



# SCOPE

## NEWSLETTER

October - November 2013

### INSIDE ISSUE '13.05



Ultimate Labs Helps Feed America



HACCP And YOU!



What the MASS SPEC can do for your company?



Ultimate Labs Makes The List!



Meet Karina Trujillo

It's now been a year since we started publishing SCOPE! I hope that it has given you a peer into the lab and why we do the things we do ... help you save lives. I'm so proud of our Team Marketing for making this possible and our newest UL member, Gloria An, who is our social media guru and public relations liaison. With Halloween and Thanksgiving around the corner, we are starting to feel festive and are reminded every day how thankful we are to be of service to you, our clients. Don't let spooky Aspergillus take over your pumpkin or stinky Salmonella get your turkey! Have a safe and healthy holiday season!

- Kim



Water Testing Services by Ultimate Labs.

Ultimate Labs performs testing according to methods listed in the United States Pharmacopeia (USP), European Pharmacopoeia (Ph. Eur. or EP) and Japanese Pharmacopoeia (JP). In addition, we perform testing according to AOAC Official Methods of Analysis, ASTM testing standards, AAMI and other standard testing compendia.

The differences between the compendial water monographs is critical for the quality control of the water system and ultimately the quality and safety of your product. Testing of water systems should begin with development or review of installation, operational and performance qualification methodology through the implementation of the IQ/OQ/PQ and routine monitoring.

The control of the microbiological quality of water systems is an important consideration for most pharmaceutical and consumer product manufacturing sites. In addition, chemical purity (often represented by Total Organic Carbon or TOC and Conductivity) is another important constituent in establishing control of purified water systems. Whether testing USP or EP Purified Water or Sterile Water for Injection, using a lab that understands

Whether testing to meet United States Pharmacopeia (USP), European Pharmacopoeia (Ph. Eur. or EP), Japanese Pharmacopoeia (JP) or other compendial requirements, our full-service, cGMP, ISO 9001 accredited microbiological testing services can provide you with timely test results that you require, backed by a staff of dedicated professionals.

# Feeding America and Ultimate Labs Partner to Help Reduce Hunger



Members of Ultimate Labs labeled a record 4-thousand six hundred cans in one afternoon as part of a hunger awareness effort in San Diego! Feeding America is the largest hunger relief agency in San Diego County. More than 73-thousand people in the county receive food from the agency each week. Corporations from throughout the county provide organized volunteer efforts to assist with the cause. The Feeding America organization relies on over 9-thousand volunteers every year to sustain operations. This allows the organization to keep costs low allowing funds to go directly to programs and help those in need in the community. Gavin Morris is the marketing and communications manager at Feeding America. He says, "Volunteers allow us to keep our overhead low so that approximately 97% of every dollar donated to the organization goes directly to feeding programs." Members of the Ultimate Labs microbiology team say they chose to donate their afternoon to this worthwhile cause because it makes a difference in people's lives and they enjoy giving back to the community. Distribution of the goods takes place via 2-hundred partnering agencies which are part of a local network. The non-profit organizations allow for the food to get out to the community via farmer's markets and other avenues. Feeding America was founded in 2007 in Sorrento Valley. The organization began distributing 3-million pounds of food a year and last year distributed a record 23-million pounds. People can volunteer individually or via a corporation. More information on volunteer opportunities can be found at [www.feedingamericasd.org](http://www.feedingamericasd.org)



Members of Ultimate Labs join forces with Feeding America. (Back left to right: Ben Rojas, Jon Grinnell, Andrea Haynes, Andrew Signorelli, Front left to right: Tracey Minutolo, Lissette Silva, Evelyn Scarpelli-Board, Nam Chantepie, Zach Folsom and Feeding America Volunteer Coordinator Teresa Dale.

## Client Spotlight

Bioserv is a leading boutique contract manufacturing service provider with over 35,000 square feet of facilities whose core competencies are centered in aseptic and non-aseptic bulk formulation; filtration; filling; stoppering; lyophilization services; labeling; finished goods assembly; kitting and packaging; as well as controlled temperature storage and distribution services to support Pre-Clinical, Phase I and II Clinical Trial drug products, medical device reagents, medical diagnostic reagents and kits, and life science reagents. In addition, Bioserv's project management and technology transfer services helps clients optimize their manufacturing timelines and schedules to assure that manufacturing operations perform seamlessly and product is delivered on time. Ultimate Labs is an extension of Bioserv's quality control department. We are happy to partner with Bioserv as they continue to grow.



## Ultimate Labs named Best Places to Work by the San Diego Business Journal

The San Diego Business Journal recently named locally based Ultimate Labs one of the Best Places to Work at a ceremony held at the Mission Bay Hilton Resort. The annual list is announced each summer by the publication in conjunction with the Best Companies Group. Nominations are accepted in the early part of the year and each nominee undergoes a rigorous qualifying round which includes employee input via a two-part survey to determine who makes the list of top 100 companies in San Diego County.

The survey and awards program is designed to identify, recognize and honor the best places of employment in San Diego, ultimately benefiting the county's economy, workforce and local businesses by sharing some of the creative programs that make them stand out. The Best Places to Work in San Diego list is composed of 100 companies ranging from small, medium, large to mega depending on employee size.

Kim Lim is the founder and CEO of Ultimate Labs. The Carmel Valley resident says this fall will mark the company's fifth year anniversary. Lim says Ultimate Labs has shown steady and solid growth in both their client base and revenue over the past five years. She is exuberant over the announcement saying, "We have achieved this honor because of our clients and our excellent team which possesses over 25 years of experience. Each and every one of them strives to give their best every day."

Many of the companies on the Top 100 list, including Ultimate Labs, have programs in place which are designed to give back to the community. Some of the volunteer programs Ultimate Labs works with include Habitat for Humanity, the San Diego Food Bank and other organizations. The company also has an employee incentive program granting awards to top performers. Team members are able to participate in cross departmental training for career growth and higher learning. Advanced certification is also promoted via employee tuition funding upon approval for continuing education.

Lim adds, "Our motto of 'helping you save lives' is the overarching message we convey and what we stand behind. We have great plans in store for the many years to come."



San Diego Business Journal's Best Places to Work award honors Ultimate Labs. (left to right: Yvette Lee, Janina Wills, CEO Kim Lim, Gloria Limas An)

## What is the MASS SPEC?

This month we're unveiling the latest addition to our arsenal of cutting edge instrumentation, the BioMerieux Vitek MS. The Vitek MS uses Matrix Assisted Laser Desorption Ionization Time-of-Flight or MALDI-TOF, an innovation in mass spectrometry to produce microbial identification results in minutes.

Currently, the most widely used methods of microbial identification, such as Vitek 2, involve phenotypic testing, relying on the "behavior" of the isolated organism in a series of biochemical tests and producing results in 2 to 14 hours. By contrast, the Vitek MS determines the identification of an organism based on its composition, ionizing the proteins from intact microbial cells. Measured for mass to charge ratio, these ions are quantified and the result represents a molecular "fingerprint" for a particular organism. This translates to a higher degree of accuracy when compared with current methods.

The Vitek MS received FDA clearance in late August. Currently we are offering identification by Vitek MS for bacteria and yeast isolates, with mold identification on the horizon!



Evelyn Scarpelli-Board showcases the Mass Spec at Ultimate Labs.



## HACCP Plans and YOU

Originating with NASA and Pillsbury Inc. to provide astronauts with safe food during space expeditions, HACCP, or Hazard Analysis and Critical Control Points, is now used to prevent hazardous contamination of finished food products in all industries. Traditionally, a "HACCP Plan" is used to set processes in place to avoid adulteration of the final product.

The FDA and USDA currently require HACCP programs for juice and meat respectively, although many other companies producing numerous other products have implemented HACCP plans to protect their customers from contaminated food products. In fact, the ISO 22000 has incorporated the following 7 HACCP principles as a standard for food safety:

- Principle 1: Conduct a hazard analysis.
- Principle 2: Identify critical control points.
- Principle 3: Establish critical limits for each critical control point.
- Principle 4: Establish critical control point monitoring requirements.
- Principle 5: Establish corrective actions.
- Principle 6: Establish procedures for ensuring the HACCP system is working as intended.
- Principle 7: Establish record keeping procedures.

Of course, a key part of established procedures for ensuring the HACCP system is working as intended involves microbial sampling and analysis; as a FDA approved lab, Ultimate Labs Inc. specializes in all microbial testing in the food industry. Environmental sampling of various pathogens including Listeria and Salmonella ensures that sanitation procedures are effective and sufficient. Representative ingredient, intermediate, and finished product testing for all forms of microbial contamination are essential to illustrating the process flow is able to control adulteration of product.

## Q&A

**T**urnaround Time for water testing  
Our turnaround time from when the sample is received is 3 business days. One should receive the report on the third day.

**S**ell to different state?  
Ultimate Labs does have several clients out of California. They have chosen us because of our quality of work.

**H**ow to ship sample?  
Ultimate Labs is in the process of putting together Ultipak 2.0 and a video demonstrating how to sample and how to package and ship samples to Ultimate Labs.

**SAME DAY  
SAMPLING  
WASH  
TEST  
STAPH  
AUDIT  
CLEAN  
SOAP  
MONITOR** ANTIBACTERIAL

## Part of Your Team: Meet Karina Trujillo

Please welcome Karina Trujillo, the newest person to join our Project Management team. Karina understands that project management demands excellent communication, superb organization skills, acuteness to detail and the ability to critically think and design successful plans for jobs. As the newest PM, Karina will primarily focus on optimizing her skills in creating or discovering the most efficient methods to meet and exceed her clients' expectations. Karina brings an infectious cheeriness to the team and enjoys the being able to integrate, practice and apply her skills on a daily basis. She feels that communication is the key to any PM/Client relationship saying, "It's important to effectively communicate with your client by knowing who to talk to, what questions to ask and actively listening to the clients' concerns."



## We Want To Hear From You

We had incredibly positive feedback from our inaugural issue of SCOPE and we'd love to hear from YOU. If you have feedback, or a story that you want us to include in one of our monthly issues or on our online website, please write, call or email. We love to hear new stories of technology, business, and bugs. Write to the address below.

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## Thank You!

"As a contract lab service, Ultimate Labs, Inc. has always provided a quality service that has met or exceeded our expectations. Their expertise and timely execution has been critical in ensuring success in meeting our client's needs and we are looking forward to working with them on future projects."

Thanks,  
Carlson Patterson  
QA Aseptic Specialist  
BioServ America