

This year promises many exciting offerings from Idaho Technology (ITI) including a new AOAC-approved *Salmonella* assay for the R.A.P.I.D.[®] LT and new warfarin genotyping assays that can be used on a variety of platforms. The *Salmonella* assay proves to be a great contribution to the food industry as manufacturers look for faster methods to test food products. The warfarin assays, as discussed in the

article, are part of the new wave of personalized medicine genotyping.

With summer coming, we thought we would tap into the experience of one of our experienced travelers and offer some tips for traveling. You do not want to miss this amusing but informational article. Enjoy the summer!

Idaho Technology Receives AOAC Approval for Salmonella Assay



Idaho Technology, Inc. (ITI) is pleased to announce that their *Salmonella* LT assay has received AOAC Research Institute approval. AOAC International is a not-for-profit scientific association committed to worldwide confidence in analytical results.

The *Salmonella* LT assay uses real-time PCR technology to identify the presence of *Salmonella* in food samples. It is used with ITI's R.A.P.I.D. LT Food Security System, which uses reduced enrichment times—only 16 hours followed by PCR—paired with real-time PCR technology to provide rapid and accurate results. The R.A.P.I.D. LT instrument combines rapid air thermocycling and a real-time fluorimeter to reliably identify test food samples in less than 35 minutes, a great improvement considering PCR testing traditionally can take several hours.

The complete system provides the easiest end-to-end PCR protocol and now is the only AOAC-approved post-enrichment pooling protocol. Using a 5:1 sample pooling approach enables the cost per test to approach that of traditional methods. "Idaho Technology's 5:1 pooling protocol can reduce PCR assay costs by up to 80%. This places the assay price in the same range as ELISA testing," says Dennis D'Alfonso, National Sales Manager.

"The validation of this test marks a major achievement for Idaho Technology as we extend our leadership role from R.A.P.I.D. pathogen identification in the biodefense market into the food security industry," states ITI Chief Development Officer Todd Ritter.

Salmonella is a microbe that lives in the intestinal tracts of animals and humans. Humans usually acquire the microbe by eating contaminated food or handling animal feces. Every year, there are 40,000 cases of *Salmonella* poisoning reported.



Salmonella (in red)

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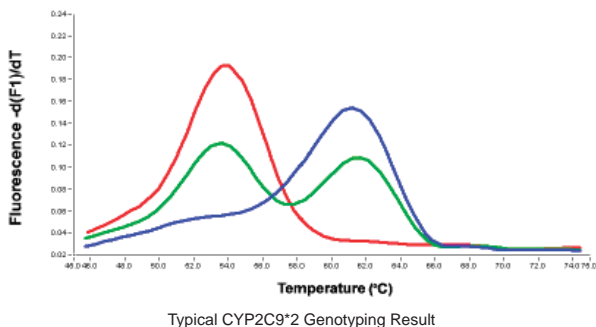
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Genotyping for Warfarin Therapy—The Beginning of Personalized Medicine

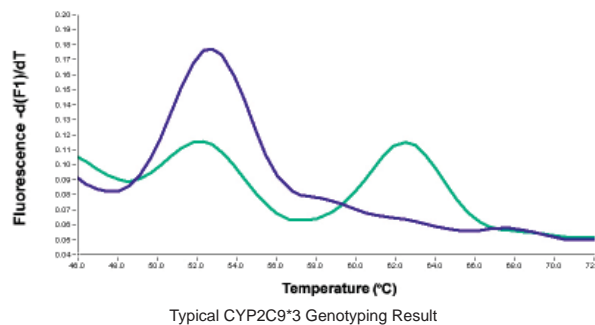
The Human Genome Project raised the expectation of personalized medicine—the ability to predict an individual’s response to a particular medicine so a doctor could adjust dosing before initiating therapy. Indeed, the Pharmacogenetics Pharmacogenomics Knowledge Base (PharmGKB) currently lists 161 variant genes that influence responses to drugs and 385 drugs that produce variable responses that are dependent upon genetic factors (<http://www.pharmgkb.org>). Despite the known gene-drug interactions and the feasibility of pre-therapy genotyping, the use of genetic testing to guide therapies has not been widely incorporated into clinical practice. Plausible reasons for this include the lack of rapid, sensitive, and specific genotyping assays for use in “real-time” clinical applications.

Warfarin is the current mainstay of anticoagulation therapy; however, the clinical use of warfarin is complicated by its narrow therapeutic range and by wide inter-individual dosing requirements. This variability leads to erratic initial dose responses with increased bleeding risk associated with over-anticoagulation or risk for a thromboembolic event if anticoagulation is subtherapeutic.

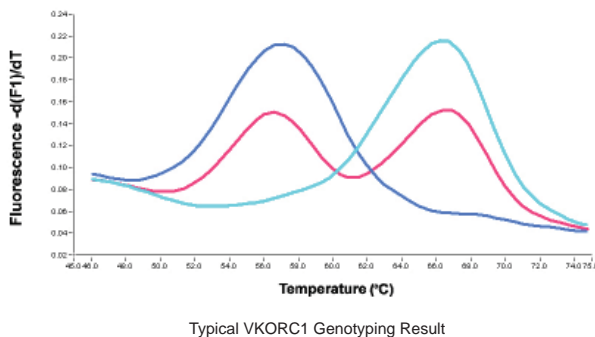
Pharmacokinetic variability in warfarin dosage arises, in part, from coding alterations in the gene for cytochrome p450 isoform, CYP2C9. The cytochrome p450 enzymes are monooxygenases that catalyze oxidative modification of substrates and are involved in the metabolism of more than 80% of pharmaceuticals, including warfarin. The CYP2C9*2 variant, a C to T substitution at codon 144 (c.332), results in the replacement of arginine by cysteine and occurs in 11%–12% of the population.



The CYP2C9*3 variant, an A to C substitution in codon 359 (c.813), results in replacement of isoleucine with leucine and is present in 7%–9% of the population. These coding variations produce reductions in enzymatic activity of 30% for *2 and 80% for *3 homozygotes. Individuals with one or more CYP2C9 variants have a significantly extended time to achieve a stable dose and have increased risk for severe or life-threatening bleeding.



The molecular target of warfarin is vitamin K epoxide reductase, an enzyme component that participates in the gamma carboxylation of multiple vitamin K-dependent clotting factors. The gene for vitamin K epoxide reductase complex subunit I (VKORC1) was recently identified along with what is suspected to be the functional variant in VKORC1 (c.1-1639 G>A) associated with variable promoter activity.



Recently, on medication labels, the FDA has begun recommending genotyping for these SNPs that are associated with warfarin dosing. In response, Idaho Technology has developed rapid genotyping assays using SimpleProbe® to genotype the CYP2C9 *2 and *3 loci, as well as the VKORC1 G-1639A locus. ITI’s advantage over other commercially available kits is rapid turnaround time, low cost, and the flexibility to use the assays on several platforms. Coupled with a 10-minute DNA extraction from buccal swabs, time to result using ITI’s assays is less than 1 hour.

The interaction between individual sensitivity to warfarin dosing and genotype represents the first clinically relevant application of personalized medicine, and Idaho Technology is excited to be involved in this market. A large clinical trial will commence later this summer, where ITI will be involved at several of the participating sites. The plan is to enroll 2000 patients with no history of warfarin therapy and evaluate the efficacy of genotype-guided dosing. Participation in this clinical trial will lead to the ITI SimpleProbe warfarin reagents being submitted for FDA approval.

Travel Tips for the On-the-Go Traveler



Last year I logged 140,000 miles on an airplane (that is more than 5 trips around the planet for you trivia buffs). After that many miles, most people feel something less than glamorous. Contrary to conventional wisdom, airport cuisine is not so . . . um . . . cuisine-like, and your internal clock is lost with your luggage three trips back. Now there are a lot of Web sites and articles detailing quick ways to get strip searched in security, how to get the middle seat on overbooked flights, and how to travel to places you don't want to go. I won't rehash those gems of wisdom, but will share with you a few things I have picked up along the way.



First Rule of Travel Club—Stay hydrated. It is harder to do with the new airport screening rules, but you will feel a lot better once you arrive at your destination. Keep the water coming in (and going out). When abroad, if fizzy water isn't your thing and your language skills are "no bueno," give the bottle a squeeze and go with the one that is the softest (no carbonation).



Second Rule of Travel Club—Sleep. Business travel gives you the opportunity to exercise your inner rock star (don't deny it). But sleep is your friend. Nap when you can. Learn to sleep on planes. Don't deny yourself the help of modern chemistry for getting to sleep on international jaunts (prescription sleep aids these days are quite nice without many lingering side effects).



Third Rule of Travel Club—Get some exercise. Go for a walk or jog. Get up early to run, or take a stroll

to dinner rather than hopping in the car. It takes some discipline, but you will feel better during and after your trip.



Fourth Rule of Travel Club—Find some decent food and have a seat. Eating for business travel is primeval—hunters and gatherers prevail. Talk up the desk people at your hotel and find out where they eat. If you are just nosing around without the inside scoop, look for local places that have people eating (it is like a star rating system: more people = more stars). Once you have found a spot, sit down and relax—food is to be enjoyed.



Fifth Rule of Travel Club—Don't overeat. It is easy to treat every morning like it is weekend brunch at the hotel buffet. It is also tempting to go for what is quick and easy (i.e., fast food). Stick with what you eat at home (assuming you treat your body as a temple and not as an amusement park). You can enjoy the occasional indulgence, but try to stick with healthier fare. And remember, you are not required to finish off every scrap of that 3000 calorie gut bomb the restaurant called "the sampler."

As you know, business travel isn't all the fun your friends think it is. If I manage to follow three or four of these recommendations while I am out there, I usually have a bit more life left in me when I make it home. After all, we all prefer to recover from weekends at work not recover from work on weekends.

Safe Travels
Matt Scullion, Business Development



Photo of the Quarter

Lupines
Alta Ski Resort
(Kathy Jedrzejczyk,
Research Associate)

Dates to Remember

May

30–31 International Hazardous Materials Response Teams (HAZMAT)
Hunt Valley, MD
www.iafc.org

31–3 European Society of Human Genetics (with
June Cadama)
Barcelona, Spain
<http://www.eshg.org/eshg2008>

June

2–4 American Society for Microbiology (ASM)
2008 108th General Meeting
Boston, MA
<http://gm.asm.org>

23–24 Biodetection Technologies 2008
Atlanta, GA
<http://www.knowledgefoundation.com>

24–26 National Defense Industrial Association
(NDIA) Joint Chem/Bioexhibit
Ft. Leonardwood, MO
<http://www.ndia.org/Template.cfm?Section=8300&Template=/ContentManagement/ContentDisplay.cfm&ContentID=22297>

July

16–18 Southwest Meat Association
Scottsdale, AZ

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

Department of State Note: The R.A.P.I.D. System and RAZOR Instrument are controlled for export under the International Traffic in Arms Regulations (ITAR), administered by the U.S. Department of State, Directorate of Defense Trade Controls (DDTC) and may not be exported or transferred to any foreign national without prior approval of the DDTC.

R.A.P.I.D.® and RAZOR® Systems Training

ITI offers training courses for the R.A.P.I.D. and RAZOR systems. Training for two people is included with the purchase of the R.A.P.I.D. or RAZOR instruments, and more can attend for an additional cost. The training courses are three days for the R.A.P.I.D. and one day for the RAZOR. Courses focus on concepts of 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.



Did You Know . . .

. . . that the RAZOR EX is reverse transcription compatible? You can now detect RNA viruses in a RAZOR pouch.

. . . that The 10™ RAZOR pouch allows you to detect 10 assays from one sample? It also includes inhibition controls to check for sample purity and is compatible with both the RAZOR EX and RAZOR instruments.

. . . that the RAZOR EX uses bar codes to load protocols? You can also view results right on the color screen. And, if you want to print a report, you can download the data by either USB or Bluetooth®.



For more information about the RAZOR EX, please contact Abby Bird at abby_bird@idahotech.com or (801) 736-6354 x. 416.



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