

Sample Collection and Preparation Steps to Ensure Quality Lab Results

Quality laboratory results begin at the investigator site. What you do during specimen collection, preparation and packaging can mean the difference in a specimen that produces a quality test result and one that must be rejected. On page 3 you will find a table that describes some of the most common causes of specimen rejection and how they can be prevented.

Communication and Planning Important During Inclement Weather

Severe weather conditions continue to challenge couriers and force some air hubs to close temporarily. As a result, some sites have experienced delays in shipping specimens to our laboratories. ICL's Logistics Department is working to assess situations daily and implement contingency plans where possible. If your site experiences severe weather conditions, consider speaking with your study monitor regarding whether subject visits should continue or, if possible, be postponed. If postponed, your site may experience fewer test cancellations due to transit delays. For questions regarding shipping during inclement weather, contact your ICL Site Services representative or e-mail us at labsitehelp@iconplc.com.

ICL Language Line Makes Communication Easier

In our recent survey only 37% of respondents were aware our Site Services Department provides on-demand language interpretation for telephone calls. The better news is that most (93%) of respondents who had actually used ICL's language service were very pleased with it. If you need translation assistance when contacting our Site Services Department, let your representative know you would like to use the language interpretation service and language you prefer. We will have a medically trained interpreter join the call.

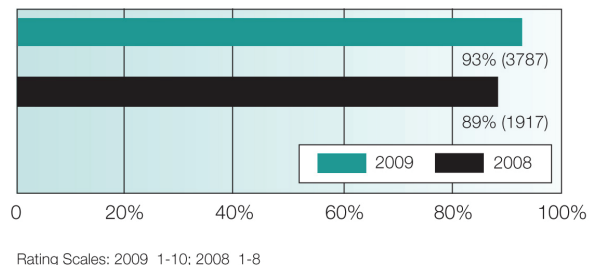
Our Resolution for the New Year – Even Better Site Support

As we start another year, our entire Site Services staff would like to thank you for the helpful feedback you have provided on a daily basis and via our 2009 Site Survey. We are committed to providing the best support in the industry to investigator sites, and we rely on your suggestions to shape our services.

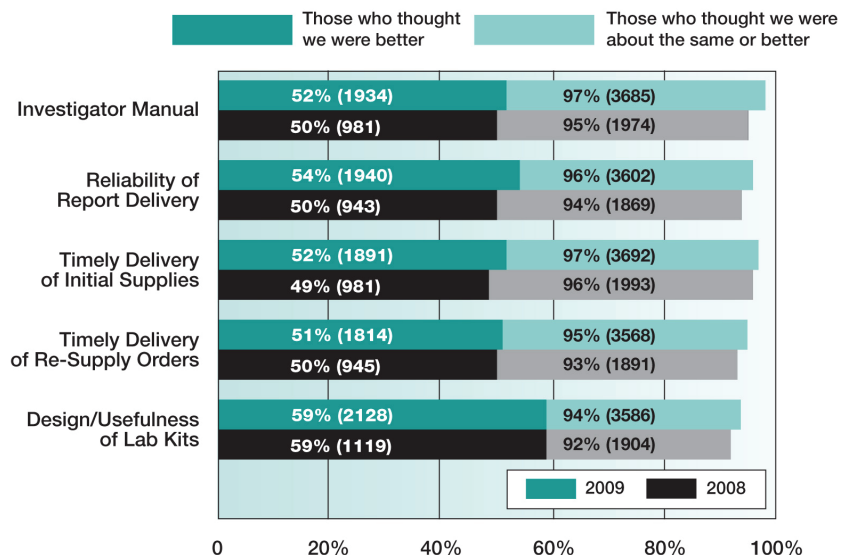
Your responses to the 2009 site survey reassured us that we are moving in the right direction to deliver the types and quality of services necessary to make your jobs easier. Our resolution for 2010 is to do even more.

What you told us in our 2009 Site Survey

Respondents Satisfied to Very Satisfied with ICL Service Levels



ICL Service Quality Compared to Other Central Laboratories



Our plans for enhanced Site Support in 2010

We're pleased with those results but not satisfied! Continuing to expand our services and enhance the quality of those we currently offer are key objectives for us at ICL in 2010. Here are just a few of the new and enhanced services that sites can look forward to in the coming year:

- More web-based instructional videos regarding specimen collection/preparation
- Great access to online information via our Investigator Resource Center
- Even more seamless Site Support with coverage expanding to 363 days per year

SITE - to - SITE

Suggestions submitted from investigator sites regarding how to make life easier!



Thanks to Donna L. Bashford, RN, BSN, Research Study Coordinator at Southern Gastroenterology Associates in New Bern, NC USA, who was the first person to send us a suggestions for our new “Site-to-Site” feature. She offers a great way for sites involved in multiple studies to organize study-specific materials for quick access. She writes:

We were wasting time in our shipping process gathering the FedEx labels, FedEx plastic biohazard sleeves, extra packaging, etc. We are using medium sized expandable file folders that will close with either Velcro or elastics. One is designated per study and includes the following: Pre-printed FedEx labels, FedEx shipping sleeves, extra ICON (or other lab) biohazard sealable pouches, the absorbent inside packaging and any other study specific requirements for shipping each lab sample. We keep all of these, labeled in a bin in our lab processing area and at our finger tips. We have saved time, we are exercising consistent shipping protocols and we are not having the lab errors we had in the past. Right next to the bin we also keep the lab manuals tabbed to the commonly used pages, again at our finger tips.

If you have a tip to make the laboratory portion of your study go more smoothly, please send it to us at labsubjects@iconplc.com. Suggestions should be relevant to a broad range of studies.

Important Information Regarding Refrigerated Shippers

If your site is using ICL’s refrigerated shipper, please note that the gel packs that must be frozen prior to shipment should be frozen at -20°C only. If gel packs are frozen at a temperature below -20°C, samples could freeze during shipment and could compromise their results or our ability to provide accurate results.

Frequently Asked Questions

Q. Why does ICL request that I call or e-mail to acknowledge receipt of their telephone message regarding a panic value?

A. Calling ICL back when we have left a phone message regarding an alert value is extremely important so that we can confirm that your site has received the result(s) and that subject safety procedures have been completed. In addition, pharmaceutical sponsors require that we report metrics regarding how long it takes for ICL to report alert values. We cannot consider the process completed until we receive your confirming call or e-mail. The College of American Pathologists, one of our accrediting organizations, also requires this procedure.

Q. Why do I need to use the Thermal Ambient Shipper? I have never used it in previous studies.

A. The Thermal Ambient Shipper is an enhanced shipper that represents considerable research on the part of ICL’s Logistics team to provide shippers that maintain appropriate temperatures while en route from sites to our laboratory facilities around the world. While you are correct that not all studies require the use of such shippers, your study sponsor has authorized your site to receive these new shippers because of the climate in your area or because of the transit route and time required for shipment to our facilities. Using the Thermal Ambient Shipper for all ambient specimens and complying with the pack-out instructions provided will offer added protection to your specimens, greater assurance of specimen integrity and more accurate test results for your study subjects.

First Quarter 2010 Holiday Schedule

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
12-February: Maha Shivaratri					Limited Service			
14-16-February: Chinese New Year							Limited Service 15 Feb.	
15-February: Presidents' Day	Limited Service	FedEx						
1-March: Holi					Limited Service			
16-March: Ugadi					Limited Service			
17-March: St. Patrick's Day			Limited Service	TNT, DHL				

Sample Collection and Preparation Steps to Ensure Quality Test Results

Sample Integrity Issue	Definition	Cause	How to Prevent
Clotting	A sequence of complex chemical and physical reactions that results in conversion of blood into a coagulated mass, making specimen unacceptable for coagulation or CBC testing	<ul style="list-style-type: none"> Gauge of needle is too large or too small for the tube vacuum Failure to adequately mix the sample with the anticoagulant in the tube following collection 	Use proper collection system as well as phlebotomy and sample handling techniques.
Hemolysis	The occurrence of a reddish tinge in the serum or plasma due to the presence of liberated hemoglobin	<ul style="list-style-type: none"> Excessive vacuum in vein, causing red cells to be drawn toward the bore of the needle too quickly Gauge of needle is too large or too small for the tube vacuum Vigorous mixing or shaking of the filled collection tube 	Use proper collection system as well as phlebotomy and sample handling techniques.
Platelet Clumping	Partial clotting of a specimen that becomes evident on a blood smear and can affect platelet results	<ul style="list-style-type: none"> Usually due to EDTA preservative not mixing properly with specimen Platelet clumping can rarely be indicative of a medical condition known as thrombocytopenia 	Proper tube inversion immediately after collection. <i>To confirm platelet clumping is not due to clinical thrombocytopenia in the study subject, obtain sponsor approval to collect a blue top tube in addition to the EDTA tube. Label it as "Special Handling for Platelets", along with the Subject ID and date of collection.</i>
EDTA Changes	Changes in the shape of blood cells collected in a tube with EDTA preservative	EDTA preservative in tube does not mix properly with specimen or act properly to preserve the cells	An occasional chemical phenomenon that cannot be prevented by the site
Age of Specimen	The elapsed time since specimen collection has exceeded the specimen stability period for the requested test	Usually caused by delays in transport time to the laboratory	Ship specimens on day of collection (unless otherwise indicated in your lab manual). Schedule collections to avoid days when no courier pickup is available (weekends and holidays).
Expired Tube	Tube manufacturer's expiration date has been exceeded	Expired tubes are a source of potential patient safety issues. Expiration dates are based on loss of vacuum within the device.	Check kits often. Use visit kits with the shortest expiration dates first. Place kit orders to ensure sufficient time for delivery.
Insufficient Sample Quantity	Amount of sample provided either not sufficient to perform the test or would not render the appropriate ratio of sample to tube preservative	Failure to collect the required amount of sample in the collection tube/transport tube	Carefully review specimen requirements in your ICL lab manual and collect accordingly.
Specimen received at wrong temperature	The sample arrived at the laboratory at a condition that is not consistent with test requirements and therefore could yield inaccurate results	<ul style="list-style-type: none"> Selection of improper shipper Improper courier handling 	Ensure frozen specimens are maintained, packed and shipped as indicated in manual. If specimens are being packaged appropriately and you receive comment frequently, contact Site Services to report problem and review other courier options.

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

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