



ICON Laboratory Services, Inc.

iSite User Guide



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What is iSite?

iSite is ICON Laboratory Services secure web portal for clinical research sites. When you register with iSite, you gain access to site-specific solutions such as: Lab Report eDelivery, Kit and Supply Ordering, E-Requisitions, Queries, Flagged Values, Specimen Collection and Shipping Videos.

Getting Started

To ensure security, only email addresses on file with ICON Laboratory Services are able to register with iSite.

NOTE: A shared email account must not be used, i.e. users must have their own iSite log in and never share log in information

If you are unsure of the email address that we have for you, if you need a new email address added to ICON's system or you are in need of this document translated to another language, please contact LabSiteHelp@iconplc.com

1. Creating an Account in iSite

First time users of iSite need to go through a **one-time registration process** to create an account

- Step 1.** To register, visit <https://isite.iconplc.com>
- Step 2.** Click **Create Account**. *The Registration screen displays*
- Step 3.** Enter the **Email Address** that is on file with ICON Laboratory Services. Click **Submit**. *Registration screen will display automated message advising of email being sent to complete the registration process*
- Step 4.** From your email account, open the message from iSite Support. Click the link. *The 'Create a New Account' screen will display*
- Step 5.** Select your **Name***, enter in a **Password****, **Confirm password** and accept the **Terms and conditions**. Click **Register**. *The 'Select Study' screen displays*

***NOTE:** If more than one name displays, this indicates our database has the email address entered associated to each contact listed. Choose the name you want associated with iSite.

****NOTE:** Follow the instructions on the Registration screen of iSite for password requirements.

The image displays four screenshots of the iSite registration process, each marked with a yellow cloud icon and a step number:

- Step 2: Log In screen** - Shows fields for Email Address and Password, with a 'Log In' button. A red circle highlights the 'Create Account' link.
- Step 3: Registration screen** - Shows a message: 'An email has been sent to the email address you provided for further steps required to complete the registration process with iSite.' Below is an email address field and a 'Submit' button.
- Step 4: Email message** - Shows an email from 'iSite Support <no-reply@iconplc.com>' with a link to continue registration: <http://frg-portdev01/ICOPortal.DEV/Account/Register/XDYDO9ZYNAFCRL21LDTMTZ/>.
- Step 5: Account Information screen** - Shows fields for Email address (pre-filled with 'annsmith@acme.com'), Name (pre-filled with 'Ann Smith'), Password, and Confirm password. It also includes a 'Register' button and a checkbox for accepting terms and conditions.

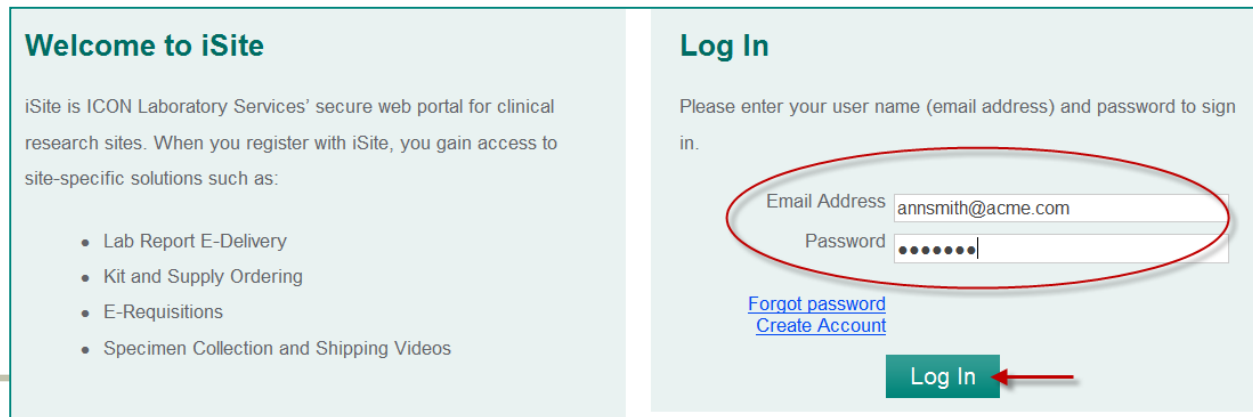
2. Log In *(One time Registration must be done first – See Creating an Account in iSite)*

Step 1. Go to <https://isite.iconplc.com>

Step 2. Enter **Email Address** used to create the account and **Password**.

Step 3. Click **Log In**. The 'Select Study screen' displays

IMPORTANT: After three unsuccessful attempts, your account will be locked.
You will need to click the **Forgot password** link to change your password.



2.1 Selecting a Study

Step 1. From the **Home** screen, in the **To Start** section, select the applicable **Study** from the drop down list.

NOTE: Only active studies that you are participating in are listed in the drop down menu.
If you are only participating in one study, it will automatically be selected for you.

Selecting the desired iSite feature

Step 1. Select **Lab Reports**, **New Lab Reports**, **Supplies and Kit Ordering** or **Instructional Videos** from the menu bar.

IMPORTANT: If you are participating in multiple studies, you must first select a study.
Otherwise, you will get the error pictured below or may be unable to select the desired feature.



3. Viewing LAB REPORTS

Step 1. From the menu bar, click **LAB REPORTS**

Step 2. Select from the list of folders on the left to find the **Site**, **Subject** and **Visit/Collection Date**. *Folders open when the plus (+) sign is clicked displaying the information.*

Step 3. Click on the applicable report. *The PDF report will open in a new window*

Folders

View Report

Please select from the list of folders on the left to find the Site, Subject, and Visit/Collection Date; then click on a report in order to view the lab report. This list can be filtered by clicking "Report Filter", selecting your criteria, and clicking Filter. The list will display based on your selections.

The PDF report will open in a new window. Please ensure pop-up blocking is disabled for this site. Adobe Reader version 7.0 or higher is necessary in order to view reports. Please click here to download [Adobe Reader](#), if necessary.

Folders Defined

Site Number

**Subject #
Subject Initials
Subject DOB**

**Visit Name
Collection Date**

**Report
(Click to open)**

IMPORTANT – AMENDED LAB REPORTS: When Lab Reports have been amended; you may see more than one version. Make sure to look for the most recent report in the folder.

3.1 Viewing NEW LAB REPORTS

Viewing **NEW LAB REPORTS** in iSite is the same as viewing **LAB REPORTS**. In addition, **NEW LAB REPORTS** has a notification feature. When New Lab reports are available, a notification is sent to the email account registered with iSite from ICOLIMS reporting.

Step 1. From the email notification, click on the link to navigate to iSite. *The 'iSite Log in' screen displays*

NOTE: If you are already logged into iSite you will be brought to the Home screen

Step 2. From the menu bar, click **NEW LAB REPORTS**

Step 3. Select from the list of folders on the left to find the **Site, Subject** and **Visit/Collection Date**. *Folders open when the plus (+) sign is clicked displaying the information*

Step 4. Click on the applicable report. *The PDF report will open in a new window*

IMPORTANT: Once a New Report is opened, it is no longer considered new.

Previously viewed reports are located under LAB REPORTS.

NOTE: New Lab Reports can be found under both LAB REPORTS and NEW LAB REPORTS in the menu bar. Opening the New Lab Report in either location will remove the report from the NEW LAB REPORTS view.

3.2 Using the Report Filter (For LAB REPORTS or NEW LAB REPORTS)

Step 1. From the menu bar, click **LAB REPORTS** or **New LAB REPORTS**

Step 2. Click **Report Filter**. *The filter selections appear*

Step 3. Select the **Site**. *The Site must be selected for the filter to function*

Step 4. Select **Subject** and or **Collection Date From, Collection Date To** from the drop down menus, click **Filter**. *The list will display based on your selections*

Step 5. Click on the applicable report. *The PDF report will open in a new window*

NOTE: To reset the filter criteria selected, click **Reset Filter**.

4. Supplies and Kit Ordering

Step 1. Select **Supplies and Kit Ordering** from the menu bar.

Step 2. If you are a Sponsor or CRO, select the required site number. Only one site may be selected at a time.

IMPORTANT: If you are a site end-user, your site number will automatically be selected by default.

HOME LAB REPORTS NEW LAB REPORTS **SUPPLIES AND KIT ORDERING** INSTR

Select Study

To Start

Please follow the instructions below to get started:

1. Select a study from the drop down list below.
2. Select one of the options from the menu bar above.

Study: 603

Supplies and Kit Ordering

Select a site from the drop down list below:

Site: 777

Select one of the options below:

[Place New Order](#)

[View Order History](#)

[View Site Inventory](#)

[View FAQs](#)

[View Lab Certificates](#)

4.1 Requesting New Supplies

Place New Order enables you to request new kits and/or supplies for a study site.

Step 1. Select **Place New order** from the **Supply and Kit Ordering** home page.

The New Order page displays.

Supplies and Kit Ordering

Select a site from the drop down list below:

Site: 777

Select one of the options below:

[Place New Order](#)

[View Order History](#)

[View Site Inventory](#)

[View FAQs](#)

[View Lab Certificates](#)

New Order

Site: 777
Investigator Name: Dhanisa Bhaskar_USA

Due Date: 12-Dec-2013

Approval is Required

Indicates if approvals, such as import approval, is required for the shipment

[Back](#)

Kits		Bulk Supplies	
Kit Name	Quantity	Supply Name	Quantity
Visit 1	0	0.01 mL Clear EDTA Monoject Becton Dickson Internal Thread	0
Visit 2	0	0.01 mL Red/Gray SST Polyethylene Fisher Conical Bottom Flat Bottom	0
Total: 0		Airbill - FedEx Domestic (Ambient)	0
		Total: 0	

[Submit Order](#)

Step 2. Enter quantity of each kit required. Note that any kit names appearing as hyperlinks are multi-visits. In order to see which visits these kits can be used for, click on the hyperlink.

Step 3. Enter quantity of each bulk supply required. To view an image of the supply, click on the hyperlink.

Step 4. Review the pre-populated due date and ensure that all supplies will be provided in advance of the date supplies are required for subject visit use

Step 5. Click Submit Order

Step 6. Click Ok on the notification confirming placement of your order

Kits

Kit Name	Quantity
V1 Kit Name	0
V1	
V2	
V3 Kit Name	0
Kit V4	0
Total: 0	

Bulk Supplies

Supply Name	Quantity	Packaging
1 L Green Magnesium Plastic Test999	0	Each
1 mL Blue	0	Each
5.0 mL Blue Sodium Chloride Polypropylene Becton Dickson Conical Bottom	0	Each
Airbill - FedEx Domestic (Frozen)	0	Each

Due Date: 16-Dec-2013

Approval is Required

Submit Order

Notification

Thank you for placing your order. For your reference, your order number is: WO2013120022

Approval for this order is required.

Click Ok to return to the Supplies and Kit Ordering main page.

Ok

4.2 Viewing Order History

View Order History permits you to review all orders that have been placed by and for a specific site, including hyperlinks to the specific components of each order (e.g.: Kit name, bulk supply and courier tracking information, for shipments which have been shipped). This information is available on the **Supplies and Kit Ordering** homepage for the last five orders placed for a specific site.

Step 1. Click on **View Order History** to view all orders placed for your site, or click directly on the recent work order you wish to view

Step 2. Click on the hyperlink to view the contents of an individual order

Select a site from the drop down list below:

Site: 101

Select one of the options below:

[Place New Order](#)

[View Order History](#)

[View Site Inventory](#)

[View FAQs](#)

[View Lab Certificates](#)

Last Five Orders Placed

Order Number	Date Ordered	Date Shipped	Status
WO2010020010	2/5/2010		Awaiting Approval
WO2010010118	1/30/2010		Awaiting Approval
WO2009100238	10/27/2009		Awaiting Approval
WO2009100225	10/27/2009		Awaiting Approval
WO2009100208	10/27/2009		Awaiting Approval

*All dates represented in GMT

4.3 Editing Orders

For orders that are in a status of **Processing**, and do not have an approval step at any stage, you have the ability to edit or cancel the requested quantities of kits or supplies. If your order is not in a status that permits editing, a notation will appear at the top of the order indicating this.

Step 1. Select **Edit Order** or **Cancel Order** as required

Step 2. If Edit Order was selected, amend the quantities of the items you wish to edit

The screenshot shows the 'Order Details' page for Site 777, Investigator Name: Bhaskar_USA, Dhanisa, Order Number: WO2013010055. The Due Date is 14-Feb-2013 and the Status is Processing. A red message states: 'This order is not in a status that can be edited'. A yellow callout bubble labeled 'Step 1' points to the 'Edit Order' and 'Cancel Order' buttons. A blue callout bubble explains: 'Radio buttons that permit you to edit or cancel orders, once they are in a suitable status'.

Kit Name	Quantity
Visit 1	2

Supply Name	Quantity	Packaging
0.01 mL Clear EDTA Monoject Becton Dickson Internal Thread	2	Each
1 L Green Magnesium Plastic Test999	2	Each

4.4 Viewing Site Inventory

View Site Inventory provides a listing of all kits and supplies that have been ordered and shipped to your site, along with information on the expiration of kits expected to be on hand at your site. By clicking on any of the hyperlinks within the bulk supplies, you will see an image of the particular item.

The screenshot shows the 'Site Inventory' page for Site 444, Investigator Name: Bhaskar_USA, Dhanisa. A blue callout bubble explains: 'The number of kits expected to be at your site that expire in the next 30 or 60 days'.

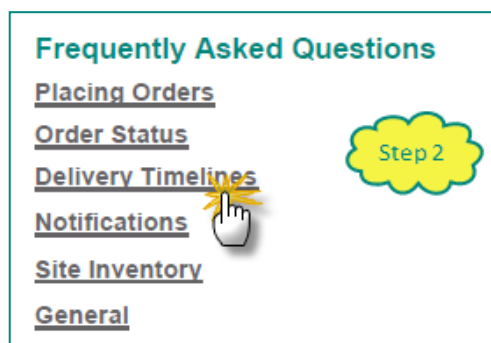
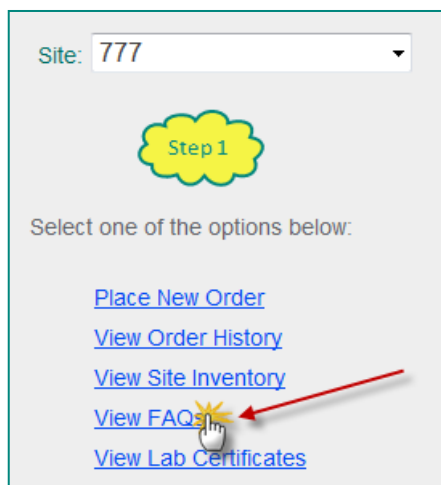
Kit Name	Quantity Shipped to Date	Quantity Expired	Quantity Received at ICL	Available At Site	Quantity On Order	Kit Expiring Quantity
Visit 1	47	0	1	46	168	Expiry Less Than 30 Days: 0, Expiry Less Than 60 Days: 0
Visit 2	58	0	1	57	74	Expiry Less Than 30 Days: 0, Expiry Less Than 60 Days: 0

Supply Name	Shipped To Date
1 L Green Magnesium Plastic Test999	4
1 L Red/Gray Non-Phthalene Becton Dickson External Thread	10
Airbill - FedEx Domestic (Ambient)	60
Component override field	5
Flask 1 L Gold Magnesium Plastic Abbott	25
Gold MGA	4
Testing Override Description	10
Vacutainer 3 mL Lavender EDTA Plastic Becton Dickson	25

4.5 Viewing FAQs

View FAQs is a page dedicated to answering a number of questions that you may have during your experience in placing an online order via iSite.

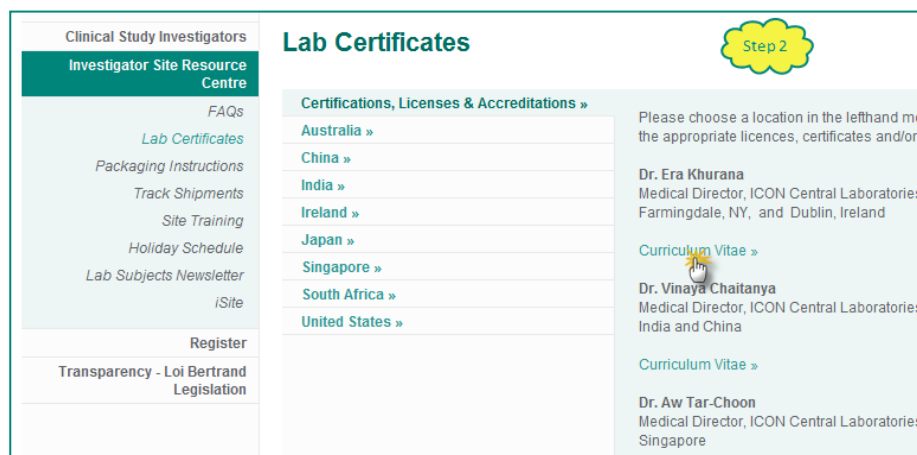
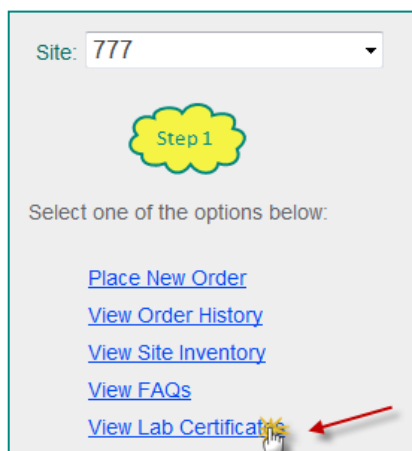
- Step 1.** Select **View FAQs** from **Supplies and Kit Ordering** homepage
- Step 2.** Click a particular topic from the list of **Frequently Asked Questions** to bring you directly to that section. Alternatively, scroll down to view all **Frequently Asked Questions**.



4.6 Viewing Lab Certificates

View Lab Certificates is a direct link to the ICON Investigator Site Resource page, listing all certifications, licenses and accreditations held by ICL. These can be downloaded and printed as necessary for your study files.

- Step 1.** Select **View Lab Certificates** from **Supplies and Kit Ordering** homepage
- Step 2.** Select the location, Curriculum Vitae or certificate you wish to view or download



5. E – Requisitions

E-Requisitions (also referred to as E-Req's) will allow you to electronically receive laboratory visits into the ICON database instead of using paper requisitions. You are also able to edit Subject Demographic or Visit information as needed to automatically update information to ICON.

Note: Please ensure all data is entered into E-requisitions is correct as this data impacts testing performed, e.g. optional tests, and the content of lab reports generated

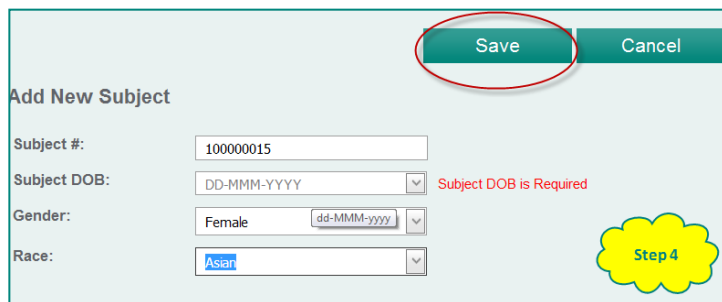
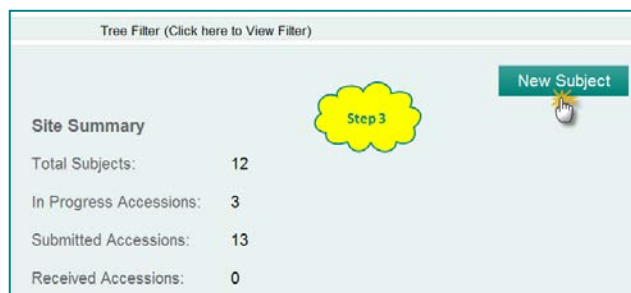
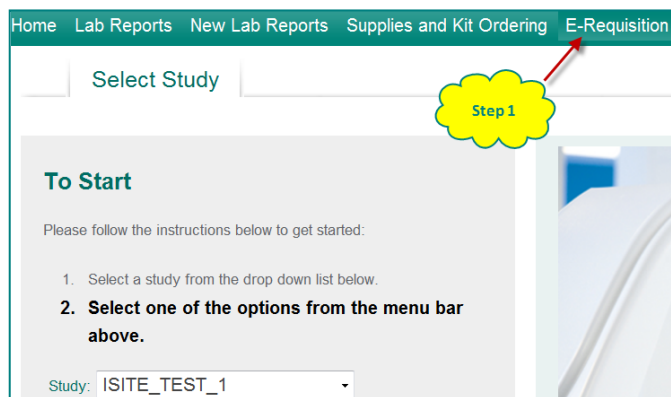
5.1 Creating a New Subject

Before an E-Requisition can be created; the Subject's information must be added.

- Step 1.** From the Menu bar, **Select E-Requisition**
- Step 2.** Click your **SITE** number on the right of the screen. *The Site Summary screen will display.*
- Step 3.** Click the **New Subject** button. *The Add New Subject screen will display.*
- Step 4.** Enter the **Subject #** and all other required information in the mandatory formats. Click **Save**.
***Subject successfully added** will display on the screen.*

IMPORTANT: All bolded field names are mandatory fields. Red warnings will display next to mandatory fields that are left blank.

NOTE: You must enter the information into the fields in the correct format. Use either the drop down menu when available or hover over the field with your mouse to see the fields required format (see Step 4 picture for example).



5.2 Editing a Subject

In the case of an error, Subject information can be updated or deleted as needed. Updates made will be live in ICON systems typically within 20 minutes of you saving the changes.

Step 1. From the E-Requisition screen, expand the Site folder in the tree to display all Subjects created for the Site. *Folders open when the plus (+) sign is clicked displaying the information.* Click the applicable **Subject number** in the tree. *The Subject Demographics screen displays.*

Step 2. Click **Edit Subject**. Update the needed fields or select Subject Terminated to delete Subject information.

IMPORTANT: Terminating a subject will prevent future visits from being submitted.

Step 3. Enter **Change Comment** and click **Save**. *Subject successfully saved will display on the screen.*

The first screenshot shows a tree view on the left with a site folder expanded. A red circle highlights the site number '002', and a red arrow points to a subject entry '000000015/---/14-Jun-1985'. A yellow cloud labeled 'Step 1' is in the top right. The main area shows the 'Subject Demographics' form with fields for Subject #, Subject DOB, Gender, Race, and Subject Terminated. A yellow cloud labeled 'Step 2' is in the top right.

The second screenshot shows the 'Edit Subject' form. A red circle highlights the 'Edit Subject' button in the top right. A yellow cloud labeled 'Step 3' is in the top left. The form includes fields for Subject #, Subject DOB, Gender, Race, Subject Terminated, Reason for Change, and Change Comment. A red circle highlights the 'Save' button in the top right.

The third screenshot shows the 'Edit Subject' form with the 'Change Comment' field filled with the text 'Incorrect race entered. Updated to correct race'. A red circle highlights the 'Save' button in the top right.

5.3 Tree Filter

Once you've selected your Site number and clicked E-Requisitions, the Tree Filter is available to use to search existing Subjects and Visits. You are able to search for a specific **Kit Number**, **Subject** and **Collection Date** range From and To.

Step 1. Click the Tree Filter. *The Tree Filter displays*

Step 2. Select your Site Number. Search by entering in applicable search fields (Kit Number) or use the drop down menus to select your search criteria (Subject, Collection Dates). Click **Filter** to display search results.

IMPORTANT: You must click **Reset Filter** to clear search fields and display all Site Subject information. Click **Tree Filter** again to close the View Filter.

The screenshot shows the 'Tree Filter (Click here to View Filter)' interface. It includes input fields for Number, Site (002), Subject (100000004/---/17-Aug-1960), Collection Date From (dd-MMM-yyyy), and Collection Date To (dd-MMM-yyyy). A red circle highlights the 'Filter' button in the top right. A red circle highlights the 'Reset Filter' button in the bottom right.

5.4 Adding a New Visit

Adding a new visit is the process to create an E-Requisition (electronic requisition).

- Step 1.** Select the applicable Subject Number in the tree. *The Subject Demographics screen displays.*
- Step 2.** Click **New Visit**. A window will display verifying the correct Subject was selected. **Click OK.** *The Add new Visit screen displays.*
- Step 3.** Using the drop down menu, choose the **Selected Visit** and **Enter Kit Number**. Click **Load Visit Info**. *The Add New Visit tabs become active.*
- Step 4.** Complete the five tabs as applicable to your Subjects visit. Click the **Tab Name** itself, or click the Next **Tab** or **Previous Tab** button to move through the tabs or click the tab name to select that tabs information.

NOTE: You are able to click the **Save** button to save your changes to return to complete at another time.

Tab	Information Needed
Subject Visit	Complete all mandatory fields. Mandatory fields are displayed in bold. Examples of fields needed could be collection date, collection time, etc.
Containers	Only check boxes for any Transport Containers that were NOT COLLECTED during the visit. By not checking a box you are letting us know that the transport container was collected. Any containers not collected will impact any Optional Testing associated with those containers. See Optional Testing for further details. NOTE: Transport containers have a blue hyperlink that allows you to click the container name to display a picture of the container selected.
Additional Info	Complete all mandatory fields. Mandatory fields are displayed in bold. Examples of additional information could be fasting status or weight, etc.
Optional Testing	Select the relevant tests that are to also be included in this visit. You are also able to select additional tests not listed in this tab. Click Are there additional tests to be ordered and enter in the test name in the open field section. *IMPORTANT: Any test that is Optional linked to a container that was not drawn will appear as a container not received in the Optional Testing Tab. If you are able to associate the test with another container that was collected during the visit, fill out the Optional Testing tab as indicated above.
Submit	After completing the needed information in the four previous tabs, click Submit . IMPORTANT: Warnings will display in red if any tabs are missing mandatory information or for other reasons. See Adding a New Visit - Visit Warnings for further instructions.

- Step 5.** After clicking Submit; the information is saved and the E-Requisition is generated. **Please print and retain a copy of the E- Requisition with your Subject visit records.** After printing and closing the E-Requisition, the Visit Summary screen will display. *Visit submitted successfully will display on the screen.*

5.5 Adding a New Visit - Visit Warnings

If warnings are listed while entering your visit information or when you are ready to submit your visit information, you will need to address them. Below is a guide on how to handle the warnings.

Warning	Action Needed
Kit Belongs to a Different Site or a Different Visit or both	Verify the Kit number you entered is correct. If not correct, update the Subject Visit tab with the correct Kit Number. If correct, you must enter comments in the Submit tab as to why you are submitting the visit with the warnings. You will not be able to Submit the visit without comments.
Missing Information	Bold fields within all Tabs are required. Missing information may be needed to move to the next tab or to submit the visit. Please follow the warnings as they appear on the screen and select the relevant tab or field to edit or add information as needed.
Visit Received Out of Sequence / Visits have been Skipped	You will need to confirm that a Visit was missed. See How to Confirm a Missed Visit.

Examples of errors:

Add New Visit 000000016/---/14-Feb-1992 Load Visit Info

Selected Visit: WEEK 1

Enter Kit Number: X329397

Kit belongs to a different Site/ Kit belongs to a different visit

Add New Visit 000000015/---/14-Jun-1985 Load Visit Info

Selected Visit: WEEK 3

Enter Kit Number: X329380

The following required scheduled visits have been skipped: WEEK 1

Subject Visit Containers Additional Info Optional Testing Submit

Subject #: 000000015

Subject DOB: 14-JUN-1985

Gender: Female

Race: White or Caucasian

Subject Visit Containers Additional Info Optional Testing Submit

If warnings are listed, please select the relevant tab to review data and make any edits that may be necessary. Otherwise, enter a reason and click submit.

Kit belongs to a different Site. Kit belongs to a different Visit.

Enter reason when submitting with warnings here

Comments go here as to why you are submitting with errors.

5.6 Editing a Visit

- Step 1.** Select the applicable Subject Number in the tree. Click the plus (+) sign to view the Visits associated with the Subject. Click on the applicable visit in the tree for the information to be displayed.
- Step 2.** Click **Edit Visit**. *The Edit Visit screen displays.*
- Step 3.** Update the applicable information in the needed tab and enter a **Change Comment** and click **Save**. **Visit submitted successfully** will display on the Visit Summary screen.

The first screenshot shows a tree view of subjects and visits. A red circle highlights the visit '000000015/---/14-Jun-1985' under subject '002'. A yellow callout bubble labeled 'Step 1' points to this visit. A red arrow points from the visit to the 'Edit Visit' button in the second screenshot.

The second screenshot shows the 'Visit Summary' screen for visit '000000015/---/14-Jun-1985'. The 'Edit Visit' button is circled in red. A yellow callout bubble labeled 'Step 2' points to this button.

The third screenshot shows the 'Edit Visit' screen for the same visit. The 'Reason for Change' dropdown is set to 'Site Override' and the 'Change Comment' text box contains 'Added Subject Weight'. The 'Save' button is circled in red. A yellow callout bubble labeled 'Step 3' points to this button.

IMPORTANT: You will need to contact Lab Site Help at labsitehelp@iconplc.com if you need to update the Visit Name, Site Number, Protocol ID, Kit Number and Subject ID.

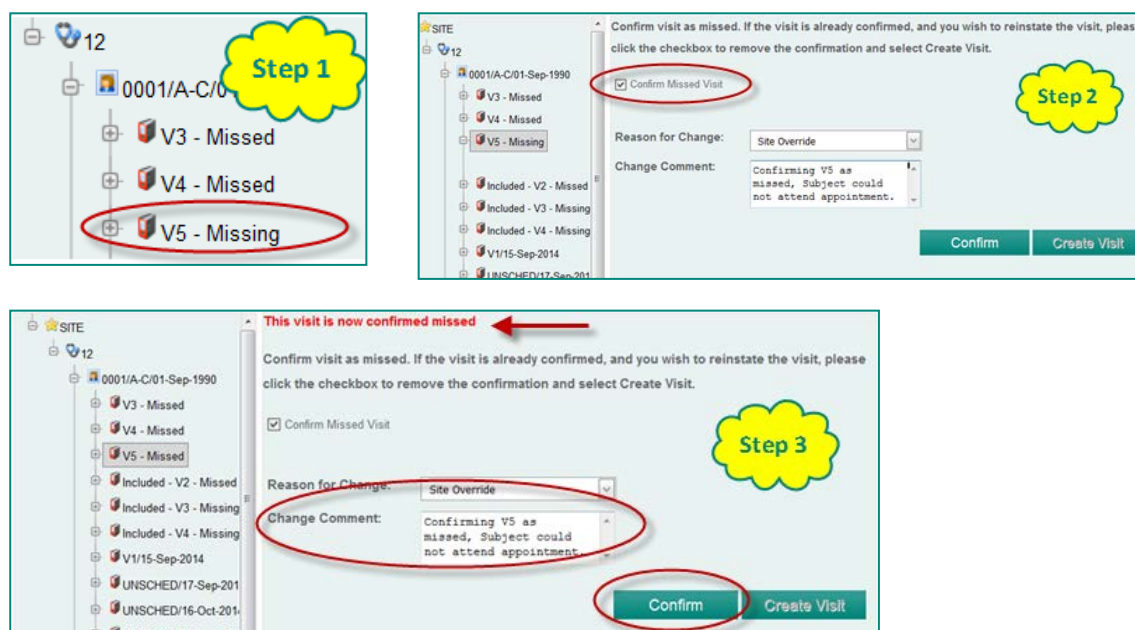
Visit Status	Definition
In Progress	A visit was created in E-Requisitions. Information was saved but not Submitted to ICON. Site can return later to complete data entry.
Submitted	All data for a Visit was entered and submitted to ICON. Samples have not yet been received at ICON.
Received	Site submitted visit information via E-Requisition and the samples were received by ICON
Missing	A visit was skipped. Data may be entered later or Site needs to confirm the visit as truly missed, i.e. will never occur. The visit must be confirmed as 'Missed' to avoid the Site receiving a query for visit received out of sequence
Missed	A visit was confirmed as missed by the Site.

5.7 Confirming a Missed Visit

The system recognizes when a visit has been missed. You will need to confirm and provide comments as to why a visit has been missed. If the visit has been missed in error, please see the Editing a Visit section of this guide.

- Step 1.** Select the applicable Subject Number in the tree. Click the plus (+) sign to view the Visits associated with the Subject. Double click on the Missing visit you want to confirm. *The Confirm Visit Missing window displays.*
- Step 2.** Click **Confirm Missed Visit** box. *A check will display in the box.*
- Step 3.** Enter the reason for the visit being missed in the **Change Comment** field. Click the **Confirm** Button. *The **visit is now confirmed missed** will display on the screen and the visit will show as Missed in the tree.*

NOTE: In case of an error (the visit wasn't missed or the wrong visit was listed as missed), the Missed Visit can be edited by clicking the Confirmed Missed Visit box (the check will no longer display) and clicking the Confirm button (visit status in the tree will return to Missing). A Missing visit can be submitted (if it was found that it really wasn't missing and needs to be entered) by selecting the Missing visit and then clicking the Create Visit button.



6. Queries and Flagged Values

Queries and Flagged Values will allow you to electronically receive and respond to query and flagged value(s) in the ICON database instead of using email or phone call. When new queries or flagged values are available, a notification is sent to the designated email account registered with ICON.

Note: Only designated email accounts of site personnel are allowed to view and acknowledge the receipt of flagged value(s) in iSite. Site Monitors/Clinical Research Associates are not allowed to view and acknowledge the receipt of flagged value(s) in iSite on behalf of site personnel.

In the summary screen of Queries and Flagged Values, you will be able to see the number of queries, escalated queries, flagged values and unread lab reports. You can click on the number in each box and it will bring you to the respective function screen.

Queries and Flagged Values

[Select here to view Flag Legend](#)

MY TO DO

00003

2775

Select link to view

Site ID	No. of Queries	No. Escalated to ICON	No. of Flagged Values	No. of Unread Lab Reports
00003	0	0	3	4
2775	101	6	9	5

6.1 Viewing and Resolving Queries

You can click on the number in “No. of Queries” to view all the queries associated to your site.

Select link to view

Site ID	No. of Queries
00003	0
2775	101

iSite will bring you to the following screen. A query description will be indicated on the website when a query is highlighted.

Open Queries (101)

Escalated to ICON (6)

Flagged Values (9)

Drag a column header here to group by that column

Issue ID	Subject	Visit	Kit Number	Collection Date	Days Old	Lab Report Held	Edit
2811508		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit
2811509		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit
2811510		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit
2811511		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit
2811512		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit
2811513		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit

Page 1 of 17 (101 items)

[1](#)
[2](#)
[3](#)
[4](#)
[5](#)
[6](#)
[7](#)
[...](#)
[15](#)
[16](#)
[17](#)
[>](#)
[>>](#)

Query:

Subject ID is missing. Please provide at your earliest convenience.

Subject ID:

Initials:

DOB:

Comments:

Escalate to ICON

Submit

Cancel

Correct Information

Subject ID

#####

- Step 1.** Click on the “Edit” button of the respective query. “Escalate to ICON”, “Submit” and “Cancel” button will change from grey to green.
- Step 2.** Enter the correct information.
- Step 3.** Click the “Submit” button.

Drag a column header here to group by that column

Issue ID	Subject	Visit	Kit Number	Collection Date	Days Old	Lab Report Held	Edit
2811508		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit
2811509		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit
2811510		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit
2811511		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit
2811512		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit
2811513		SCREEN	BA40397		241	<input checked="" type="checkbox"/>	Edit

Page 1 of 17 (101 items) << < [1] 2 3 4 5 6 7 ... 15 16 17 > >>

Query:
Subject ID is missing. Please provide at your earliest convenience.

Subject ID:
 Initials:
 DOB:
 Comments:

Escalate to ICON Submit Cancel

Correct Information

Subject ID

Most queries that you respond to will be resolved immediately however there is a subset of queries that require work to be performed by the Site Service Specialist after you submit your answer. There are also validation rules in place for lots of queries which will help verify your answer or possibly ask you for additional information. One query type we wanted to point out that may not be as straight forward at first glance are queries with multiple demographic inconsistencies on one visit. This type of query may appear on multiple lines however you will see they are all linked through the same kit number; simply review all demographic information, make any updates as necessary, and submit the answer. Upon submission of the first query all the remaining demographic queries will disappear as well since they were all addressed in the query response.

Note: If the required information could not be provided due to various reasons, please provide an explanation or clarification into the comment box and click “Escalate to ICON” button. The query will be escalated to the Site Services team who will investigate the issue and either resolve the query or contact you for further information. Queries that have been escalated to the Site Services team through this method as well as queries that require further work by a Site Services Specialist will appear under the “Escalated to ICON” tab.

6.2 Viewing and Confirming Flagged Values

The designated flagged value recipient will have additional access to view and acknowledge the receipt of flagged value in iSite. When new flagged values are available, a notification is sent to the designated email account registered with ICON. Other members at your site will have access to flagged values as well. If you or anyone at your site confirms a flagged value the value will be removed from the Flagged Value table.

Step 1. Click the “Flagged Values” tab to view all flagged values.

Step 2. Review and check the box of flagged values.

Step 3. Click the “Submit” button.

The screenshot shows the iSite interface for viewing and confirming flagged values. At the top, there are three tabs: "Open Queries (101)", "Escalated to ICON (6)", and "Flagged Values (9)". A red arrow points to the "Flagged Values (9)" tab, labeled "Step 1". Below the tabs, a message states: "Please check the box and use submit button to confirm flags. You can contact ICON Laboratory Site Services for any updates or questions regarding flagged values on this table. To view historical flagged values for a visit, please click on Kit Number link." Below this message, a green bar indicates "Total call values selected: 4." and a grey bar says "Drag a column header here to group by that column". The main table has columns: Subject, Kit Number, Collection Date, Visit, Flag, Test, Result, Reference Range, Comments, Issue ID, and a checkbox. The table contains 10 rows of data. A red arrow points to the checkbox in the fourth row, labeled "Step 2". At the bottom right, a red arrow points to the "Submit" button, labeled "Step 3".

Subject	Kit Number	Collection Date	Visit	Flag	Test	Result	Reference Range	Comments	Issue ID	<input type="checkbox"/>
555666/NA/01-JUL-1976	BA20465	23-Mar-2016	SCREEN	EXCLUSION	WBC	2.00	No Reference Range		2823405	<input checked="" type="checkbox"/>
555666/NA/01-JUL-1976	BA20465	23-Mar-2016	SCREEN	PANIC	Sodium	161	100 - 120		2823400	<input checked="" type="checkbox"/>
555666/NA/01-JUL-1976	BA20465	23-Mar-2016	SCREEN	PANIC	Total Bilirubin	57.00	Less than or = 1.20		2823404	<input checked="" type="checkbox"/>
555666/NA/01-JUL-1976	BA20665	31-Mar-2016	Week 24	LABPANIC	WBC	42.25			2824161	<input checked="" type="checkbox"/>
555666/NA/01-JUL-1976	BA20665	31-Mar-2016	Week 24	LABPANIC	WBC	42.25			2824265	<input type="checkbox"/>
555666/NA/01-JUL-1976	BA20665	31-Mar-2016	Week 24	LABPANIC	WBC	42.25			2823600	<input type="checkbox"/>
555666/NA/01-JUL-1976	BA20665	31-Mar-2016	Week 24	LABPANIC	WBC	42.25			2823601	<input type="checkbox"/>
555666/NA/01-JUL-1976	BA20665	31-Mar-2016	Week 24	LABPANIC	WBC	42.25			2824300	<input type="checkbox"/>
555666/NA/01-JUL-1976	BA20665	31-Mar-2016	Week 24	LABPANIC	WBC	42.25			2828101	<input type="checkbox"/>

Need to see a flagged value that you already confirmed? Navigate to the Lab Reports section of iSite, choose your visit from the tree, and click on the link to retrieve the historical flagged value report.

You can also view flag legend in iSite by clicking “**Select here to view Flag Legend**” as depicted below.

Queries and Flagged Values

MY TO DO

00003

2775

Select link to view

Site ID	No. of Queries	No. Escalated to ICON	No. of Flagged Values	No. of Unread Lab Reports
00003	0	0	3	4
2775	101	6	9	5



Flags for Call Values

Flags	Descriptions
HP	High Panic
LP	Low Panic
H	High
L	Low
E	Exclusion
A	Alert
Dp+	Positive delta from previous visit
Dp-	Negative delta from previous visit
Db+	Positive delta from baseline
Db-	Negative delta from baseline
Dpb+	Positive delta from previous and baseline
Dpb-	Negative delta from previous and baseline
Dp+Db-	Positive delta from previous and negative delta from baseline
Dp-Db+	Negative delta from previous and positive delta from baseline
T, G or TG	Toxicity grade prefix

7. Instructional Videos

See your laboratory manual come to life with easy-to-follow animations of our most common specimen collections and shipping instructions. This section of iSite can be accessed without selecting a specific study or site number.

Step 1. Select required specimen type or packaging/shipping tab

Step 2. Select the specific instructional video to be viewed. This video will play automatically once it has been selected.

atch videos

Step 1

Instructional videos organised by specimen type and packaging/shipping instructions

Listing of available videos within each category

Sample Collection - Serum

Blood Sample Collection - Whole Blood

Urine Sample Collections

Other Sample Collec...

C-Peptide
C-Peptide

CH50
CH50

Gold Top SST Tube
Gold Top SST Tube

Step 2

8. Changing Your Password

If you need to change your password, you may do so directly from iSite.

Step 1. From the menu bar, click **MY ACCOUNT**. The 'My Account' screen displays

Step 2. Click **Change Password**. The 'Change Password' screen displays

Step 3. Enter your **Current password**, **New Password** and **Confirm new password**. Click **Change Password**.
When entered correctly, "Congratulations! Your password has been changed successfully" will display.

NOTE: Follow the instructions on the Change Password screen for password requirements.

The image shows two screenshots of the iSite interface. The left screenshot is the 'My Account' page, with a menu bar at the top containing 'HOME', 'LAB REPORTS', 'NEW LAB REPORTS', 'MY ACCOUNT', and 'AB'. A yellow cloud labeled 'Steps 1 & 2' points to the 'MY ACCOUNT' menu item. Below the menu, there is a 'My Account' heading and a link 'Change password' circled in red. The right screenshot is the 'Account Information' page, which has three password input fields: 'Current password', 'New password', and 'Confirm new password'. A red arrow points to the 'Change Password' button at the bottom, which is also labeled with a yellow cloud 'Step 3'.

9. Logging Out of iSite

Step 1. From any tabbed window, click **Log Out**. The window displays "You have successfully logged out"

The image shows two screenshots of the iSite interface. The left screenshot shows a 'Welcome Ann Smith' message with a 'Log Out' button circled in red. The right screenshot shows the 'Log Out' page with the message 'You have successfully logged out.' and a link 'Click here to log back in.'

10. Trouble Shooting

Please see the below for trouble shooting iSite. For further assistance on any of the below questions/answers please email: LabSiteHelp@iconplc.com. For toll-free access information to your local Site Services telephone number, please go to: www.iconplc.com/labsitehelp.

Q. When I try to register with iSite or reset my password, I get a message that an email will be sent to the email address I provided but it does not arrive.

A. Make sure that the email you entered is correct. If entered correctly it may be that we do not have the correct email on file for you. To ensure security, only email addresses on file with ICON Laboratory Services are able to register with iSite.

Please check your Spam/Junk email folders as the email from iSite may have been delivered there.

If you are trying to register and do not receive the email, please also try the "Forgot Password" link as your email address may be already registered in iSite. You only need to register your email one time in iSite. Once an email is registered, you will need to Log In. If you are sharing your email with others at your location, it may be that

someone else has registered your group email. You will receive an email to reset your password if the email address is already associated with an iSite account.

If you do not receive an email after trying the “**Create Account**” and “**Forgot Password**” links or are unsure of the email address that we have for you or your site, please contact us as listed above.

Q. I am trying to Log In to iSite but I am getting an error that my attempt was unsuccessful.

A. First, you need to be registered. If you have not registered as of yet, please see the **Creating an Account in iSite** section of this guide. If you have already registered, please make sure that the user name and password you have entered is correct. If you are not sure of what your Password is, click **Forgot password**.

Q. When I try to login to iSite, I get an error message that my account is locked.

A. Accounts are locked after three unsuccessful attempts to login. Please reset your password using the “**Forgot Password**” link. Resetting the password will unlock your account.

Q. The email account that you have for me on iSite, I am no longer using. What do I do?

A. Please contact Lab Site Help for assistance in changing the email that ICON Laboratory Services has on file for you. Your old account will be deactivated and you will need to create new iSite account using the new email address once your email address is updated in ICON database.

Q. The email you have for me is correct but the name listed on iSite (Welcome Name) needs to be changed. What do I do?

A. Please contact Lab Site Help for assistance in changing the name that ICON Laboratory Services has on file for you.

Q. I am trying to create / change my password but I am getting errors.

A. Passwords are required to be a minimum of 8 characters in length and must contain at least one upper case letter, one lower case letter, one number and one special character (see the iSite Change Password screen for further information on special characters). Make sure that the Password and Confirm Password match. Please also note that you are unable to use your last two previously used passwords.

Q. I had access to iSite in the past but my login does not seem to be working now.

A. Use the “forgot password link” to receive a new password for access. If you do not receive the password email from us then please contact Site Services directly either through Labsitehelp@iconplc.com or through our call center.

11. Frequently Asked Questions

Please see the below for Frequently Asked Questions about iSite. For further assistance on any of the below questions/answers please email: LabSiteHelp@iconplc.com For toll-free access information to your local Site Services telephone number, please go to: www.iconplc.com/labsitehelp

Q. How long are my reports stored in iSite?

A. Reports for all of the active studies that you are participating in will be available to you as long as the Study is active. If you need to keep reporting after the Study is no longer active, please make sure to print or save your reports to another location **prior** to the Study closure.

Q. I am looking for an amended lab report, where would I find it?

A. When Lab Reports are amended; you may see more than one version in the folder. Make sure to look for the most recent report. Please see the **Viewing Lab Reports** section of this guide for further information.

Q. I am looking for a new lab report but it is not available under the “New Lab Reports” tab, where can I find it?

A. It’s possible that your site has over the allotted number of isite users we can setup per site. In cases like these you may still have access to the lab report however it will be under the “Lab Reports” tab. Please contact Site Services if you wish to check if there is an option to add you as a main site contact.

Q. I am participating in multiple Studies. Can I view reporting for each Study on one iSite account or do I need multiple iSite accounts?

A. For all active Studies that you are participating in where ICON is the Central Laboratory, you are able to view the reporting. Please see the **Selecting a Study** section of this guide for further information.

Q. Will my lab reports prior to me having iSite be available for view on iSite?

A. Site level users will have the ability to view all ICON Laboratory Services reports for their site provided that the study is still active. CRA and Sponsor level users will have the ability to view only the laboratory reports that were delivered after the user was setup as report recipient in ICON database. You will not need a different log in for each study.

Q. I see my visit but no lab report, is it missing?

A. It’s possible for your visit to appear but no associated lab report because your lab report is not ready yet.

Q. How long before I will be logged out of iSite due to inactivity?

A. For security purposes, your session will end after fifteen minutes of no activity.

Q. Where can I find information on ordering and tracking supplies?

A. A separate FAQ page specifically for kits and supplies is located on the ‘Kit Supplies and Ordering’ homepage.

NOTE: FAQ’s for E-Requisitions can be found on the E-Requisition Tab in iSite.