DHHS / FDA
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LITMUS and FDA Collaboration Leads to Global Food Safety Breakthrough

LITMUS, LLC, a leading global technology innovations company, recently announced a breakthrough which will dramatically improve current testing methods to detect foodborne pathogens such as *Salmonella*, *Listeria*, *Campylobacter*, and *E. coli*. This advancement in bacterial pathogen-testing technology provides more accurate results, thereby reducing the risk of contaminated foods reaching consumers. The new procedures are the result of a two-year collaboration between LITMUS and NCTR scientists.

According to CEO and founder of LITMUS, Mark Diggs, "One of the key issues in protecting the public from bacterial outbreaks is being able to quickly and accurately detect bacterial pathogens before they hit the grocery shelves. This is no simple matter and the available testing methods simply take too long."

The quality of perishable food (such as seafood) is assured when this sensor is included in the packaged food. The sensor is easy to understand — yellow indicates food is safe, while any other color indicates it is not safe to eat. (image courtesy LITMUS)

Currently, most food products are tested by "culturing" samples to see if any bacterial pathogens are present. This process typically takes two to three days — a substantial delay for perishable products like meats and fresh produce waiting to enter the supply chain. The new LITMUS methods bypass the culturing and identification phase by directly detecting and identifying individual bacteria in one step, and providing results in less than 15 minutes.

Food contamination is a major health concern. The Centers for Disease Control and Prevention estimates that unsafe foods cause as many as 76 million illnesses in the U.S. annually and the Department of Agriculture estimates that the national costs associated with foodborne illness could be as much as $37 billion annually. Applying these new LITMUS technologies will help prevent illnesses and save money.

MicroArray Quality Control Project Achieves Its Goal and Expands

The MicroArray Quality Control (MAQC-I) project, led by Dr. Leming Shi of NCTR, evaluated the reproducibility, reliability, quality, and data analysis concerns of microarray experiments across different laboratories and platforms. One hundred thirty-seven scientists from 51 organizations (including government agencies, manufacturers of microarray platforms and RNA samples, microarray service providers, academic laboratories, and other stakeholders) designed a study plan. Two distinct, commercially available reference RNA samples were generated and analyzed at multiple test sites using a variety of microarray-based and alternative technology platforms, resulting in a rich dataset with over 1,300 microarray hybridizations. Findings of the MAQC-I project were published in a series of articles in the September 8, 2006, issue of *Nature Biotechnology*. Using the published data, facilities are able to demonstrate the quality of their work, technology developers have a metric against which to compare their work, and individual labs have the ability to directly compare statistical methods and imaging settings.

The MAQC project has expanded its scope (called MAQC-II) by adding new workgroups that will analyze patient data from large-scale clinical studies and toxicogenomics experiments, identify best practices for genome-wide association studies, and recommend methods to evaluate the performance of predictive models and classifiers.

NCTR's Animal Care Facilities Receive Excellent Rating

NCTR's animal care and use program and animal facilities received its triennial assessment by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC), International on June 14 and 15. NCTR has been fully accredited by AAALAC since 1977 — demonstrating a continued commitment to excellence in the conduct of experiments using animals. AAALAC accreditation symbolizes quality, promotes scientific validity, demonstrates accountability, and shows a genuine commitment to humane animal care.

The animal care and use program and facilities were rigorously reviewed during the 2-day visit. Excellence was noted in the sanitation/maintenance program, the level of certification and training of animal-care personnel, and in the Institutional Animal Care and Use Committee proceedings.

Publications Recently *Accepted* in Nationally Recognized Scientific Journals

Arlt, V.M., Glatt, H., Gamboa Da Costa, G., Reynisson, J., Takamura-Enya, T. and Phillips, D.H., (2007), Mutagenicity and DNA adduct formation by the urban air pollutant 2-nitrobenzanthrone, *Toxicological Sciences.*

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Chen, D., Chen, J.J., Cheng, G.C. and Soong, S., A two-stage binomial test approach of gene identification in oligonucleotide arrays, *Journal of Biopharmaceutical Statistics.*

Chen, J.J., Lee, T., Delongchamp, R.R., Chen, T. and Tsai, C., Significance analysis of groups of genes in expression profiling studies, *Bioinformatics.*

Chen, J.J., Statistics for environmental teratogenesis, *Encyclopedia of Quantitative Risk Assessment.*

Chen, J.J., (2007), Key aspects of analyzing microarray gene expression data, *Pharmacogenomics,* 5:473-482.

Dearfield, K.L. and Fuscoe, J., (2007), Impact of genomic technologies on regulatory policies - presentations at the 37th annual meeting of the Environmental Mutagen Society, *Environmental Molecular Mutagenesis,* 48(5):347-348.

Dobrovolsky, V.N. and Heflich, R.H., On the use of the TRExtm tetracycline-inducible gene expression system *in vivo*, *Biotechnology and Bioengineering.*

Evans, R. and Siitonen, P.H., Determination of caffeine and sympathomimetic alkaloids in weight loss supplements by high performance liquid chromatography, *Journal of Chromatographic Science.*

Gopee, N., Roberts, D.W., Webb, P., Cozart, C., Siitonen, P.H., Warbritton, A.R., Yu, W.W., Colvin, V.L., Walker, N.J. and Howard, P., (2007), Migration of intradermally injected quantum dots to sentinel organs in mice, *Toxicological Sciences.*

Guo, L., Mei, N., Dial, S.L., Fuscoe, J. and Chen, T., Comparison of gene expression profiles altered by comfrey and riddelliine in rat liver, *BMC Bioinformatics.*

Latendresse, J.R., Muskhelishvili, L., Warbritton, A.R. and Tolleson, W.H., Two cases of uveal amelanotic melanomas in transgenic Tyr-HRAS+ Ink4a/Arf heterozygous mice, *Toxicologic Pathology.*

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Liu, Z., Chen, H., Shaw, N., Chen, S., Wang, B., Hopper, S.L., Chen, L. and Cerniglia, C.E., (2007), Crystal structure of an aerobic FMN-dependent azoreductase (AzoA) from *Enterococcus faecalis*, *Archives of Biochemistry and Biophysics,* 463:68-77.

Mehta, J.L., Sanada, N., Chen, J., Hu, C., James, P., Dandapat, A., Sugawara, F., Inoue, K., Kawase, Y., Jishage, K., Suzuki, H., Li, D., Shirai, M., Schnackenberg, L., Beger, R., Hermonat, P.L., Thomas, M. and Sawamura, T., (2007), Deletion of LOX-1 reduces atherogenesis in LDLR knockout mice fed high cholesterol diet, *Circulation Research,* 100:1534-1536.

Mei, N., Guo, L., Liu, R., Fuscoe, J. and Chen, T., Gene expression changes induced by tumorigenic pyrrolizidine alkaloid riddelliine in liver of Big Blue® rats, *BMC Bioinformatics.*

Moffit, J.S., Koza-Taylor, P.H., Holland, R.D., Thibodeau, M.S., Beger, R., Lawton, M.P. and Manautou, J.E., Differential gene expression in liver associated with the hepatoprotective effect of peroxicome proliferators, *Toxicology and Pharmacology.*

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Slikker, W., Hotchkiss, C.E., Divine, B.L., Sadovova, N.V., Twaddle, N.C., Doerge, D.R., Scallet, A.C., Patterson, T.A., Hanig, J.P. and Paule, M.G., (2007), Ketamine-induced neuronal cell death in the perinatal rhesus monkey, *Toxicological Sciences.*

Wagner, R.D., Effects of microbiota on GI health: Gnotobiotic research, *GI Microbiota and Regulation of the Immune System.*

Wright, L.K., Popke, J., Allen, R.R., Paule, M.G., Pearson, E. and Hammond, T., (2007), Effect of chronic MK-801 and/or phenytoin on the acquisition of complex behaviors in rats, *Neurotoxicology and Teratology,* 29:476-491.

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