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**AI introduces Sed-Rate Analyzer**

*Don Wiggin*

Consistent with its objective to bring products to market with significant user benefits, Advanced Instruments has introduced the ESR Stat™ for rapid sed-rate determinations. ESR Stat offers dramatic improvements in turnaround time and sample requirements. Where the traditional Westergren methodology is based on a 1 mL sample and 1 hour cycle time, the ESR Stat gives a 3 minute result from 20 µL of sample.

ESR Stat uses a capillary tube for sample collection and analysis. It spins the tube and monitors sedimentation with a laser. At the end of the programmed cycle, it displays the result with the sample identification. An accessory printer is available and there is no operator intervention or visual interpretation needed.

Users have reported an increase in test requests based on the early availability of results. Sed-Rate has not previously been considered a stat test even though admit/discharge or other clinical decisions may be supported by ESR information. It is not unusual for doctors to call the lab for a progress report on a 1 hour Westergren test.

ESR Stat is a sleek, compact, and quiet instrument. These benefits are available at a cost that compares favorably with products that are sold on a "per-test" basis. Competitive cost analyses are available, as are correlation studies that show equivalence to other methods. Call Advanced Instruments for more information on the ESR Stat. Bring your Sed-Rate testing into the age of laser kinetics.

**Advanced Instruments, Inc. Acquires Delta Instruments**

Expanding its portfolio in the dairy industry and milk control laboratories

Norwood, Massachusetts USA and Drachten, Netherlands – March 07, 2003 - Advanced Instruments, Inc. today announced the acquisition of Delta Instruments B.V., a well-established manufacturer of analytical instrumentation for the analysis of milk and dairy products based in the Netherlands.

Under the agreement, Advanced Instruments acquired 100 percent of the stock of Delta Instruments. Financial terms were not disclosed. The product portfolio will continue to be marketed under the Delta Instruments brand and will be sold through a combined Delta Instruments and Advanced Instruments global distribution network. For the US market, all commercial and technical support including product distribution, spare parts and repairs, and training will be provided from the company's corporate headquarters in Norwood, MA. A network of local field representatives will also be established to support the US market.

Advanced Instruments has been a leading supplier of instrumentation for the analysis of milk and dairy products. The company's products include cryoscopes used to detect added water in milk, the Fluorophos® system used to measure the degree of pasteurization, the QCount™ and PetriScan® systems for automated microbial analysis, and the Autoplate® 4000 Automatic Plater which simplifies the time consuming processes required for microbiology testing in the dairy lab. Advanced Instruments' products are sold by a direct sales force in the US and through a global distribution network of 124 representatives in 85 countries.

Commenting on the acquisition, Advanced Instruments President and CEO John L. Coughlin

*continued on last page*

**In Memoriam: Bud Wiggin**

*Don Wiggin*

Advanced Instruments' Founder and Chairman, Bud Wiggin, passed away last February, after a debilitating heart attack. For those of us who were fortunate to know him as a younger man with boundless drive, it was difficult to watch his strength ebb. All of us in the Advanced community continue to live with his legacy, his commitment and his demanding standards.

Bud Wiggin started Advanced Instruments in the basement of his home, and while the company soon grew into a substantial enterprise, it never outgrew his vision of a nimble and innovative organization. He had a sign in his office with a quotation by Nobel-Laureate Albert Szent-Gyorgi: "To see what everybody has seen, yet think what nobody else has thought..." It is a statement that describes his personal vision, and the type of institution he has built.

In directing the company he had one overriding standard: Can we do this better? Can we bring something new to the game? He had little interest in "me too" products, or excuses for doing something "the way it has always been done." He was continually fascinated with new ideas, and the company gave him the platform from which to try them out. He enjoyed selling and he thrived on meeting new people, and seeing old friends. Through his business activities, Rotary Club service, tennis clubs, and college reunions, he touched numerous people. We are all better for having known him.

Gale Wiggin will take over as Chairman of the Board, responsibilities for which she is more than capable. She has been an equal partner with Bud for 56 years of marriage, has served as Treasurer of the company since its founding, and is well known to all of us in the company. The family intends to continue its ownership and direction of Advanced Instruments, believing that as a closely held company it can best continue to provide stability, balanced growth, opportunity, and market leadership. The Wiggin Family is tremendously proud of the dedicated organization that has become Advanced Instruments.



# Control Solutions and Materials

*Ken Micciche*

Control solutions and materials can be defined as a solution or patient specimen used solely for quality control purposes. Control products are available commercially in liquid or lyophilized form and are packaged in small amounts suitable for daily use. Control materials are widely available and can be purchased from the same companies that sell reagents and instrumentation. It is common for laboratories to purchase complete testing packages, which serve to enhance their quality control program.

By purchasing from a sole source, differences in products and effects on method or instrument performance can be minimized. Good control materials should have the same matrix as the specimens being tested so that they behave the same as the patient specimen. By developing materials to minimize alterations, a manufacturer can help to eliminate interferences in the testing process.

Controls and materials such as Protinol® - Protein Based Controls, Renol™ - Urine Controls, Clinitrol™ 290 - Reference Solution, and the Osmolality Linearity Set are designed to perform optimally. These liquid controls and materials are a good value as they reduce waste due to stability, eliminate vial to vial variability, and reduce operator errors that are frequently associated with the reconstitution process, all while enhancing laboratory quality and confidence in testing.

## Basic Quality Control Practices

**CLIA '88** – Clinical Laboratory Improvement Amendments of 1988, which are requirements for general quality control (QC) provisions and personnel qualifications for moderate complexity testing.

**JCAHO** – Joint Commission on Accreditation of Healthcare Organizations follows CLIA '88 and requires that users of moderate-complex methods run two or more external controls daily. Laboratories must be certain that these results meet JCAHO's QC acceptance criteria before patient results are reported.

**CAP** – Controls must be included with all tests, even those identified in CLIA '88 as waived. The College of American Pathologists requires an audit trail that ties patient results to both a positive and negative control each day of use.

## Advanced Instruments ControlLine™ Products

These products help clinical laboratories achieve the most accurate results with the only comprehensive set of control solutions and materials designed specifically for osmometers.

These quality, reliable products can help laboratories avoid expensive workflow disruptions and ensure the reliability of patients' results. With tighter tolerances than multi-analyte controls, it is easier for users to identify when action needs to be taken due to results found outside satisfactory control limits.

**Protinol®** - Protein-Based Controls. This product is designed specifically for clinical laboratories testing blood samples and formulated to produce the most consistent, reliable results in the human serum range. It is formulated at three levels to allow users to comply with CLIA '88 quality control requirements. The product is premixed and ready to use in three, 3 mL vials per kit. Levels include 240 Low, 280 Normal, and 320 High mOsm/kg H<sub>2</sub>O.

**Renol™** - Urine Controls. Renol is the world's only osmometer-specific control solution for laboratories testing urine samples. The aqueous-based control material is manufactured to extremely tight tolerances for better repeatability and the most precise control over patient results. Renol comes premixed and ready to use in four, 3 mL vials of each value per kit. Formulation values include 300 and 800 mOsm/kg H<sub>2</sub>O. These concentrations are close to medical decision levels where performance is critical for the use and interpretation of the test. In order to comply with CLIA 493.1218, laboratories should perform and document control procedures using at least two levels of control materials daily.

**Clinitrol™** - 290 Reference Solution and Calibration standards. These premixed and ready-to-use reference solutions and calibration standards meet CLIA 493.1217 regulations.

Laboratories will use Clinitrol 290 to monitor operator technique, which is of particular importance with several shifts. Additionally, when following a calibration routine, Clinitrol 290 is a valuable tool for calibration verification.

**ControlLine™** products designed specifically for osmometers can strengthen QC programs. The user can 1) track results, 2) identify shifts, trends, and random errors, 3) apply control rules, and 4) implement corrective actions.

*To order, call 800-225-4034 or 781-320-9000*

# Advanced Instruments to present CLMA seminar

*Don Wiggin*

Advanced Instruments will present a seminar titled "Meeting Regulatory Requirements for Osmolality Testing" at this year's CLMA (Clinical Laboratory Management Association) meeting, held June 22-24<sup>th</sup> in Salt Lake City. The seminar will be led by Raymond Karcher, PhD., Laboratory Director of William Beaumont Hospital in Royal Oak, Michigan. Dr. Karcher has been a long-time customer and associate of Advanced Instruments. Dr. Karcher also presented at last year's Osmolality Roundtable, held here in Norwood, MA.

As part of the "Industry Solutions" program at CLMA, this year's presentation will offer background on the technique and clinical applications of Osmolality. The regulatory framework and specific compliance issues that osmometer users must face will also be

discussed. Finally, Dr. Karcher will discuss Advanced Instruments' ControlLine™ products. ControlLine products are the only set of control solutions and laboratory supplies designed specifically for osmometers. They offer excellent dimensional stability and the tightest tolerances, producing the highest instrument accuracy ratings.

Because this is such a timely subject, CLMA has invited Advanced Instruments to present "Meeting Regulatory Requirements for Osmolality Testing" on Sunday, June 22 and Monday, June 23. Breakfast will be served and free samples of various ControlLine products will also be available to those who participate in the seminar.

# New Fungicidal Application for SGE

*Anthony Pappas*

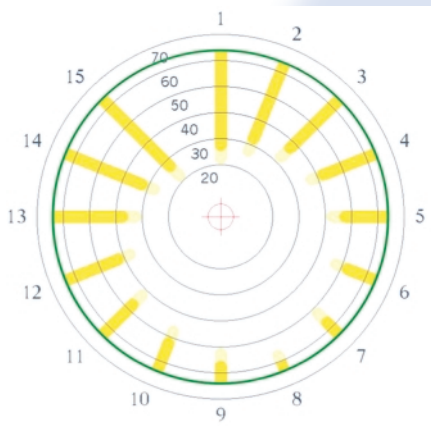
The Spiral Gradient Endpoint test (SGE™) provides highly sensitive and repeatable MIC determinations by a novel patented agar dilution method. The test utilizes the unique plating action of the Autoplate® 4000 Automatic Plater to achieve the equivalent of eight two-fold dilution plates. This is accomplished by plating a liquid sample onto the surface of a rotating agar plate in an Archimedes spiral. The volume deposited is precisely controlled and exponentially reduced as the mechanism “spirals” out across the plate. The pattern produced generates a concentration gradient of sample that is extremely useful for the study of antimicrobial compounds and their effects on microbial growth.

Spiral Biotech and its customers are always developing new and exciting applications for the SGE software. The newest application was developed for anti-fungal compounds. The data was accepted by *Phytopathology* and presented at the APS annual meeting in Milwaukee, Fall of 2002. The methodology was developed by Drs. Forster, Kanetis, and Adaskaveg of the University of California – Riverside. The technique, therefore, for utilizing SGE for fungicides is known as the “Forster Technique.”

The following abstract titled *Spiral gradient dilution – a rapid, single-plate method for determining EC50 values of fungicides* is one of two articles that has recently been published in *Phytopathology*.

*In vitro* toxicity of fungicides against target organisms is commonly expressed as EC50 values that are based on measuring fungal growth of spore germination on culture media amended with serial dilutions of the fungicide. Because this procedure is time-consuming, the Spiral Gradient Endpoint test (SGE) for bacteria was adapted for the use with fungi as a rapid, single-plate assay. A fungicide solution was plated onto agar medium using a spiral plater, forming a 2.5-log dilution in a radial concentration gradient. Fungal mycelium or spores of up to 15 isolates were then plated along the gradient of a single plate. After incubation, the radial distance where 50% reduction of growth or spore germination occurred was converted into a local fungicide concentration using SGE software (Spiral Biotech, Inc.). EC50 values of fludioxonil obtained for *Botrytis cinerea* and *Monilinia fructicola* and of myclobutanil for *Chondrostereum purpureum* were very similar to those obtained from a series of single-dilution plates. Spiral gradient dilution has potential for mass screening of fungal isolates for establishing baseline sensitivities.

H. FORSTER, L. Kanetis, and J.E. Adaskaveg. Dept. Plant Pathology, Univ. of California, Riverside, CA 92521. *Phytopathology* 92:S26. Publication no. P-2002-0184-AMA.



# Spiral Biotech to Present PetriScan® Data at IAFP

*Anthony Pappas*

In the food and dairy industries, aerobic plate counts are determined by a time consuming and laborious hand-counting method. 3M™ Petrifilm™ is widely used in these industries as a substitute for traditional agars. Petrifilm is also an easy-to-use methodology designed to enumerate aerobic bacteria in food and dairy samples. Petrifilm is recognized as a standard in microbiological food analysis by almost all regulatory bodies.

The PetriScan® Automated Colony Counter was developed to improve this process and increase efficiency in the microbiology laboratory. Spiral Biotech scientists compared PetriScan automated counting results to manual counts of food, dairy, and milk products plated on 3M™ Petrifilm™ Aerobic Count Plates. Spiral Biotech will present results of this study at the International Association of Food Protection (IAFP) annual meeting in August. All AOAC methodologies and recommendations from 3M were followed during the study. The results are fantastic! These findings establish the PetriScan as a comparable and practical alternative to the standard method of manually counting Petrifilms. Join us at the 2003 IAFP conference in New Orleans and view the results!

# Advanced Instruments' Laboratory Services

*Eileen Garry*

Advanced Instruments' state-of-the-art laboratory provides technical applications support, product development, quality testing, and technical service. The R & D Laboratory is certified by the College of American Pathologists and staffed by 4 scientists covering a broad range of disciplines. Advanced Instruments' staff has formal training and experience in biology, laboratory science, analytical chemistry, food and dairy science, *in vitro* diagnostics, and regulatory affairs. These specialties complement the chemistry, food and dairy, and microbiology product lines. The staff participates in verifying new instrument performance specifications by comparing standard or manual methods to new instrument prototypes. In addition, experiments are performed and research is conducted to evaluate new applications on existing products. The laboratory runs in-process and finished-product quality control testing to ensure that products meet and exceed quality standards. The staff also develops and updates documents such as specifications, product inserts, and material safety data sheets. Stability studies are also conducted for label claims on all consumable products. In order to receive product approvals and develop standards for use in various industries, Advanced Instruments collaborates with agencies such as the FDA, NCIMS, ISO, IDF, and AOAC. The R&D laboratory continuously provides expert scientific support to customers and distributors worldwide. Look for the PetriScan® poster presentation at the IAFP meeting this summer in New Orleans.



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## FREE Renol™ Urine Control Sample

Renol is the world's only osmometer-specific control solution for laboratories testing urine samples. Interested in receiving a free sample of Renol Urine Control?

Simply contact Customer Service at 800-225-4034 or 781-320-9000 and get your free sample today!

If you are interested in receiving this newsletter electronically, please visit:

[www.aicompanies.com/newsletter](http://www.aicompanies.com/newsletter)

## Upcoming EVENTS

IFT (Institute of Food Technologists)

July 13-16  
McCormick Place, Chicago  
Booth #326

AACC (American Association of Clinical Chemistry)

July 22-24  
Pennsylvania Convention Center, Philadelphia  
Booth # 1706

IAFP (International Association for Food Protection)

August 10-12  
Hilton New Orleans Riverside, New Orleans  
Look for SBI's Microbiological Methods Poster:  
"Enumerating 3M™ Petrifilm™ Aerobic Count Plates Using the PetriScan® Automated Colony Counter" on August 11 from 3-6pm

ICAAC (Interscience Conference on Antimicrobial Agents and Chemotherapy)

September 14-16  
McCormick Place, Chicago  
Booth #740

## Looking for a local dealer?

Visit [www.aicompanies.com](http://www.aicompanies.com) and click on the [Find a local dealer](#) icon or call 800-225-4034.

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## Autoplate® 4000 User Tips

At the end of each day, run a Power Clean sequence before you power down. This fills the automated spiral plater tubing with water and will keep the tubing soft and pliable, extending the life of the equipment.

### *AI Acquires Delta...continued from page 1*

said, "Delta Instruments is a perfect fit with our company. It provides a complete line of products for manual and automated analysis of dairy products such as fat and protein content and Delta's products are used by the world's leading dairy processing companies." Advanced Instruments is well recognized in the dairy lab market as the world's largest supplier of cryoscopes for analyzing added water in milk. Coughlin said, "Together, we can provide a comprehensive portfolio of analytical instrumentation for dairy labs and dairy processing companies. The Delta products will increase our dairy market presence worldwide and the Advanced Instruments infrastructure and financial strength will allow Delta to quickly expand into the US market."

Founded in 1955, **Advanced Instruments, Inc.** is the world's largest supplier of freezing-point osmometers used in hospital clinical laboratories, pharmaceutical, and biotechnology laboratories. The company is also a leading supplier of analytical instruments and test kits for the food, dairy, and industrial microbiology markets. Based in Norwood, Massachusetts USA, the company also produces Fiske® Associates brand diagnostic instruments and operates Spiral Biotech, Inc., a wholly-owned subsidiary. Advanced Instruments' products are supported by a worldwide network of direct sales people and independent dealers and distributors. Advanced Instruments can be found online at [www.aicompanies.com](http://www.aicompanies.com) or contact Customer Service at 800-225-4034 or +1-781-320-9000.

**Delta Instruments B.V.**, headquartered in Drachten, Netherlands, has been in operation since 1985. The company specializes in the development, production, and supply of high-quality instruments for the analysis of milk and dairy products. Delta Instruments products include the LactoScope™ and LactoScope FTIR™ infrared spectrophotometers for the accurate determination of fat, protein, lactose and total solids in milk and various milk products including ice cream and other specialty and complex products. Delta also manufactures the SomaScope™ instrument, which measures the total somatic cell count in raw milk. The CombiScope™ precision analyzer measures both the chemical composition and total somatic cell count of raw milk.