AMPLITIMES

Idaho Technology Inc.

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Ribbon Cutting Marks Future Growth for Idaho Technology

In this troubling economy, Idaho Technology is pleased to say that it is continuing to grow. This growth was particularly evident with the dedication of ITI's new building in the University of Utah Research Park on April 6, 2009. The dedication was marked by the presence of Utah Senator Bob Bennett, Salt Lake County Mayor Peter Corroon, and ITI employees.

CEO Kirk Ririe talked about the humble beginnings of the company at a potato equipment shop in Idaho Falls, Idaho, to its place in Research Park. He then remarked that [this building] would "nurture our company as we strive to launch the next generation technology in diagnostics." Ririe went on to comment about the debt of gratitude owed to partners such as the University of Utah, National Institutes of Health, and the Department of Defense and added that it was ITI's "absolute necessity to repay this debt. We do this by helping educate the next generation of scientists, engineers, and business people [by] helping them supplement their experience with hi-tech business experience."

(l to r) Mayor Peter Corroon, CFO Monty Botosan, CEO Kirk Ririe, President Randy Rasmussen, Senator Bob Bennett, CDO Todd Ritter

Senator Bennett talked about the growth in the current area where ITI is located. Reminiscing about his days as an officer at nearby Fort Douglas, he talked about how the rifle range was located where ITI now sits, and how he and fellow officers would come out to practice shooting. Senator Bennett commented that at the time there was no idea of businesses occupying the land, just jackrabbits and the occasional snake. He said the presence of businesses indicates the growth in the Salt Lake Valley and around the University of Utah, and he is delighted to see the growth continue.

Mayor Corroon echoed Senator Bennett's remarks saying that he was excited when he heard of great projects involving hi-tech and life science business.

ITI's new 50,000 sq. ft. building consists of three floors with spectacular views of the Salt Lake Valley. It houses the instrument production department, Quality Assurance, Materials, Receiving and Shipping, reagent production labs, oligo production labs, organic chemistry labs, and administrative offices. These departments had been housed in three different buildings with two of the buildings 10 miles away from the corporate building. With the move to the new building, Idaho Technology is now once again all located in Research Park.

Inside this Issue

OEM Manufacturing

In April 2009 ITI relocated their Reagent Manufacturing Operations into their new Salt Lake City facility located at the base of the beautiful Wasatch Mountains. This move completes the consolidation of all ITI departments into a single campus located within the University of Utah Research Park and gives Reagent Manufacturing better access to critical ITI support groups such as Quality Assurance, Technology Transfer, Reagent Development, and Executive Management.

Before relocating to Research Park, much time and effort was spent in critically examining ITI's reagent manufacturing space and identifying areas for improvements such as manufacturing processes, instrumentation layout, environmental requirements, and material and product flow. This information was incorporated into the new facility's design and resulted in a space tailor-made for ITI's diverse reagent manufacturing needs.

The Reagent Manufacturing facility occupies the entire second floor of ITI's new three-story corporate building and consists of two departments: IT BioReagents and IT BioChem.

IT BioReagents manufactures freeze-dried reagent kits used in the identification of viral and bacterial organisms via real-time PCR. These include biothreat and food pathogen identification reagent kits, and a variety of DNA/RNA extraction kits. In addition, IT BioReagents also manufactures the highly specialized PCR-in-a-pouch RAZOR® product and has set aside space within the facility for the transfer of the new pouch-format FilmArray™ product line later this year.

IT BioReagents is registered with the FDA Center for Devices and Radiological Health as a Contract Manufacturer and currently manufactures several IVD pathogen identification reagent kits.

The reagent manufacturing space uses a linear manufacturing flow process and consists of formulation laboratories, freeze-drying rooms, a wet room specific for buffer formulation, and packaging and labeling areas.

IT BioChem manufactures synthetic oligonucleotides both modified and unmodified which are used as primers and probes for PCR,and other scientific applications. In addition, IT BioChem also manufactures the Hi-Res Melting® dye LCGreen® Plus.

IT BioChem is one of a handful of fully cGMP compliant oligonucleotide manufactures and is registered with the FDA Center for Devices and Radiological Health as a manufacturer of Analyte Specific Reagents (ASR's).

Finally, IT BioChem has expanded their department by adding a fully equipped Organic Chemistry Laboratory complete with two Ph.D. chemists whose responsibilities include chemistry support for both reagent and oligonucleotide manufacturing, and development of novel molecules useful in PCR.

Both IT BioReagents and BioChem have invested heavily in equipment and expertise both of which are necessary for continual product improvement and meeting customer's high expectations.

IT BioChem has added critical equipment necessary for Quality Assurance including a ultra performance liquid chromatography (UPLC) and mass spectrophotometer both of which are used in the final QC and release of the product. In addition, both departments have recently incorporated dispensing and formulation robots, as well as other specialized production equipment.

Finally both departments have undertaken substantial automation projects which help improve product quality and streamline and improve production processes. These projects have involved multiple departments and have included the writing, validation, and implementation of highly specialized software necessary for the planned process improvements.

IT BioReagents and BioChem supplies products world-wide and current customers include the U.S. Government, major universities, clinics and hospitals, and fortune 500 companies.

ITI Food Girl Blog

We have just launched our ITI Food Safety Blog where our "Food Girl," Tiffany Colton, writes about the experiences of marketing our Easy Accurate and Timely (EAT) food testing equipment which identifies food borne pathogens such as *Salmonella*, *Listeria*, and *E. coli* O15:H7. Check it out at http://itifoodbites.blogspot.com/ and become a follower. We would love to hear your comments!

Researcher of the Year Awarded for BRCA Mutation Detection

ITI would like to congratulate Nienke Van der Stoep of Leiden University Medical Center, Netherlands, for receiving a Researcher of the Year Award from *Bioscience Technology*. Dr. Van der Stoep and EuroGentest colleagues worked tirelessly to validate the BRCA1 mutation detection using ITI's LightScanner® Hi-Res Melting® System.

Dr. Van der Stoep's research goal was to evaluate Hi-Res Melting as a new method for high-throughput mutation scanning that could ultimately be used in personalized medicine. A mutation in the BRCA genes greatly increases the probability of developing breast cancer. A patient testing positive for BRCA1 or BRCA2 can elect to increase surveillance or even do prophylactic mastectomy surgery, which has been demonstrated to dramatically reduce the chance of getting breast cancer.

Gene sequencing is very expensive and not always covered by insurance. In fact, the American Civil Liberties Union is challenging Myriad Genetics, holder of the patents involving commercial testing for and reporting of BRCA1 and BRCA2 gene mutations. Older scanning methods, such as single-strand conformation polymorphism (SSCP) and denaturing high pressure liquid chromatography (dHPLC) are time-consuming and expensive; but still being used. A fast, cost-effective method of BRCA1 mutation scanning would make the test available to more people, and in turn, help those people at high risk for breast cancer make significant life-saving decisions in their health care. A more cost-effective test would also be less of an economic strain on the health care system. The LightScanner dramatically reduces the overall costs of sequencing projects because of the simplicity and reliability of high resolution melting curve analysis for discovering mutants.

Van der Stoep's study involved 170 BRCA1 variants and 197 wild-type samples and generated guidelines for setting up and using Hi-Res Melting as a scanning and genotyping technique for new genes. These guidelines can be easily adapted to a quality system in an individual diagnostic laboratory.

The results of the studies showed that all heterozygous variants could be detected (100% sensitivity). Two blind studies resulted in 100% detection (sensitivity) of all variants and showed an average specificity of 98%, indicating a low incidence of false positives. Additionally, genotype analysis for 9 different common polymorphisms created a fast screening and detection method for frequently occurring polymorphisms, omitting unnecessary sequence analysis for these nonpathogenic variants.

A complete description of Dr. Van der Stoep's research is found in the March 3, 2009, issue of *Human Mutation*.

Photo of the Quarter

Moose at Snowbasin
(Sarah Fowden, Research and Development)

Dates to Remember

July

12–14 **International Association for Food Protection (IAFP)**
Grapevine, TX
http://www.foodprotection.org/events/iafp-annual-meeting/

19–23 **ASCLS/AACC - Clinical Lab Expo**
Chicago, IL
http://www.aacc.org/events/2009am/Pages/default.aspx

Editor's Note: If you have comments or suggestions for articles, please e-mail the editor at loretta_orgill@idahotech.com.

ITI Instrument Training

Idaho Technology is committed to our customers success. To ensure you are satisfied with our products, we have an excellent team of technical support representatives ready to assist you with all of your questions. Additionally we offer specialized training courses at your site or here in Salt Lake City. Courses focus on operation, sample preparation, reagent setup, and software. If you would like to attend or schedule a training course, please contact our training staff at 1-800-735-6544 x 439 (R.A.P.I.D.®, RAZOR® EX), or 1-800-735-6544 x 424 or 801-556-5346 (LightScanner®, LightScanner 32).

LightScanner Webinars

The following webinars can be accessed via http://www.idahotech.com/Support/Webinars.html:

- *LightScanner Automation Robot System for Auto Plate Loading into a LightScanner System*
- *Advanced Applications using Hi-Res Melting and the LightScanner System*
- *Understanding the Melting Curve*
- *LightScanner Step-by-Step Animation*
- *Audio Slideshow - The LightScanner System*
- *Somatic Mutation Detection in Primary Tumor Samples*
- *LightScanner Primer Design Software Training*

If you have any questions about the topics of these webinars or would like more information, please contact Cameron Gundry at cameron_gundry@idahotech.com or (801) 736-6354 x 444.

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