from the ground up, it retains many of the features and procedure paths that are familiar to users of earlier versions of our software.

The changes in Pyros® EQS fall into two major categories: the underlying system level and in the application features. The changes at the system level include a completely new database engine and new ways in which the program interacts with your computer's operating system. At the application level, new features are included and many improvements have been made to those that existed previously. Users familiar with Pyros® and Pyrosoft® 11 software will feel right at home when using Pyros® EQS as the new application retains much of the "look and feel" of the predecessor programs (see figure 1). This enables experienced users to become proficient with minimal additional training. This article reviews the new software and describes a number of the changes and new features that we hope will enhance your endotoxin testing experience.
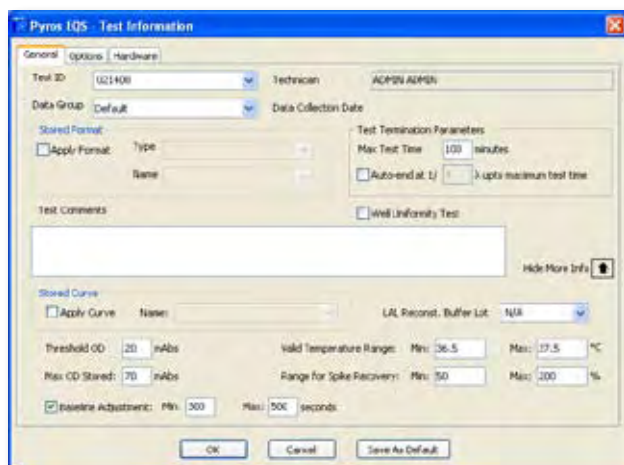
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NEW Product Report

figure 1

System Level Features

Stand-alone and Network Versions

Pyros® EQS has been designed to provide options that meet a range of needs, from small, single user installations, right up to enterprise-level multi-user, multi-facility systems. Pyros® EQS is pre-configured to adapt to environments that require either a server-based database with client workstations or all-in-one environments where both the database and the application are resident on the same workstation. The type of configuration is user-selected at installation using simple on-screen graphical instructions. Accordingly, a lab may have multiple workstations running Pyros® EQS and utilizing a central database or multiple stand-alone workstations. A fully-networked enterprise could even have more than one facility using a common database.

New Database Engine

With Pyros® EQS, users get the power of an Oracle® database engine. Widely used within the pharmaceutical industry, this database offers virtually unlimited storage and industrial strength database management tools. By implementing an Oracle® database, Pyros® EQS allows customers to scale from a single stand-alone workstation installation to multiple workstations in a client server environment, typical in the large industrial setting.

Security

Pyros® EQS does away with the need to have additional user names and passwords that are specific to the application. The software can utilize the network-level user authentication and passwords so that you only need to remember your usual log-in user ID and password. Users and administrators will appreciate the ability to manage security and access in this simplified approach. Routine changes in network passwords will automatically update in Pyros® EQS. These capabilities, coupled with the robust security provisions of the Oracle® database, offer Pyros® EQS users assurance of ease of use and data integrity.

Installation

The installation of Pyros® EQS and its Oracle® database is very straightforward and is guided by easy to follow on-screen instructions. The system requirements are described in detail in both the comprehensive Pyros® EQS User Manual and the handy Quick Install Guide that comes with the software. The stand-alone workstation computer requirements include a PC running Windows® XP and at least a Pentium® 4 processor and 1 gigabyte of random access memory. In a network-based client server configuration, the same workstation requirements apply, but the Oracle® database is installed on a network server.

Other System Features

- **Capacity:** Unlike some other databases, the size of the database that can be managed by Oracle® is only limited by the physical storage capacity provided by the user.

- **Back-up Capability:** The Oracle® database has a superior backup capability.

- **Stability:** The Oracle® system is a stable platform on which to store your data and is widely used in the healthcare industries.

Application-Level Features

figure 2

New, Simplified Application Management Screen

Pyros® EQS has a new Main Application Screen or "home" screen that consolidates all major functions of the software into 4 button-accessible categories: Collect Data, Analyze Data, Audit Trail, and Trend Data (figure 2). In addition, there is a horizontal menu bar in the top left of the Main Application Screen that access a number of administrative functions. Pressing any of the four main buttons will immediately bring the user to the main screens for those functions. Returning to the Main Application screen is as easy as closing out the current screen.

Hierarchical User-Access Designation

Pyros® EQS provides different levels of access for users. Those with Administrator level access decide on the activities that can be performed by other levels of user. Important among these is the control of Read/Write access and Data/Report Approval. At set-up, the user is guided through screens that enable the allocation of Administrator, Supervisor, and Technician privileges. With these designations, Pyros® EQS permits the control over who can allocate privileges, modify system settings, run tests, approve tests, and implement overrides. In addition, all of these actions are monitored and recorded within the Audit Trail functions of the software.

Multiple Standard Curve Options

Pyros® EQS allows multiple approaches to standard curves. One or more standard curves can be run with the test or standard curve parameters can be stored for use as an Archived Curve. Alternatively, parameters can be manually entered as a Keyboard Curve. All of these options are clearly presented with in the standard curve information dialog box.

NEW Product Report

Data Security and User Rights Management

User access control and data security are key requirements for laboratories performing tests under GMP and the requirements of 21 CFR Part 11. Pyros® EQS permits the assignment of multiple levels of access rights. These are administrator, supervisor, and technician. Administrator-level users may set up data-groups, data-group access, and read and write permissions for the other two levels. By setting up data-groups within the database, administrators can partition data, and access to that data, by product type, department, facility, etc. Only those individuals with specific privileges can access, create, and/or modify data within those data-groups. This is accomplished through a simple on-screen process using the User and Data Group Management dialog box. Certain key functions are restricted to administrator-level users. These include the establishment of new test settings, test information attributes, and the modification of the test parameters. In addition, the signing off of completed tests is restricted to administrators and designated supervisors.

Security features include a Global User Identifier or "GUID" assigned to each completed and signed off test. This is listed in the Report ID for completed and signed off reports. Any change to any aspect of the test or the report will cause the "GUID" to change. This allows easy determination of any changes to a completed test report. Backing this up is a comprehensive Audit Trail function that will track key changes made (see below).

Robust Internal Quality Checks

Pyros® EQS offers users multiple levels of tests for assay validity. These allow users to determine, at a glance, whether the test results meet the pre-set requirements for validity and whether any results are Out Of Specification. Two types of elements are evaluated to determine test validity. The first category involves basic system function and addresses elements such as instrument temperature, optical density artifacts, tube removal and data transmission errors. The second category comprises of what are called Conditional Tests. These involve verification that assay-derived values meet their pre-determined, often user-defined, criteria. These include the following: correlation coefficient, negative control validity, CV limit for standards, CV limit for samples, positive control recovery, range of positive product control recovery, and endotoxin limit. Detailed explanations of these self-check functions are given in the User Manual.

Audit Trail

A robust and secure audit trail is a key feature for compliance with 21 CFR Part 11. The Pyros® EQS audit trail function is comprehensive and allows users to feel confident in their ability to ensure both the integrity of their data and regulatory audit compliance. The audit trail function records key test, system, and user information and all important changes to them. Additionally, the user can enter comments such as reason for change, in order to ensure that valuable information to explain why changes were made is captured. The Audit Trail feature offers users four
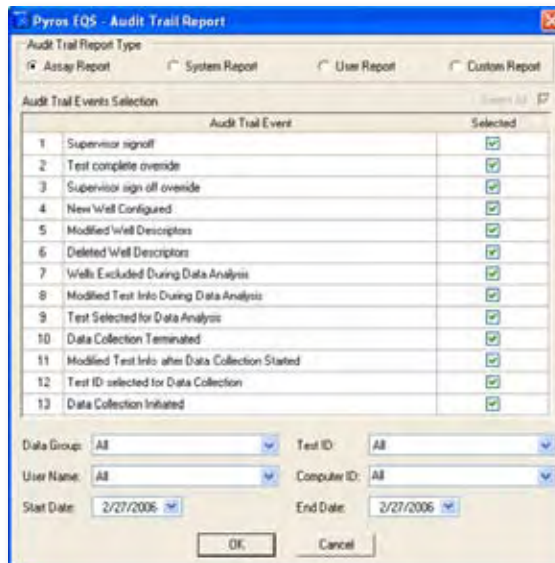

figure 3

levels of reports. These include separate reports for Assay, System, and User information. Also, a Custom audit trail may be selected in which the user can create a report based upon selected elements from the first three categories (figure 3). All of these features are easily accessible by selecting the Audit Trail button on the main screen.

Trend Data

Pyros® EQS includes powerful features for reviewing historical data. Results can be plotted by user, sample type, technician ID reagent lot number or instrument ID to enable trends to be identified and evaluated. Trending reports are easily generated by accessing the Trend Data Report Parameters screen and selecting the appropriate data delimiters. The output format can be selected as either report or plot by clicking a graphical button on the screen (figure 4).
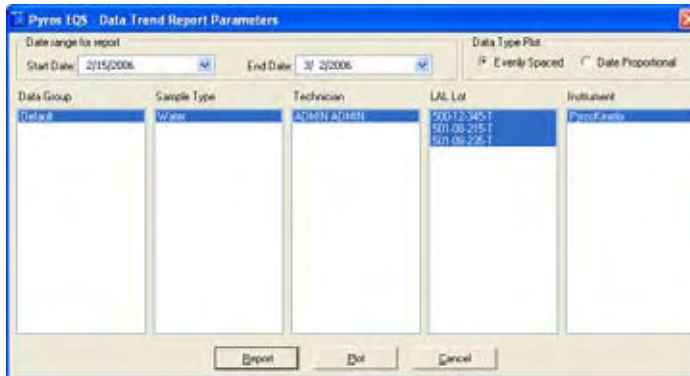

figure 4

User Manual

Users will appreciate the very detailed explanations and instructions that are provided in the User Manual binder that is provided with Pyros® EQS. In addition to the hard copy, an electronic copy may be viewed by clicking the Help button in the main screens. The manual provides user-friendly explanations of all of the Pyros® EQS functions. An appendix provides detailed explanations of the underlying mathematical operations that support the determinations of endotoxin concentration.

In conclusion, Pyros® EQS is a sophisticated, secure, and stable application. Pyros® EQS with the Pyros Kinetix® tube reader come together to provide a highly flexible system that is custom built for endotoxin testing with the greatest sensitivity available.

Fungitell®, Pyros® and Pyros Kinetix® are trademarks of Associates of Cape Cod, Inc.
All other trademarks mentioned are the property of their respective owners.

LAL News and Events 2008

2008 ACC EVENTS SCHEDULE

May 13, 2008. LAL Users Group Meeting, Homewood Suites, Lansdale, PA.
Join the LAL Users Group at: http://www.microbiologyforum.org/LAL.htm
For details, click on the "Information is available here." link under "The next meeting of the LAL User's Group will be May 13, 2008".
Registration: contact Karen McCullough at karenzm@embarqmail.com
Featured speaker: Dr. Michael Dawson, *"Test Method Development for Bacterial Endotoxins: The Unspoken Essential"*

October 27-28, 2008 PMF Bacterial Endotoxin Summit - San Francisco, CA
Watch for details at www.microbiologyforum.org (or subscribe to the PMF list at this website).

November 3-5, 2008. Amsterdam, Netherlands, Center for Professional Advancement course: **"Endotoxin Testing: Drugs, Medical Devices and Biopharmaceuticals."**
Director: Dr. Michael Dawson.

TRADESHOWS

ASCO	May 30th - June 3rd	Chicago, IL
IACP	May 31st - June 3rd	Washington, DC
Bio2008	June 17th - 20th	San Diego, CA
AAPS Biotech	June 22nd - 25th	Toronto Canada
AACC Annual Meeting	July 27th - 31st	Washington, DC
PDA/FDA	September 8th - 12th	Washington, DC
IDSA / ICAAC	October 25th - 28th	Washington, DC
Soc. Glycobiology	November 12th - 15th	Dallas-Fort Worth, TX
AAPS	November 16th - 18th	Atlanta, GA
ASH	December 6th - 9th	San Francisco, CA

2008 ACC LAL WORKSHOPS

LAL Workshop - Mid-Atlantic
April 29th - May 1st
Durham, NC

LAL Workshop - Northwest
June 10th - 12th
San Francisco, CA

LAL Workshop - Northeast
June 24th - 26th
East Falmouth, Cape Cod, MA

LAL Workshop - Southern
September 23rd - 25th
San Antonio, TX

LAL Workshop - Northeast
October 21st - 23rd
East Falmouth, Cape Cod, MA

For more information or to register for a workshop, visit our website at www.acciusa.com or call (888) 395–2221

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