

Preventing and Responding to Lab Queries

You have just arrived in the clinic with a busy day ahead and you open your e-mail or go to the fax to discover several queries from ICON Central Laboratories. We know that is not your favorite way to start your day, so we thought an article that gave some insight into the query process as well as how they can be prevented might make life easier for our investigator sites.

Why Do You Receive Them?

ICON Central Laboratories issues queries for a variety of reasons; however there is one goal in mind – clean data. Most of the data captured by our laboratory is needed to issue accurate laboratory test results and complete reports. We are also accountable to the Study Sponsor and accrediting organizations to meet quality standards for laboratory reporting.

What Happens (Or Doesn't) If You Don't Complete And Return Query Forms?

If you have received a query, it is likely that the lab report will not be issued until it is resolved. A query may be generated by a phone call, email, or fax depending on your site's location and resources available.

Typically, when a query is generated our Site Services Department makes several attempts to reach site personnel to resolve the issue. Queries are usually sent to the Clinical Research Coordinator we have listed for the site but queries may also be directed to the Investigator (if no CRC is on file) or even the CRA (especially true for sites outside the United States). Open queries that have not been successfully resolved within a reasonable period of time will be escalated to the Study Sponsor for follow up with the site.

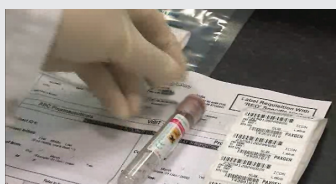
What About Queries That Are Associated With Critical Values?

Although the lab report will not be issued until a query is resolved, ICON Central Laboratories will continue to call critical values or a value that meets the alert value criteria established by the Study Sponsor. These are only called to the site, and not the sponsor, until the open query is resolved, so it is important to follow up with your medical monitor to discuss such values, if required.

New Instructional Video Now Available

In a continuing effort to assist our sites and also improve result quality, we have developed a new video, which demonstrates the proper collection procedure for PAXgene samples. This video is now available for viewing at our Investigator Site Resource Centre at www.iconplc.com/labsitehelp, under "Site Training", or you may click on the image below to view it now.

How to Collect PAXGene Samples



We're Making Queries More Site Friendly

In March 2010, we began including your site's toll free number (if one is currently available in your country) for cost-effective follow-up with ICON Central Laboratories' Site Services Department. For a complete list of toll free numbers to reach our Global Call Center, visit us at www.iconplc.com/labsitehelp.

What Can You Do To Prevent Queries?

Check your kit supply regularly. Most of our queries are for visits names that are incorrect or out of sequence. Anticipate your study subject's visit and ensure you have the appropriate visit kit in your inventory. Call our Site Services Department for an expedited shipment. If an expedited shipment is not available then you may also convert one of your other kits to the kit you need by crossing out the visit name on the requisition and labels and writing in the correct visit name. If you decide to convert a kit, remember only to collect the required specimens for your study subject's visit. If you are unsure what to collect, simply refer to the lab manual or call one of our Site Service Specialists.

Also, it is important to check the expiration date of the kit. A kit's expiration date is based upon the earliest expiration date of a tube included in the kit. **Using an expired kit should be a last resort.** However, if this is your only option, **replace the tube that has expired with one that is in date AND write on the requisition that "expired tubes have been replaced."** Submit a resupply order immediately to ensure that kits with proper expiration dates are available for future study visits.

Keep us informed. Using the incorrect kit will always result in a query. However, sometimes, even using the correct visit kit is not enough to avoid a query. ICL's

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database expects visits to occur in a specific sequence. When visits are received out of the expected sequence, a query is generated. For example, if a subject missed a lab visit and the subsequent lab visit is sent to our laboratory, we will issue a query to find out what happened to the prior visit. To avoid such a query please notify us of “missed” visits before the subject’s next visit is sent to ICON. The easiest way to do this is to either call one of our Site Service Specialists or send an email to LabSiteHelp@iconplc.com and give us the details of the missed visit. Please indicate the protocol, site number, subject id, and name of the missed visit.

Properly complete the lab requisition. ICON Central Laboratories only prints information on requisitions that we require for the study sponsor’s database. Therefore, it is critical to answer every question listed. The non-demographic section of the requisition typically generates the most queries. This section includes the collection date and time and other questions such as fasting status, subject weight, and other questions that have been designated by the study sponsor. One common mistake is the failure to record the subject’s weight in the proper unit of measure. Weight should be provided in kilograms.

Don’t forget to send us your requisition. It seems simple enough; however many sites fail to include their completed requisition when sending us lab specimens. This is especially true when shipments are broken out into ambient and frozen shipments. Please include the appropriate portion of the requisition with each type of shipment.

Ashes, Ashes, We All Pull Together

ICL wishes to take this opportunity to extend our thanks to all of the hard-working site staff who pulled together and worked so closely with our Global Site Services and Logistics Team at all of our locations, to help us help you ensure that your invaluable clinical trial specimens were handled as safely and properly as possible during the past week’s airspace shutdown in Europe and beyond. Whilst our skies are clearing of volcanic ash, we look ahead to clearer views and as always, we welcome your comments on how this situation was handled, were our communications to your site useful, and how might we serve your site better during future crises. Feel free to write to us at LabSubjects@iconplc.com to provide feedback.



www.nationalgeographic.com

Helpful Hints from our Logistics Department

We recently asked our Logistics Department to offer some tips to investigator sites that will improve the quality and timeliness of sample shipments and ensure better overall service. Their list of helpful tips is provided below:


- Sites can ship multiple visits under the same airbill number and in the same kit box if it fits.
- Do not use packaging that is not intended for specimens (for example, packaging used to ship documents) to ship specimens. Such packaging does not comply with IATA requirements and can also compromise the integrity of samples.
- Remember to contact your courier service provider for pickup and transit time schedules prior to holidays.
- Feel free to contact ICON Site Support with any questions or concerns not resolved with local courier service providers.
- If your site is in need of later pickup times, contact courier as soon as possible to allow time to adjust their operations plan.
- Temperature control packaging is available from ICON to protect samples from seasonal extreme heat or cold.

Do you have questions or need more information regarding ICON Central Laboratories’ site related services? Visit our Investigator Site Resource Centre at www.iconplc.com/labsitehelp.

Spotlight on Reporting

Over the coming months, ICON Central Laboratories is looking to update the look and feel of our Laboratory Reports. To improve ease of use to our Investigator Sites and to ensure that we are providing the most useful information on our Lab Reports, we would love to have some feedback from those of you who use these on a daily basis.

Please email us at LabSubjects@iconplc.com to provide any insight you might have. Please be specific with your comments and provide study and site details, if possible, so that we can review your comments along with the current delivery method and reporting structure for your study or studies. We look forward to hearing from you and thanks, in advance, for your valuable input!



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Protocol # **ICON Central Lab**

Central Laboratories Print: 26-APR-2010 13:15:21

Site #	Investigator	Collection Date/Time	Received Date/Time	Report Date/Time
# (631) 306-5301	(631) 306-5399	21-SEP-2009 08:59:00	21-SEP-2009 09:00:54	21-SEP-2009 17:33:00

Subject Visit # **UNSC/ETERM**

#	INITIALS	SEX	BIRTHDATE
P-M	PJM	F	26-AUG-1968

ACCESSION #	LABORATORY #	SCREEN #
T404938	42402513	

LAB USE ONLY

*** RE-QUEUED *** N

CTR#: NDA

INVESTIGATOR

John Doe, MD
Doe Clinical Research Center
111 Main Street
Farmingdale, NY 11735

COMMENTS

LABORATORY REPORT

TEST NAME	RESULTS	ABNORMALS	UNITS	REFERENCE RANGE
--- CHEMISTRY ---				
GLUCOSE, FASTING, SERUM	84		mg/dL	70-112
UREA (BUN)	12	258	mg/dL	9-24
CHOLESTEROL, TOTAL	187		mg/dL	0-199
ALKALINE PHOSPHATASE	92		U/L	40-135
AST	30		U/L	0-37
ALT	34		U/L	0-47
LDH			U/L	110-250
SODIUM	139		mEq/L	134-146
Gamma GT	20		U/L	0-33
CHLORIDE	103		mEq/L	95-113
BICARBONATE	28		mEq/L	20-31
CREATININE	0.8		mg/dL	0.5-1.0
URIC ACID	4.4		mg/dL	2.2-6.4
TOTAL PROTEIN	7.4		g/dL	6.1-7.5
ALBUMIN	4.4		g/dL	3.7-4.9
TOTAL BILIRUBIN	0.5		mg/dL	0-1.1
DIRECT BILIRUBIN	0.1		mg/dL	0-0.2
CALCIUM	9.1		mg/dL	8.4-10.2
POTASSIUM	4.2		mEq/L	3.6-5.2
DIRECT BILIRUBIN	0.4		Mg/DL	0-.7
PHOSPHORUS	2.2		mg/dL	2.4-4.9
AMYLASE			mg/dL	LESS THAN 150
ALP			MCG/DL	30-160
TRIGLYCERIDES			ug/dL	229-429
			%	20-55
			g/dL	GREATER OR = 40
			Mg/DL	65-179
			mEq/L	1.4-2.1

No or negligible significance;
Related to underlying condition or disease
Age;
Clinically significant (to be followed
record on AE page.
Exclusionary result.

Date: _____
Investigator or Sub-Investigator _____

REPORT COMPLETE

Second 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
1-May: Labour Day					Closed	TNT	Limited Service	
3-May: May Day			Limited Service	TNT, DHL Specialist As Normal	Closed			
28-May: Vesak Day							Limited Service	
31-May: Memorial Day	Limited Service	FedEx, UPS, DHL Specialist As Normal						
7-June: June Holiday			Limited Service	TNT, DHL Specialist As Normal				
4-July: Independence Day	Limited Service	FedEx						

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

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www.iconplc.com/labsitehelp



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