

Change of Seasons May Necessitate Use of Special Shippers

Sites in both the Northern and Southern hemispheres are facing the most extreme seasons of the year - summer or winter. In preparation for extreme temperatures, ICL recommends that sites in these locations take appropriate measures to protect samples from extreme temperatures.

- **All sites in regions of extreme cold** (<0°C or <32°F for prolonged periods) may contact ICL to request Extreme Ambient Shippers which can be used to protect samples from cold temperatures (up to -18°C or 0°F). These boxes are recommended by ICL in particular for sites in Russia and Ukraine.

- **ALL sites in regions of extreme heat** (>25°C or >77°F) are provided with Thermal Ambient Shippers by ICL which are used to protect samples from hot temperatures. Please ensure you are using these shippers when shipping ambient samples and request additional shippers as you need them.

These shippers are easy to use and you may order them by contacting your ICL Site Services team by phone or by sending an e-mail request to labsitehelp@iconplc.com.

Preparing for Your Study Monitor's Visit

Laboratory testing comprises a significant amount of the study activity and source documentation in clinical studies. Consequently, reviewing lab information is often a major focus of a study monitor's site visit. We recently worked with study monitors to develop the following checklist of lab-related items to help sites prepare for an upcoming monitoring visit.

- Check frozen sample storage to ensure all study samples have been shipped, in accordance with timeframes indicated in the study.
- Review all copies of lab certificates and Curriculum Vitae (CVs) to ensure that they have not expired. (Note that updated certificates can be accessed via ICL's Investigator Site Resource Center at www.iconplc.com/labsitehelp.*
- Check your ICL kit supplies for any expired kits, discard expired kits at site and contact ICL Site Services to order more, if needed.*
- Ensure that lab reports for each study subject's visit have been placed in subject's study binder in the proper visit sequence.
- Check all lab reports to ensure they have been properly reviewed, documented and signed by the clinical investigator. If you should be noting the clinical significance of abnormal labs in your EDC, have this up to date and reconciled with notes made on paper lab reports.
- Make sure clinically significant results reflect documented follow-up, as required by study protocol. If results represent Adverse Events (AEs) or Serious Adverse Events (SAEs), ensure files reflect required subject & sponsor follow-up.

* These items may not be reviewed during your site visit; however, they are important to ensuring proper management of lab-related activities and documentation.

Plan Ahead for the Holidays

The last quarter of the year marks a period with many observed holidays around the world. This year a number of holidays will be celebrated near weekends, which makes planning for specimen shipments even more challenging. All ICON Central Laboratories facilities will be open to receive and process specimens throughout the holidays with the exception of December 25 when our Dublin Laboratory only will be closed.

The table below indicates 4th quarter holidays on which sites should be aware of courier closings and limited service at select ICL Site Services locations. Sites should also consider their local courier holiday schedule when planning shipments.

- Sites with 1 day transit time to their ICL facility should ship specimens:
No later than Wednesday, 23 December prior to Christmas
No later than Wednesday, 30 December prior to New Year
- Sites with 2 day transit times to their ICL facility should ship specimens:
No later than Tuesday, 22 December prior to Christmas
No later than Tuesday, 29 December prior to New Year

DATE (HOLIDAY)	NEW YORK		DUBLIN		INDIA		SINGAPORE	
	SITE SERVICES	COURIERS NOT DELIVERING	SITE SERVICES	COURIERS NOT DELIVERING	SITE SERVICES	COURIERS NOT DELIVERING	SITE SERVICES	COURIERS NOT DELIVERING
16-October: Deepavali					Limited Service			
26-October: October Holiday			Limited Service	TNT, DHL				
1-November: Karnataka Rajyotsava					Limited Service			
2-November: Guru Nanak's Birthday					Limited Service			
15-November: Deepavali							Limited Service	FedEx
26-November: Thanksgiving	Limited Service	FedEx						
27-November: Thanksgiving	Limited Service							
27-November: Hari Raya Haji							Limited Service	FedEx
25-December: Christmas Day	Closed	FedEx	Closed	TNT, DHL	Closed		Closed	FedEx
26-December: St. Stephen's Day / Muharram			Limited Service	TNT, DHL	Limited Service			
28-December: Bank Holiday			Limited Service	TNT, DHL				
1-Jan. 2010: New Year's Day	Closed	FedEx	Closed	TNT, DHL	Closed		Closed	FedEx

ICON Launches New Website

In October, ICON plc, the global company of which ICON Central Laboratories is a part, launched a new corporate website. The new website now integrates all ICON divisions' web-based information into one central resource for investigator sites, including those previously found on ICL's website, www.icolabs.com.

ICL's Investigator Site Resource Centre, where many of our sites obtain helpful information regarding specimen collection, packaging, shipping, frequently asked questions and links to a variety of additional related resources, can now be accessed via www.iconplc.com.

For faster, more direct access to the Investigator Site Resource Center, simply type www.iconplc.com/labsitehelp into your browser or save this link as a "favorite" for future use.

Visitors to the ICL website, www.icolabs.com, will be redirected automatically to the new site for the next few months. However, sites are encouraged to make note of ICON's new web address in their lab manuals and become familiar with how to locate online resources for any other ICON divisions with which they may be working.



Thanks for the Feedback!

ICL is pleased to have received over 4,000 responses to our 2009 Investigator Site Survey. Your feedback will be invaluable to ICL as we continue to enhance the services we offer to ICL study sites worldwide.

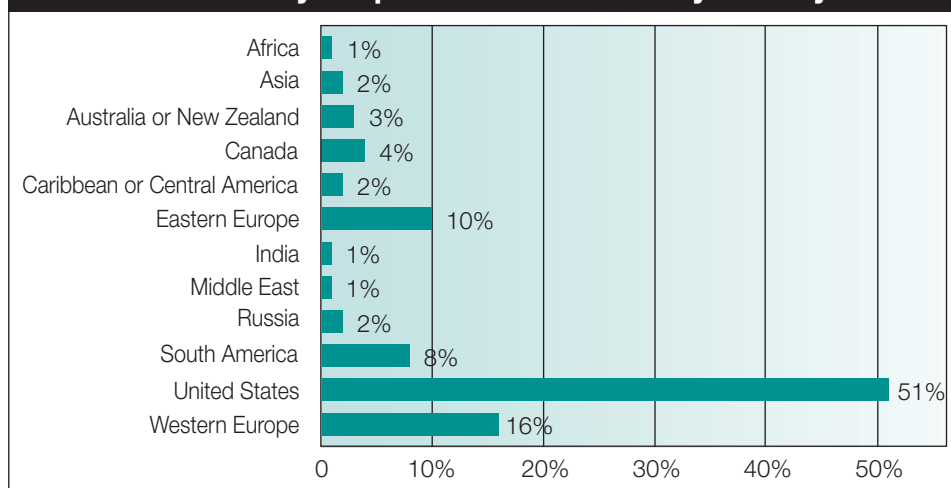
To encourage response to the survey, those completing the survey were entered into a drawing to win one of 15 iPod Nanos®. The lucky winners are listed below.

Thanks again to all who participated. We look forward to sharing some of the feedback and trends in future issues.

iPod Nano® winners were:

Ana De Sousa, *Montreal, Quebec Canada*
 Anton Sodomov, *Zaporizhzhya, Ukraine*
 Rom Kuras, *San Francisco, CA USA*
 Sandra T. Baigorria, *Cordoba, Argentina*
 Dawn Finkler, *Oak Brook, IL USA*
 Julian Gheorghe Diaconescu, *Craiova, Romania*
 Mary Ann Hudson, *Overland Park, KS USA*
 Alicia Gonzalez, *Toluca estado de Mexico, Mexico*

Site Survey Respondent Distribution by Country



Denise Darlington, *Hamilton, New Zealand*
 Kevin Sieja, *Denver, CO USA*
 Rosa Gloria Najera Hernandez, *Coahuila, Mexico*
 Marcel Ionescu, *Craiova, Romania*
 Jene Formaro, *Clive, Iowa USA*
 Marta Roeder, *Campbell, CA USA*
 Sue Healey, *Spokane, WA USA*

iPod is a trademark of Apple Computer, Inc.

Site to Site

In our recent survey we noted that 59% of the 2,856 study coordinators responding had more than 5 years of clinical trial experience. We thought it might be helpful to put this experience to work by encouraging sites to send in tips for more easily managing subject visits and lab-related activities. If your site has a helpful tip for our new "Site to Site" newsletter feature, please provide the following information:

- Your name and position (may be used in our newsletter publication and/or on our website)
- Your clinical investigator's name
- Your city, state/province country
- Your e-mail address and phone number
- A brief summary of the challenge your site had and the solution your site implemented to respond to it. Remember that these should be solutions that are generally helpful to sites, regardless of the study in which they may be participating.

Email to:
LabSubjects@iconplc.com

We've Heard You! New E-mail Report Features and Report Formats

In response to feedback from our investigator sites, ICL will be making changes to our e-mail reporting procedures and formats. In the coming weeks, ICL will introduce a new method of e-mailed reports that will send multiple reports in one e-mail message. This new procedure will help sites by reducing the volume of e-mail messages they receive from ICL.

We will also be enhancing the appearance of lab reports in general. The few minor changes you will see include the Lab Director's name moving from the bottom of the form to the top, the protocol number moving to the upper right of the report, and based on updated ISO regulations, the Lab Directors names for any alternate ICL testing locations referenced on the report, if applicable. You will also notice that our hard copy reports will be delivered in black and white shortly, making them more legible and easier to photocopy and maintain in your study files. These changes are strictly aesthetic in nature and will not affect the report content, test result sequence or other information that your study requires.

As always, we appreciate our investigator sites' suggestions and are glad to respond with these new service features. If you have questions or concerns regarding these changes or any other aspect of your ICL service, please contact your ICL Site Services representative or e-mail us at labsitehelp@iconplc.com.

Frequently Asked Questions

Q. Is there a way to re-order supplies via e-mail? If so, what information is required?

A. YES, you can easily re-order ICL lab supplies via e-mail. Simply send a message to labsitehelp@iconplc.com at least 2 weeks prior to your need to have the supplies at your site. Please include the following information in your e-mail request:

- Protocol Number
- Site/Investigator Number
- Your Name
- Phone Number
- And of course, Supply Details, including
 - o Kit Names
 - o Quantities Requested
 - o And Requested Due Date

Q. I enjoy reading ICL's Lab Subjects newsletter but would like to see more information specific to the study in which my site is involved. Why don't you include this type of information?

A. A number of respondents to our recent site survey asked this question. Our Lab Subjects newsletter is distributed globally to sites participating in hundreds of different ICL-supported clinical trials. We provide updates and helpful tips that can be useful to all sites, regardless of the study in which they are involved. Also, ICL is contractually obligated to study sponsors to maintain the confidentiality of the studies we support and therefore cannot reference specific protocols in publications for general distribution. Many study sponsors prepare and distribute study-specific newsletters. ICL may use those publications to update sites regarding study-specific lab issues.

Q. I'm involved in a study that requires the use of very small tubes. The ICL barcode label I have is longer than the tube, itself. How should I affix the label to the tube?

A. ICL recently changed to a smaller 1"x 1" label so this should not be a problem in the future. However, for sites that may still have the larger 1"x 2" labels, please use the following method to affix the label: Starting under the cap, place the label on the tube with the barcode label running down the tube, being sure that the entire barcode is affixed to the side of the tube. Wrap the remaining portion of the label that does not contain the barcode around the bottom of the tube. This approach will enable ICL to scan the barcode and readily process the specimen.

To send us ideas or suggestions for future newsletter topics, contact us at LabSubjects@iconplc.com.

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