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in this ISSUE

FEATURES

High Throughput Model 20G Osmometer optimizes cell culture process development 1

Model 2020 Osmometer advances with LIMS 1

3320 ethanol application to be presented at the Fuel Ethanol Workshop 2

Evaluation of a New Tear Osmometer Instrument for Repeatability and Accuracy Using Nanoliter-Sized Samples 3

Spartanburg Regional Medical Center examines lab technology, details instrument selection process 3

EVERY ISSUE

From the president 2

Upcoming events 4

Technical support 4



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High Throughput Model 20G Osmometer optimizes cell culture process development

Mammalian cell culture process development requires a range of parameters to be monitored, including nutrient depletion and build up of toxic waste products. Rapid, high-volume process development requires that these parameters be measured quickly, accurately, and preferably, using an automated platform. Osmolality, measured using freezing point depression, has long been a key measurement parameter in identifying ideal conditions for cell growth.

Bringing these factors together, Advanced Instruments will introduce to the biotech market the High Throughput Model 20G Osmometer, capable of measuring the osmolality of 96 samples in less than 35 minutes using freezing point depression technology.

Designed specifically to work seamlessly with other automated systems to reduce the time for cell culture process optimization, the Model 20G is the "fastest osmometer in the world." Its system incorporates eight computer-controlled osmometers and a robotic sample handling system, all enclosed in a safety cabinet.

Ninety-six sample tubes are presented to the system at the start of a cycle in a modified, microplate (SBS) format. The automated sample handling system moves the tubes and probe cleaners to and from

(continued on page 4)

The Model 20G incorporates eight computer controlled osmometers and a robotic sample handling system, all enclosed in a safety cabinet.



Model 2020 Osmometer advances with LIMS

A Laboratory Information Management System (LIMS) is computer software that is used in the laboratory for the management of samples, data entry by laboratory personnel, instruments, standards and other laboratory functions such as invoicing, plate management, and work flow automation. A LIMS and a Laboratory Information System (LIS) perform similar functions. The primary difference is that LIMS are generally targeted toward environmental, research or commercial analysis, such as pharmaceutical or petrochemical, and LIS are targeted toward the clinical market (hospitals and other clinical labs).

Today's trend is to move the whole process of information gathering, decision making, calculation, review and release out into the workplace and away

from the office. The goal is to create a seamless organization where:

Instruments used are integrated in the lab network; receive instructions and worklists from the LIMS and return finished results including raw data back to a central repository where the LIMS can update relevant information to external systems.

Lab personnel will perform calculations, documentation and review results using online information from connected instruments, reference databases and other resources using electronic lab notebooks (ELN's) connected to the LIMS.

Management can supervise the lab process, react to bottlenecks in workflow and ensure regulatory demands are met.

(continued on page 2)

from the PRESIDENT

Welcome to another edition of *Advanced Laboratory News*. Our goal is to keep you updated and educated about our products and their many and varied applications.

In this latest edition, you'll learn how osmolality measurement is assisting ethanol producers to maximize yield and minimize their investment in the expensive enzymes necessary to facilitate ethanol production.

You'll also read about our latest addition to the family: the Model 3100 Tear Osmometer. This novel product is the result of years of extensive research and is aimed at the market for diagnosing dry eye syndrome. The Model 20G is our first robotically controlled osmometer, capable of processing 96 samples in under 35 minutes. Aimed at the biotech industry, the Model 20G is focused on the application of cell culture and media development and production where rapid analysis of 96 well plates is necessary. And, we'll see how one lab evaluated their processes and technology to improve quality in healthcare services.

Advanced Instruments, Inc. has been in the business of providing osmolality measurement for 52 years and we continue to be surprised at the many applications of our freezing point technology. We hope this latest newsletter informs and entertains you and we welcome your comments, criticisms and suggestions.

John L. Coughlin, President and CEO
Advanced Instruments, Inc.

Model 2020 Osmometer advances with LIMS



Only the Model 2020 Osmometer offers on-board data management, automated sample handling, and flexible reporting options for seamless instrument operation.

(continued from page 1)

LIFE SCIENCE LIMS Biotechnologies have introduced a number of changes in the Life Science field. High Throughput technology is utilized in the fields of drug candidate screening, gene screening, and protein screening. These developments in biotechnology make LIMS a new necessity, even in fundamental laboratories.

In the case of a lab that carries out many different tests for multiple customers—a sample-centric approach is preferable because the sample type can drive the process configuration. If a lab carries out a single test while utilizing high throughput testing—an approach should be used in order to optimize the workflow.¹

Hospital and other clinical labs are now seeking solutions where LIS capability is common.

ADDING VALUE The Model 2020 is our first instrument that works with LIMS. After receiving end user input requesting such functionality, we have worked quickly to make it a reality.

The LIMS compatible interface of the Model 2020 Osmometer is a unidirectional interface with standardized serial port output messages, intended to aid the user in collecting and parsing data by computerized means for documenting instrument operation and test results.

The LIMS compatible interface utilizes the instrument serial port to output a series of delimited serial port strings. These strings are only output after the user activates the

LIMS mode via the setup menu. When active, all serial port output is suppressed and replaced by these strings.

SET UP AND OUTPUT FORMAT Once the LIMS mode is activated, all standard serial port messaging is suspended (unless Factory mode or FLASH UPDATE mode has been activated). Each serial port message string is sent in ASCII II format. The data exchange of the serial port remains in accordance with ANSI/TIA/EIA standards.

Output is unidirectional and initiated by the instrument. The user will need to supply a PC interface and software for the collection and processing of the serial port message strings.

This functionality is now available in all Model 2020 Osmometers as of May 2007.

¹Source: www.wikipedia.org

3320 ethanol application to be presented at the Fuel Ethanol Workshop

There's a storm brewing in corn country: It's called ethanol, and corn from the midwest is coming to your local filling station. Advanced Instruments is pleased to contribute to this growing industry of renewable fuel sources.

Hundreds of products come from corn. It is processed into food ingredients and is a feedstock for industrial chemicals and pharmaceutical components. It is also an abundant source of starch with a wide range of functional properties. And, because corn starch is uniform, it can be processed into industrial products with precise specifications.

However, corn starch has to be converted to sugar before fermentation can begin. Efficiency achieved early in the process underlies all downstream gains, and Advanced Osmometers are being used to monitor this starch conversion.

Our method gives critical results in two minutes, the old method requires twenty. We do it at less cost, without generating hazardous waste like the manual titrations do.

Our method gives critical results in two minutes, the old method requires twenty. We do it at less cost, without generating hazardous waste like the manual titrations do.

This ethanol application will be presented at the Fuel Ethanol Workshop (FEW), an industry trade show that has doubled in size this year and is expected to draw 5,000 attendees. A combination seminar and trade show, FEW will feature technical workshops on anaerobic digestion and dry fractionation of corn. Other sources of ethanol,

particularly biomass from primary switchgrass and residues from other crops, and new processes for biodiesel production will also be presented.

We're enthusiastic about our participation in the FEW and expect an attentive reception at our exhibit. Several industry journals have already published our method, and our midwest sales manager, Steve Upchurch, is feverishly trying to keep up with the response. Because this is a young, rapidly growing industry, we will be on the lookout for additional opportunities.

The following is an abstract of poster #390/B592 that was presented in May at the 2007 Association for Research in Vision and Ophthalmology (ARVO) Annual Meeting held in Fort Lauderdale, Florida.

Evaluation of a New Tear Osmometer Instrument for Repeatability and Accuracy Using Nanoliter-Sized Samples

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ABSTRACT

Purpose: Tear osmolality and osmolarity have been reported to change with ocular surface disease such as dry eye. However, it has been difficult to analyze these changes in dry eye patients because past instruments were difficult to use and/or required large volumes of tear samples. In this study, we evaluated a new tear osmometer instrument that measures the osmolality of nanoliter-sized samples by freezing point depression, a standard technique for determining osmolality.

Methods: Four standardized solutions were tested using 0.5 μ L samples for repeatability of measurements and comparability to standardized technique. Two known standard salt solutions, a normal artificial tear matrix sample, and an abnormal artificial tear matrix sample were repeatedly tested (n=20 each) for osmolality using the Advanced Instruments Model 3100 Tear Osmometer (0.5 μ L sample size) and the FDA approved Advanced Instruments Model 3D2 Clinical Osmometer (250 μ L sample size). Both instruments provide end-point measurements independent of operator biases. Data was analyzed using EP Evaluator™ Release 7 version 0.0.288 (David Rhoads Associates, Inc.) to assess the repeatability and percent recovery for each of the 4 samples.

Results: The tear osmometer was easy to use and required minimal training to enable users to become proficient in the technique. The precision data including the mean and standard deviation for the 290 standard solution, the 304 reference solution, the normal value-assigned 306 sample, and the abnormal value-assigned 336 sample were 291.8, 4.4; 305.6, 2.4; 305.1, 2.3; and 336.4, 2.2, respectively. The percent recoveries for the 290 standard solution, the 304 reference solution, the normal value-assigned 306 sample, and the abnormal value-assigned 336 sample were 100.3, 100.2, 99.8, and 100.3, respectively.

Conclusion: The repeatability data is in accordance with data obtained on clinical osmometers using larger sample sizes. All 4 samples tested on the tear osmometer have osmolality values that correlate well to the clinical instrument method. The tear osmometer is a suitable instrument for testing the osmolality of nanoliter-sized samples, such as tears and therefore may be useful in diagnosing, monitoring, and classifying dry eye patients.

Spartanburg Regional Medical Center examines lab technology, details instrument selection process

By Sandy Hammett, Coordinator of Chemistry and Special Chemistry at Spartanburg Regional Medical Center

Laboratory technology can be a powerful tool in the quest for continuous improvement. Recently, Spartanburg Regional Medical Center went through the process of evaluating our lab to determine how processes and technology could be improved as part of the overall mandate to improve accuracy, efficiency, and quality in healthcare services. This initiative was organized to eliminate clerical errors, expedite requests from hospital staff to verify instrument results and patient tests, and directly link instrument results to patient samples.

Our current osmometer handled the laboratory workload and provided accurate results, but we also needed a solution that would enable our team to utilize new technology, to efficiently label and track patient samples throughout the handling and testing process; and to avoid misidentification and transcription errors.

Our previous method of handwriting lab results and hand labeling instrument control solutions was becoming outdated. The addition of a barcoding solution would make our jobs more efficient, and provide a method to directly link the instrument results to patient samples. Before deciding to purchase the new osmometer, we took a few precautionary steps to ensure that our decision was the best one.

EVALUATE TRENDS First, we evaluated the clinical trends and available industry research. We wanted to evaluate the peer reviews of other instruments on the market to support our

The new instrument fits into our lab perfectly—allowing us to supply the hospital staff and patients with efficient and secure results while utilizing the latest in barcode technology.

choice. To do this, we turned to The College of American Pathologists (CAP), which provides proficiency samples, as well as a benchmark for comparison against similar instruments. We learned the Advanced® Model 3320 Osmometer is most widely used and all remarks were positive from similar hospitals and lab facilities.

DETERMINE JOB SIZE Using our laboratory records, we compiled the overall size and demand of the job, including the average number of samples we run a day and per week. Then, we took into account how much space was available.

REVIEW USABILITY Another requirement was “ease of use.” Our lab team did not want a lengthy training program to stand in the way of testing patient samples—nor did we want to spend time referring to an instruction manual while trying to operate the instrument. We found that the Advanced® Model 3320 Osmometer is user friendly—even with the technology upgrade and barcoding feature.

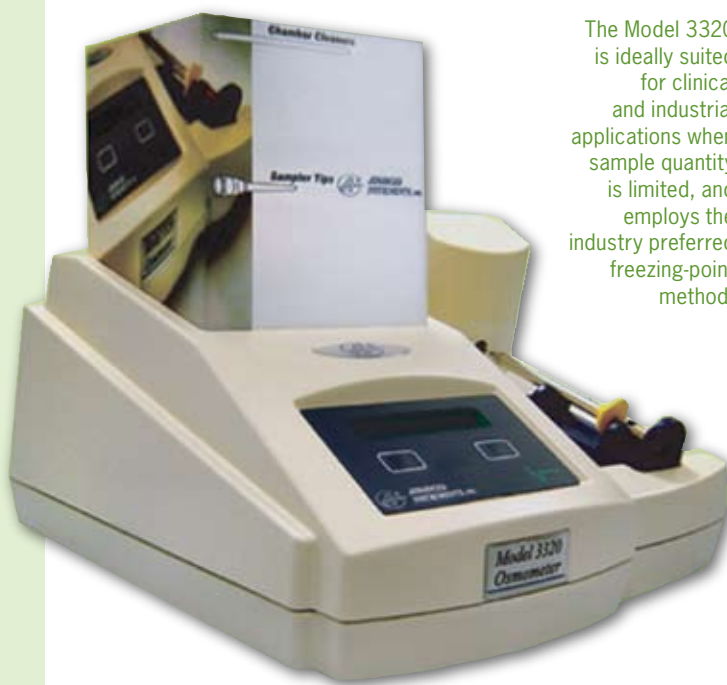
CONFIRM RELIABILITY Instrument reliability was another crucial factor. Machine downtime is not an option when catering to a busy emergency room. Luckily, we have experience with Advanced Instruments equipment and know firsthand that their history of reliability is unsurpassed.

The Model 3320 is ideally suited for clinical and industrial applications when sample quantity is limited, and employs the industry preferred freezing-point method.

INSTRUMENT CARE The ongoing service and maintenance of the machine was an additional, important aspect that we considered. We sought a solution that requires minimal routine maintenance and calibration—meaning that we can do our job and not worry about stability.

Given our present requirements, we found many 3320 features were upgraded to cater to laboratory technicians. The new model can barcode up to 20

(continued on page 4)



Spartanburg Regional Medical Center examines lab technology, details instrument selection process *(continued from page 3)*

characters in length, and the barcode port provides power to the scanner, virtually eliminating the need for external power connections and power bricks.

The scanner can be used in either hands-on or hands-free mode, enabling the lab technician to work on other priorities, if needed. Moreover, the scanner and osmometer can decode all standard 1D, RSS-14, RSS Limited and TSS expanded barcodes, allowing positive ID of all patient samples and controls.

Once installation was complete, we began the process of implementing the new barcoding system. With the new labels, we are able to easily look up accession numbers and print the test results from the lab computer system when necessary.

In the end, all the research proved worthwhile; the new instrument fits into our lab perfectly—allowing us to supply the hospital staff and patients with efficient and secure results, while utilizing the latest in barcode technology.



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Model 20G Osmometer *(continued from page 1)*

the eight osmometers. Results are then displayed on a color, touch screen monitor and can be automatically transferred to a central database. Consumables for the osmometer are in a sterile format so that the package does not contaminate the sterile area where individual cell culture reactors are opened and sampled.

Developed in collaboration with a leading biotechnology company and one of the most eminent cell culture process development researchers in the world, the Model 20G will have a strong presence in biopharmaceutical cell culture process development.

upcoming EVENTS

TRADE SHOWS 2007 Advanced Instruments and Advanced Instruments' subsidiaries, Delta Instruments and Spiral Biotech, are participating in a number of trade shows and exhibitions in the United States and Canada. Go to www.aicompanies.com/expos to see which shows we are participating in this year.

SCHEDULE A DEMO When you visit www.aicompanies.com/expos, you will find links to products that will be featured at each of the shows. Because Advanced Instruments has product lines in the Clinical and Microbiology (and Dairy) markets, a second link on the same page will produce a list of expositions specific to your industry. Make the most of your time at these conferences by contacting us directly for a personal demonstration appointment.

SCIENTIFIC POSTERS PRESENTED Advanced Instruments is pleased to announce acceptance of

two posters, based on research conducted by our R&D department and in collaboration with our colleagues in universities and labs nationwide:

- "Evaluation of a New Tear Osmometer Instrument for Repeatability and Accuracy Using Nanoliter-Sized Samples" (with Mount Sinai School of Medicine) at May's ARVO 2007;
- "Performance Characteristics of a New Single Sample Freezing Point Depression Osmometer" at the July 2007 Clinical Lab Expo.



The Model 3100 can produce an accurate osmolality measurement of a tear sample in less than 15 minutes.

technical SUPPORT

24-Hour Support, 7 Days a Week

Technical Support is available around the clock for all domestic Advanced Instruments, Fiske® Associates, and Spiral Biotech customers. Call toll free — (800) 225-4034 or (781) 320-9000.



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