



A Symbol of Excellence

Central Laboratories

ICOLabs User Manual

ICOLabs™ User Manual

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1.0 Introduction

ICOLabs™ is a web-based remote data access system that provides users near real time remote access to reports and monitoring tools used to view clinical trial laboratory test results, microbiology, specimen storage and kit data. The user has access to protocol specific data for the purpose of viewing on screen, saving as a PDF, printing to paper or exporting into a spreadsheet application. Data presented in ICOLabs are downloaded from ICON Central Laboratories' primary clinical database and, as such, are not representative of final, cleaned data. Final, cleaned data for clinical analysis are available upon request through the ICON Central Laboratories Global Data Services Department.

ICOLabs provides the user with 24-hour/7-day per week access to their protocol-specific data. Six major types of information are provided by ICOLabs. These are:

- Laboratory Reports
- Microbiology Reports
- Site Visit Activity Statistics
- Safety Data
- Specimen Storage Status
- Kit Inventory Data

Data are exported on a near real time basis from the ICON Central Laboratories' clinical database to the ICOLabs web application.

ICOLabs has been designed to be user-friendly, straightforward, intuitive and reliable. This has been accomplished via a completely web-based system with screen formats that any user can utilize with minimal or no training. Data are presented in various reports that the user can customize by selecting pertinent criteria. The report views and/or custom searches can be saved so the user can access these reports over and over again.

The ICOLabs homepage includes a unique feature called the ICONtroll Panel that enables the user to customize the home page for a specific protocol. The user has the ability to create custom searches and select up to five of these searches as Favorite Reports. The Favorite Reports readily appear on the user's ICONtroll Panel and can be generated by simply clicking on the appropriate icon. The user also has the ability to select up to four Key Indicators for their protocol. Key Indicators provide study statistics such as the total number of subjects screened, total number of subjects enrolled, total number of active sites and total number of abnormal result flags.

The Standard Reports available in ICOLabs permit the user to review various types of data in a number of different formats. The Standard Reports offer the ability to:

- View a listing of all new and/or amended laboratory and microbiology reports;
- View selected laboratory results;
- Trend laboratory data by subject or study population;
- Review enrollment and site status reports;
- Track kit inventory and kit expiration status;
- Track specimen storage status.

Each report has its own report filter page based on the content of the report. Filtering allows the user to select specific criteria before the report is generated, so that the report is customized based on the users needs.

2.0 Definitions

Term	Definition
Abnormal Value	A value that is lower or higher than the established result range for the test, taking into account the subject's age, sex and other attributes.
Accession Number	The unique order number assigned to tests accompanying the same test requisition.
Alert Values	Values that have been designated to be worthy of telephone notification to the clinical investigator because they fall so significantly outside of the normal range that special care of the study subject may be required.
Amended Report	A report that contains updated information (e.g. collection, demographic or result information). To determine what information has been updated, please refer to the comments section of the lab report.
Analyte	A single test value. Generally, this term is used to refer to a single test value that is reported for a panel of tests.
CLW	Acronym for "Central Laboratory Worksheet," the comprehensive document used to determine how the trial sponsor wants every aspect of their protocol set up and reported.
Clinical Trial Sponsor	A pharmaceutical or biotechnology company that is conducting a clinical trial.
Collection Date	The date the study subject had their blood drawn and other specimens taken at the investigator site.
Conventional Units	Non-SI units of measure (See SI Units) used in the United States and a few other countries, rather than fully adopting the metric system/ SI units. Although the US mainly uses conventional units for reporting analytes they have adopted SI Units for enzymes and other analyte testing.
Delta Value	A test result value that represents an absolute or percentage level of change (higher or lower) than a previous value for the same test on the same subject in the study. Delta values are established by the clinical trial sponsor to monitor changes in the clinical condition of a single study subject.
Department	A grouping of individual tests that is formally recognized by the laboratory. Panels may be established in recognition of similar processing methods (e.g. a chemistry panel) or because together the tests in the panel provide a comprehensive clinical picture of a particular medical condition (e.g. a thyroid panel).
Exclusions	Test values that are at a level (high or low) that would prohibit a study subject from entering or continuing to participate in the clinical trial.
Expiration Date	The date until which a collection kit may be used. Several kit components have individual expiration dates. The collection kit expiration date is determined by the earliest expiration date of any individual kit component.

Hover	The ability to “mouse over” a particular data field to view additional information.
Investigator	Short for “Clinical Investigator.” Refers to the physician contracted by the clinical trial sponsor to screen, enroll, and manage a study subject as well as document the subject’s clinical condition.
Kit	Refers to the box of specimen collection tubes and materials prepared by ICON Central Laboratories and sent to the site for use in collecting specimens at a subject’s study visit.
Locked	When a subject visit is received with missing or discrepant demographic or collection information, ICON Central Laboratories “locks” the visit from reporting to the site and inclusion in data transmissions to the client. A visit will also be locked if a requested update is being made to any visit or subject. All testing is performed per usual, unless the missing information prevents the proper testing from being performed. Likewise, all panics, exclusions, and other client-defined abnormal values to be called to the sites are triggered and called as per usual, without delay.
PACS	Short for “Protocol Administration Computer System.” PACS is ICON Central Laboratories’ proprietary computer system that provides for the custom setup and management of clinical trials.
Panic Value	A test result that is recognized as being so abnormal that it is cause for immediate notification of the clinical investigator for rapid medical response to the study subject.
Protocol	The written document that provides the specific procedures to be followed, clinical tasks to be performed and the time intervals at which such activities should be completed. The protocol defines the specific laboratory tests that should be performed at each visit in the study.
Reference Range	The range of result values for a particular test that is considered normal for a study subject in a certain age, sex and, in some cases, race category.
Report Date	The date the ICON Central Laboratories result report was generated.
Result	Short for “test result”. Synonymous with “lab value.” The quantitative or qualitative outcome of a test performed by the laboratory.
Screening	The initial study visit at which a potential study subject is considered for participation in a particular clinical trial.
SI Units	An international system of rational and internally consistent units of all types of scientific quantities. This international system of units is known as SI for its French name, <i>Système International d’Unités</i> . These units are used for many analytes regardless of study/ lab origin, but this metric system has not been widely adopted by the United States and a few other countries for measuring all analytes’ units.

Site	Short for "Clinical Investigator Site." The location at which the physician participating in the clinical trial works and sees study subjects.
Site ID	The number assigned to a specific site to distinguish it from another site location in the study.
Sponsor	Short for "Clinical Trial Sponsor," this term refers to the specific pharmaceutical or biotechnology company responsible for the clinical development of the new drug.
Study	Short for "Clinical Study." Refers to all of the activities that occur as the clinical protocol is conducted.
Subject	Short for "Study Subject." The term given to individuals who participate in clinical trials. This term is preferable to "patient" when the individual is participating in a clinical trial.
Subject ID	The unique identifier assigned by the trial sponsor to a study subject. This identifier typically has the same format for all study participants and may be numeric or alphanumeric. Clinical trials do not permit the use of study subject names, so the Patient ID is critical in appropriate tracking of study data.
Test	The diagnostic activity performed by the laboratory that renders a clinical result for diagnosis or clinical monitoring purposes.
Unscheduled Visit	A visit completed by the study subject that was not a standard visit anticipated in the clinical protocol. Unscheduled visits are usually conducted if there is reason to be concerned about the subject's clinical condition, thereby justifying the need for additional testing and monitoring.
Visit Name	Refers to the formal label given to a specific study visit in a clinical protocol to better describe that visit. For example, "enrollment visit" or "dosing visit." The visit name may also represent a particular time point in the study such as "Week 2."
Visit Number	The sequence number applied to a visit in a clinical protocol, such as Visit 1, Visit 2, etc. These represent the chronological order in which the study visits occur.

3.0 System Requirements

ICOLabs has been designed so that an approved user can access ICOLabs via any web browser, without additional applications being installed on the client's PC. The following requirements are recommended for best performance:

Windows

- A PC with a Processor: 1 gigahertz (GHz) or faster.
- Microsoft XP or Later windows Operating system
- RAM: 1 gigabyte (GB) (32-bit) or 2 GB (64-bit)
- Free hard disk space: 1 GB or more.
- Internet access.

Browser

- Internet Explorer 8 or later.
- Microsoft Edge
- Google Chrome 3.2 and later

NOTE: Pop-Up blocker software must be configured to allow Pop-Ups from the ICOLabs website. Failure to do so will result in reports being blocked from view.

For the best experience and the least chance of losing your work, don't use your browser's Back button. Instead use the navigation buttons and links we've built into our webpages, which include auto-saves as part of their functionality.

4.0 Getting Started

Access to the ICOLabs system is granted once the ICON Laboratories Project Manager requests access on your behalf.

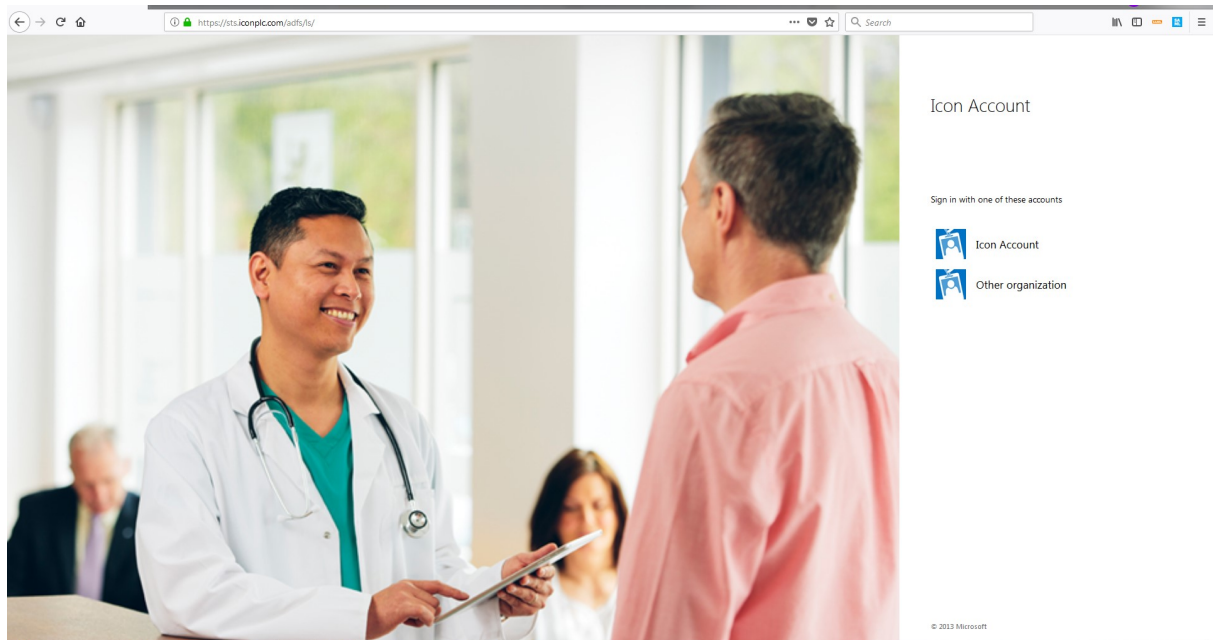
NOTE: Please contact your ICON Central Laboratories Project Manager for any questions regarding the setup of studies or users in the ICOLabs system.

A link will be sent to the new user by email to complete the registration process. The link will expire within 7 days. If the user fails to login before the time frame, the link will be expired and a new registration link will need to be sent. (Please contact ICOLABS support in this case)

After completing the registration process the user must log in and run a report on any protocol to prevent his/her access from being retired.

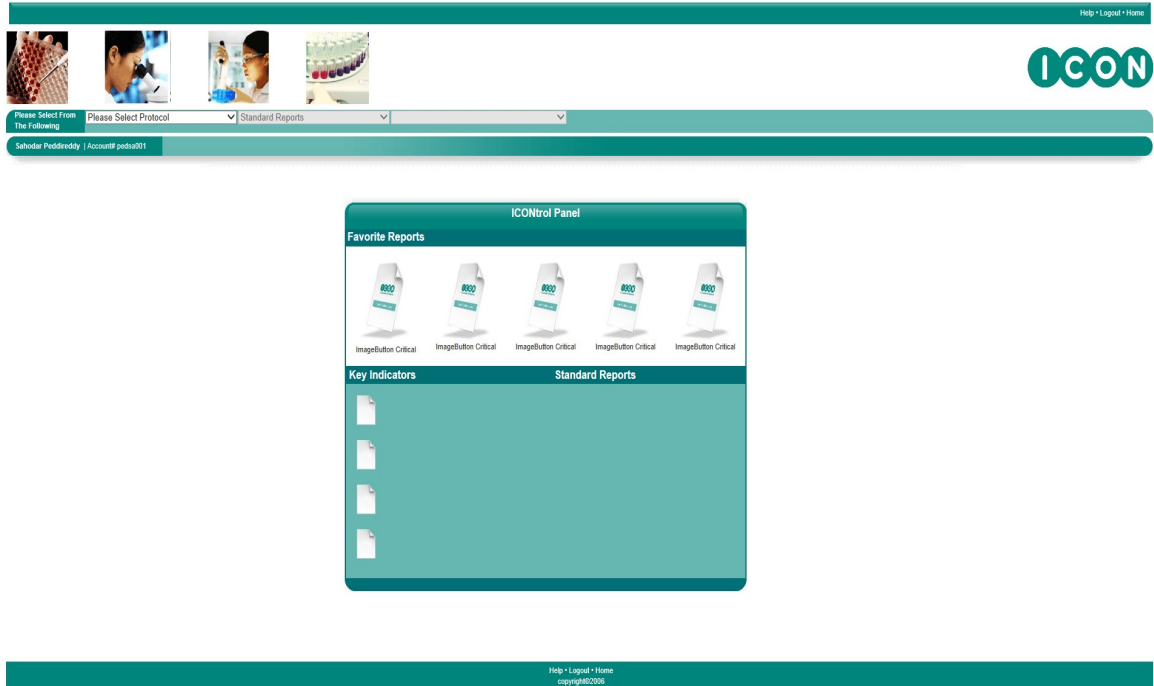
If the user is working on behalf of a company that uses the ICON SSO (Single Sign On) method you will be directed to a separate login page. On that page you have the option to select your organization

Note: This E-Mail/Organization selection will only be required one time per Device. All subsequent logins will be automatically redirected to ICON ADFS login page.



The user is prompted for the organization's credentials → enter the user's ICON Windows User ID and Windows password for ICON authentication

If authentication is successful, the user will be directed to the ICOLabs Home page for protocol selection



If you are not working on behalf of an organization that is not using the ICON SSO (Single Sign on) then you will see the following screen. If you are not sure just use the link (<https://rda.ICOLabs.com/iconstudyreporter/>) and the system will redirect you automatically based on your login.

Logging Into the ICOLabs System

First Time ICOLabs Users:



User Login

User ID:

Password:

[Forgot User Name](#) | [Forgot Password](#)
 Contact ICOLABS Support
 Email: ICOLabsSupport.Support@icoplabs.com
 Telephone: + (1) 516-574-5474
 Find a toll free number for your location

Figure A – User Login Screen

1. The system will prompt you to enter and confirm a new password.

Password Change

USER NAME:
[REDACTED]

LOGIN ID: [REDACTED]

Please enter a password with a minimum of 8 alphanumeric characters.

New Password:

Confirm New Password:

Your password has expired or change password was requested.
Please enter a new password

NOTE: The password must be at least 8 alphanumeric characters. Passwords may not be reused and are required to change every 120 days.

2. Upon successful change of password, the Terms and Conditions screen will appear.
3. To accept the Terms and Conditions, click on Accept. Failure to accept the Terms and Conditions will prohibit the use of ICOLabs.
4. Once accepted, the ICOLabs home page, ICONtrol Panel, will appear.

Returning ICOLabs Users:

1. Log into ICOLabs using the following URL:
<https://rda.icolabs.com/ICONStudyReporter> At the User Login prompt, enter your username and password.

NOTE: Three unsuccessful login attempts will lock the user account. Please contact the ICON RDAS Department to unlock your account and reset your password.

2. Upon successful login, the ICOLabs home page, ICONtrol Panel, will appear.

5.0 ICOLabs Homepage Navigation

When you have successfully logged into the ICOLabs application, the homepage will display. To activate the ICONtroll Panel (Figure B), and/or to view reports for your protocol, you must select the protocol that you would like to work with from the *Please Select Protocol* dropdown bar. If only one protocol is assigned, the ICONtroll Panel will default to the assigned protocol. Once a protocol is selected, the ICONtroll Panel will activate with your Favorite Reports, Key Indicators and the Standard Reports listings. The *Standard Reports* dropdown bar will populate with standard reports. The *Custom Searches* dropdown bar will populate with any custom searches that you have created for the selected protocol. (Please refer to Custom Searches in Section 8.0 for instructions on setting up custom searches.)

The toolbar located beneath the Protocol Selection, Standard Reports and Custom Searches bar is the *User Account* toolbar. This toolbar displays the User's full name and Account #. The **Manage Profile** link opens the User Maintenance screen. (Please refer to Manage Profile in Section 9.0.) The **Manage Custom Searches** link opens the Manage Custom Searches screen.

Located in the top right and the bottom center of the screen are links to **Help**, **Logout** and **Home**. Clicking on the **Help** link will generate the User Manual. When clicking on the **Logout** link, the system will log you out of the system. A warning message will redisplay, requesting that all active windows must be closed out. The Logout function will log the user out of the main ICOLabs page or Filter page. Clicking on the **Home** link will generate the ICOLabs home page and will maintain the protocol that you have previously selected.

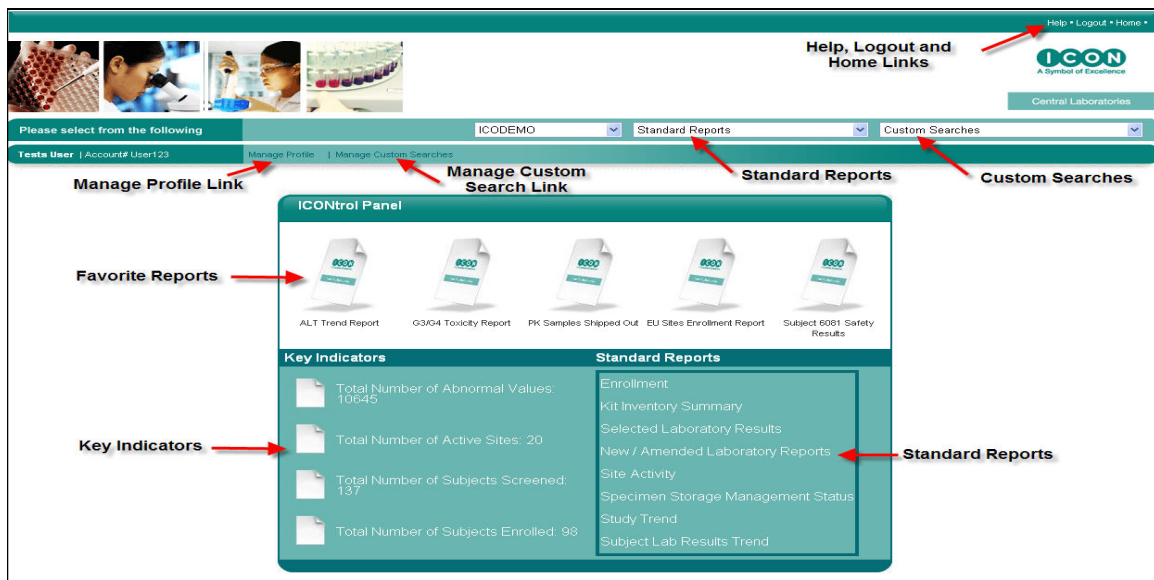


Figure B – The ICONtroll Panel

6.0 Global System Behavior

The user can accomplish the following tasks from the ICONtrol Panel or Filter page:

- Change protocols
- Select Standard Reports
- Select Custom Searches.
- Access the homepage and the ICONtrol Panel by clicking on **Home**
- Log out of the system by clicking on the **Logout** link. Please note that it is the responsibility of the user to close all open report windows prior to logging out of the system.
- Access the online user manual by clicking on **Help**

The user can accomplish the following tasks from the Report output pages:

- Save or Print reports by clicking on the **Print** link.
- Export reports to a tab-limited or a .csv Microsoft Excel® file by clicking on the **Export** link.

Please note the following potential data access restrictions when viewing reports:

- If the subject visit is locked, the word “LOCKED” will appear in place of Test Result. The Units, Result Flags, and any associated comments will be blank. When the visit becomes unlocked, the result data will become available to view online.
- If the user is blinded to specific test(s), the word “BLINDED” will appear in place of the Test Result, Result Flags, and any associated comment.
- If a test has results that are pending, the system will display “PEND” as the lab result for that test.
- Reports can only be run for one protocol at a time. The User cannot merge data across two or more protocols. The user can however, execute multiple reports to view different reports against each other.

Please note that the system is designed to timeout after a period of inactivity. When this occurs, all report windows will become inactive and a message will appear stating that the session has timed out. Clicking the **Return to Login** button will generate the ICOLabs Login web page. An attempt to access the inactive report page will display a “Session not Active” message; clicking **OK** will close the report page.

7.0 Standard Reports

ICOLabs includes an extensive suite of standard reports that can be used to access General Laboratory and Microbiology reports, view selected lab results, view and graph trends, view subject status and enrollment reports, view specimen storage data and kit inventory reports.

To generate a standard report, select the report from the *Standard Report* dropdown menu or choose the report from the ICONtrol Panel.

Once the report has been selected, the filter screen for that report will generate. Filtering allows the user to view specific information within a report. Each report has its own filtering capability, based on the report content and the protocol-specific parameters that were established at the time of the study's setup. (See Figures E and F)

7.1 *New/Amended Laboratory Report*

▪ **New/Amended Laboratory Report Filter Page**

➤ **Site Criteria – Investigator(s)**

By default, all Investigators are listed alphabetically by last name then by first name and credentials. To sort by Investigator Number, click on **List by Number**. The default sort is ascending. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Investigators. To view specific Investigator(s), highlight the Investigator(s) and then click on the down arrow to select the highlighted Investigator(s). Once the Investigator(s) populate in the **Selected** box, the Site(s) box will populate with the corresponding Site Numbers associated with the selected Investigator(s).

➤ **Site Criteria – Site(s)**

The default sort for sites is in ascending alphanumeric order. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Sites. To view a specific Site(s), highlight the Site(s), and then click on the down arrow to select the highlighted Site(s). Once the Site(s) populate in the **Selected** box, the Investigator(s) box will populate with the corresponding Investigator Numbers associated with the selected Site(s).

➤ **Test Criteria – Units of Measure**

By default, Conventional Units are the units of measure that will display on the screen and on reports. To change the units of measure to Standard International (SI) units, click on the **SI Units** button.

➤ **Sort By**

The Sort By filter option allows the user to select how the report will be sorted. By default, the report is sorted in ascending order by Investigator, then by Subject ID and chronologically by Visit Name. To change the sort order, click on the down arrow and select the field to sort by. Click the appropriate **Ascending** or **Descending** button to sort the selected field.

Once the filter selections have been made, click on the **Show Report** button to generate the report. Clicking on **Show Report** without making any filter selections will result in generating all new and/or amended laboratory reports.

To make any changes to the filter selections that were chosen, use the **Reset** button to reset all of the filter choices that were previously selected. To deselect specific filter choices, use the up arrows to remove the selections, uncheck checked selections, or use the “Ctrl” key and click on the values that you want to deselect.

▪ **New/Amended Laboratory Report Description**

The New/Amended Laboratory Report (Figure D) displays a summary listing of all new/amended General Laboratory and/or Microbiology reports that the user has not reviewed or has not marked as reviewed. The user has the ability to view the General Lab and/or Micro reports by using the built in drill down capability. The user can choose to mark reports as reviewed so that the reports will be cleared from the report queue, or if the user chooses not to mark the reports as reviewed, the reports will remain in the queue.

The following will trigger an amended report:

- Pending results that have been released
- Modified test results (with the exception of a deleted test result)
- Additional test results
- Added, modified, and/or deleted test specific comments

Please note that any visits that are locked will be excluded from the New/Amended Laboratory Reports.

This report includes the following fields, as displayed in Figure C:

- Investigator Name
- Site #
- Subject ID
- Subject Initials
- Collection Date
- Visit Name
- General Lab Accession #
- Micro Accession #
- Flagged Results

This report will list all subjects that have a new and/or amended general laboratory and/or microbiology report. The Flagged Results column will display a ‘Y’ or ‘N’. If ‘Y’ is displayed then one or more of that subject’s results for the subject visit was out of normal range. If ‘N’ is displayed then all results for that subject visit are within normal range.

To sort the report, click on the **Ascending** or **Descending** button and then click a column in the report.

To view a different page on the report, click on the appropriate page number. Page numbers are located at the bottom of the report.

Hovering Capability

This report has hover capabilities on the following fields:

- Investigator Name - Displays the investigator name, the investigator address and telephone number
- Site # - Displays the shipping address
- Subject ID - Displays the subject ID, subject screen ID, subject initials, gender, date of birth and the race code (If applicable)

Drill Down Capability

This report has drill down capabilities when clicking on the **General Lab Accession #** or the **Micro Accession #**. Clicking on one of these fields will generate the General Laboratory or Microbiology Report. (Please refer to the General Laboratory and Microbiology Sections in 7.9 and 7.10 for report descriptions.)

Marking Reports as Reviewed

To mark a report as reviewed, click the box in the Clear Lab Report(s) column, next to the report reviewed. When all reports that have been reviewed have been marked (Figure C), click on **Clear Selected Reports** to remove the reports from the queue.

NOTE: Clicking on the Clear button removes a report from the queue, regardless of whether the General Laboratory and/or Microbiology report was reviewed. If the row contains both General Lab and Micro reports, both will be cleared from the queue and marked as reviewed.

Clearing All Reports

To clear all reports for all visits that are listed on the New/Amended Laboratory Report that was generated, you must simply click on the link "Clear All Reports."

Clearing All Reports on a Page

To clear the reports for only the visits that are listed on the displayed page is a two step process. You must first check the box labeled "Select All Reports on Page" by doing this a check mark will be placed in each one of the check boxes that are listed on the page in the "Clear Lab Report" column next to the visit. Once this is done, you must then click on the "Clear selected Reports" link. By doing this, you will clear only the reports that are listed on the displayed page.

Your Filter Criteria
Protocol: ICODEM0
All Sites
All Investigators

New / Amended Laboratory Reports [Clear all reports](#) • [Refresh](#) • [Print](#) • [Export](#)

Select All Reports on Page Page 1 of 32
 Clear Selected Reports Ascending Descending

Clear Lab Report (s)	Investigator Name	Site #	Subject ID	Subject Initials	Collection Date	Visit Name	General Lab Accession #	Micro Accession #	Flagged Results
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	25-FEB-2004	SCREENING	B342848	B342848	Y
<input checked="" type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	16-MAR-2004	BASELINE	B352158		Y
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	23-MAR-2004	DAY 7	B356048		N
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	14-APR-2004	WEEK 4	B364378		Y

Click in Box to Mark Report Reviewed

Figure C – Marking the New/Amended Laboratory Reports as Reviewed

General Laboratory and/or Microbiology reports can also be marked as reviewed when reviewing the report, itself. Please refer to General Laboratory and Microbiology Reports in section 7.9 & 7.10 for report description.

Refresh

Clicking on **Refresh** will refresh the screen and update the queue and the report to reflect any reports that were marked as reviewed. Upon marking a report as viewed through the General and/or Microbiology Report and returning to the report page, clicking **Refresh** will remove these reports from the report page.

Print

Clicking on **Print** will generate the Print Preview page of the report. From this screen, clicking on the Printer icon will generate the Print dialog box. The report can also be saved as a PDF document from this screen by clicking on the Save icon.

Export

Clicking on **Export** will open the File Download dialog box. The file can be opened or saved as a Microsoft Excel® comma separated file. If **Open** is chosen, without saving the report, Microsoft Excel® will auto format the report text. To keep the format the same, choose to **Save** the report as a .csv file and then import the .csv file into any spreadsheet application.

Your Filter Criteria

The box entitled Your Filter Criteria contains the filter criteria that were selected when the report generated.

Your Filter Criteria

Protocol: ICODEMO
 ALL Sites
 ALL Investigators

New / Amended Laboratory Reports [Clear all reports](#) · [Refresh](#) · [Print](#) · [Export](#)

Select All Reports on Page
 Clear Selected Reports

Page 1 of 32 Ascending Descending

Clear Lab Report (s)	Investigator Name	Site #	Subject ID	Subject Initials	Collection Date	Visit Name	General Lab Accession #	Micro Accession #	Flagged Results
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	25-FEB-2004	SCREENING	B342848	B342848	Y
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	16-MAR-2004	BASELINE	B352158		Y
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	23-MAR-2004	DAY 7	B358048		N
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	14-APR-2004	WEEK 4	B364378		Y
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	10-MAY-2004	WEEK 8	B373284		Y
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	08-JUN-2004	WEEK 12	B383472		Y
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	02-JUL-2004	WEEK 16	B391950		N
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	02-AUG-2004	WEEK 20	B400746		N
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	31-AUG-2004	WEEK 24	B409555		Y
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	28-SEP-2004	WEEK 28	B418000		N
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	27-OCT-2004	WEEK 32	B427232		N
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	29-NOV-2004	WEEK 36	B436638		Y
<input type="checkbox"/>	Bella, Nicole MD	5842	6009	JSJ	21-DEC-2004	WEEK 40	B444587		N

Figure D – New and Amended Laboratory Reports

7.2 Selected Laboratory Results

- **Selected Laboratory Results Filter Page (Figure E & F)**
 - **Site Criteria – Investigator(s)**
 By default, all Investigators are listed alphabetically by last name then by first name and credentials. To sort by Investigator Number, click on **List by Number**. The default sort is ascending. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Investigators. To view specific Investigator(s), highlight the Investigator(s) and then click on the down arrow to select the highlighted Investigator(s). Once the Investigator(s) populate in the selected box, the Site(s) box will populate with the corresponding Site Numbers associated with the selected Investigator(s).
 - **Site Criteria – Site(s)**
 The default sort for sites is in ascending alphanumeric order. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Sites. To view a specific Site(s), highlight the Site(s), and then click on the down arrow to select the highlighted Site(s). Once the Site(s) populate in the Selected box, the Investigator(s) box will populate with the corresponding Investigator Numbers associated with the selected Site(s).
 - **Subject Criteria – Subject ID(s)**
 By default, all Subject IDs are listed alphabetically by Subject Initials – Subject ID. To sort by Subject ID, click on **List by Number**. The

default sort is ascending. To sort in descending order, click on **Sort Desc**. If a selection is not made, the report will default to include all Investigators. To view specific Subject(s), highlight the Subject ID(s), and then click on the down arrow.

- **Subject Criteria – Birth Date**
Enter a range of **Birth Dates** in DD-MMM-YYYY format in the **FROM** and **TO** fields.
- **Subject Criteria – Gender (If applicable)**
By default, both **Male** and **Female** are selected. To view only Male subjects, uncheck the **Female** checkbox. To view only Female subjects, uncheck the **Male** checkbox.
- **Subject Criteria – Race Code(s) (If applicable)**
By default, all race codes are selected. To view specific race code(s), select the **Race Code(s)** by clicking on the appropriate Race Code.

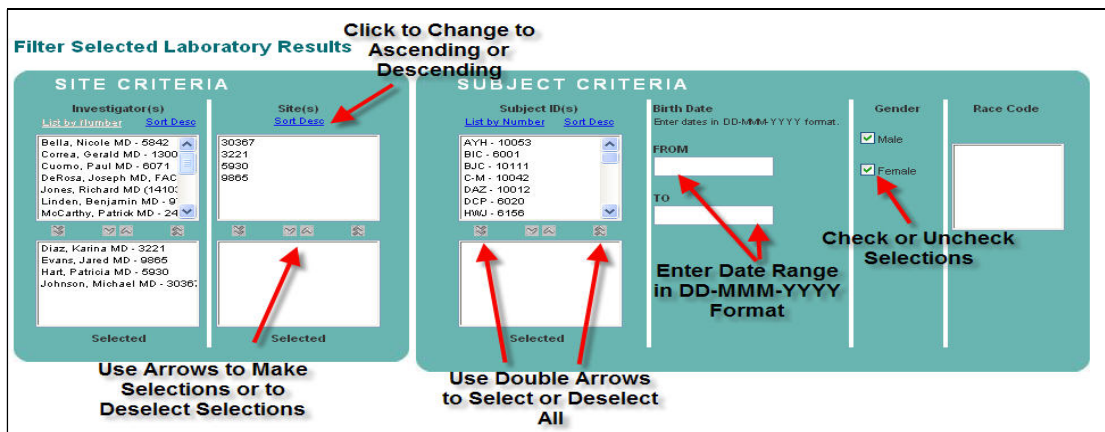


Figure E – Selecting Subject Criteria from the Filter Page

- **Visit Criteria – Visit(s)**
By default all visits are selected. To view specific Visit(s), select the **Visit(s)** by clicking on the appropriate visit(s).
- **Visit Criteria – Collection Date**
Enter a range of **Collection Dates** in DD-MMM-YYYY format in the **FROM** and **TO** fields.
- **Test Criteria – Department(s)**

By default, all Departments are selected. To view specific Department(s), select the Department(s) by clicking on the appropriate **Department**. Once the Department(s) has been selected, the **Test Name(s)** criteria box will populate with the associated Test Names of the chosen Department(s).

➤ **Test Criteria – Test Name(s)**

By default, all Test Name(s) are selected. If a Department(s) was selected then the Test Name(s) for that department will populate. To select specific Test(s), click on the associated **Test Name(s)**.

Test Criteria – Result Flag

By default, all Result Flag(s) are selected (although they are not checked off). To view specific Result Flag(s), check off the appropriate **Result Flag(s)**.

➤ **Test Criteria – Exclusion(s) (If applicable)**

By default, Exclusion(s) are selected (although not highlighted). To view only results that are flagged as Exclusion, click on the **Exclusion** value.

➤ **Test Criteria – Toxicity Grade(s) (If applicable)**

By default, all Toxicity Grade(s) are selected (although not highlighted). To view only specific Toxicity Grade(s), click on the appropriate **Toxicity Grade**.

➤ **Test Criteria – Delta Flag(s) (If applicable)**

By default, all Delta Flag(s) are selected (although not highlighted). To view only specific Delta Flag(s), click on the appropriate **Delta Flag**.

➤ **Test Criteria – Units of Measure**

By default, Conventional Units are the units of measure that will display on the screen and on reports. To change the units of measure to Standard International (SI) units, click on the **SI Units** button.

➤ **Sort By**

The Sort By filter option allows the user to select how the report will be sorted. By default, the report is sorted in ascending order by Investigator, then by Subject ID and chronologically by Visit Name. To change the sort order, click on the down arrow and select the field to sort by. Click the appropriate **Ascending** or **Descending** button to sort the selected field.

➤ **Items to Show**

All – By default **All** is selected. Selecting **All** will result in viewing all results, reviewed and not reviewed.

Reviewed – Selecting **Reviewed** will result in viewing data that has been marked as reviewed.

Not Reviewed – Selecting **Not Reviewed** will result in viewing data that has not been marked as reviewed.

VISIT CRITERIA

Visit(s): SCREENING, BASELINE, DAY 7, WEEK 4, WEEK 8, WEEK 12, WEEK 16, WEEK 20, WEEK 24, WEEK 28, WEEK 32, WEEK 36

Collection Date: Enter dates in DD-MMM-YYYY format. FROM: [] Calendar TO: [] Calendar

Enter date Range in DD-MMM-YYYY Format or Use the Calendar

Make Selections by Clicking on the Value (All is Selected by Default)

TEST CRITERIA

Department(s): CHEMISTRY, FLOW CYTOMETRY, HEMATOLOGY, MISCELLANEOUS

Test Name(s): ALBUMIN, ALKALINE PHOSPHATASE, ALT, AMYLASE, AST, BICARBONATE, CALCIUM, CHLORIDE, CHOLESTEROL, TOTAL, CREATININE, GLUCOSE, FASTING, SERUM, HDL- CHOLESTEROL, LDH, LDLC/HDLC, LDL-CHOLESTEROL, MAGNESIUM, P-AMYLASE, PHOSPHATE

Result Flag:

- H - Normal
- H - High
- L - Low
- HP - High Panic
- LP - Low Panic
- HA - High Alert
- LA - Low Alert
- A - Abnormal
- AA - Abnormal Alert
- AP - Abnormal Panic

Exclusion(s): []

Toxicity Grade: []

Unit of measure:

- Conventional
- SI Units

By Default, All Values are Selected (Although Not Checked Off). To Make a Selection, Check the Appropriate Value(s).

Select Unit of Measure (Conventional is Default)

Sort By:

1. Investigator Name [v] Ascending Descending

2. Subject ID [v] Ascending Descending

3. Visit Name [v] Ascending Descending

Select Sort Order; Value to Sort By, Ascending or Descending

Items to Show: All Reviewed Not Reviewed

Select All, Reviewed, or Not Reviewed (All is Default)

Figure F – Selecting Visit, Test and Sort Order on the Filter Page

Once the filter selections have been made, click on the **Show Report** button to generate the report. Clicking on **Show Report** without making any filter selections will result in generating all laboratory results.

To make any changes to the filter selections that were chosen, use the **Reset** button to reset all of the filter choices that were previously selected. To deselect specific filter choices, use the up arrows to remove the selections, uncheck checked selections, or use the “Ctrl” key and click on the values that you want to deselect.

NOTE: If the report output contains over 65,000 rows of data, a message will generate indicating that only the first 65,000 rows of data will generate on the report. To continue to display the report, click OK, otherwise, use the filters to minimize the output of the report.

- **Selected Laboratory Results Report Description**

The Selected Laboratory Results report allows the user to view a specifically defined set of laboratory results. With the use of the filtering capability, the generated report is customized based on the selected criteria. This report also has drill down capabilities to view the General Lab and/or the Microbiology Lab Report.

This report includes the following fields, as displayed in Figure G:

- Investigator Name
- Site #
- Subject ID
- Subject Initials
- Collection Date
- Visit Name
- Accession #
- Department
- Test Name
- Test Results
- Units
- Flag

Please note the following about the Selected Laboratory Results report:

- ❑ If the subject visit is locked, the word “LOCKED” will appear in place of Test Result, Result Flags, and any associated comment. When the visit becomes unlocked, the result data will become available to view online.
- ❑ If the user is blinded to specific test(s), the word “BLINDED” will appear in place of the Test Result, Result Flags, and any associated comment.

To sort the report, click on the **Ascending** or **Descending** button and then click a column in the report.

To view a different page on the report, click on the appropriate page number. Page numbers are located at the bottom of the report.

Protocol: ICODEMO | Tests User | Account# User123 |

Your Filter Criteria

Protocol: ICODEMO
 All Sites
 Subject ID:

Selected Laboratory Results [Print](#) [Export](#)

Ascending Descending

Investigator Name	Site #	Subject ID	Subject Initials	Collection Date	Visit Name	Accession #	Department	Test Name	Test Results	Units	Flag
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	LDH	234	U/L	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	BICARBONATE	26	mEq/L	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	ALKALINE PHOSPHATASE	94	U/L	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	TOTAL PROTEIN	8.3	g/dL	H
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	SODIUM	140	mEq/L	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	CHLORIDE	104	mEq/L	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	CALCIUM	9.1	mg/dL	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	LDL-C/HDL-C	3.19	RATIO	H
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	ALT	17	U/L	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	AMYLASE	108	U/L	H
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	CHOLESTEROL, TOTAL	162	mg/dL	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	TRIGLYCERIDES	179	mg/dL	H
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	UREA (BUN)	15	mg/dL	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	POTASSIUM	4.3	mEq/L	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	AST	25	U/L	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	HDL - CHOLESTEROL	32	mg/dL	L
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	MAGNESIUM	1.5	mEq/L	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	CREATININE	0.9	mg/dL	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	TOTAL BILIRUBIN	0.3	mg/dL	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	PHOSPHATE	3.7	mg/dL	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	URIC ACID	8.3	mg/dL	N G1
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	LDL-CHOLESTEROL	102	mg/dL	H
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	GLUCOSE, FASTING, SERUM	77	mg/dL	N
Stevens, Paul MD	30402	6081	ALC	28-APR-2004	SCREENING	B369475	CHEMISTRY	ALBUMIN	4.3	g/dL	N

Figure G – Selected Laboratory Results

Hovering Capability

This report has hover capabilities on the following fields:

- Investigator Name – Displays the investigator name, the investigator address and telephone number.
- Site # - Displays the shipping address.
- Subject ID – Displays the subject ID, subject screen ID, subject initials, gender, date of birth and the race code (If applicable).
- Test Result – If the test result is underlined, there is a test-specific comment associated with the test result. Hovering over the test result will display the test comment.
- Flag – Hovering over the result flag will display the reference range for that specific test.

Drill Down Capability

This report has drill down capabilities when clicking on the Accession #. Clicking on this field will generate the General Laboratory and/or Microbiology Report (Please refer to the *General Laboratory and Microbiology* sections in 7.9 & 7.10 for report description.) If both a General Laboratory and Microbiology Report exist for the Accession #, then both reports will generate.

Print

Clicking on **Print** will generate the Print Preview page of the report. From this screen, clicking on the Printer icon will generate the Print dialog box. The report can also be saved as a PDF document from this screen by clicking on the Save icon.

Export

Clicking on **Export** will open the File Download dialog box. The file can be opened or saved as a Microsoft Excel[®] comma separated file. If **Open** is chosen, without saving the report, Microsoft Excel[®] will auto format the report text. To keep the format the same, choose to **Save** the report as a .csv file and then import the .csv file into any spreadsheet application.

Your Filter Criteria

The box entitled Your Filter Criteria contains the filter criteria that were selected when the report generated.

7.3 Subject Results Trend

▪ **Subject Results Trend Filter Page**

- **Subject Criteria – Subject ID(s)**
By default, all Subject IDs are listed alphabetically by Subject Initials – Subject ID. To sort by Subject ID, click on **List by Number**. The default sort is ascending. To sort in descending order, click on **Sort Desc**. This report requires the user to select one Subject ID. Highlight the Subject ID and click on the down arrow to select the highlighted Subject ID.
- **Test Criteria – Department(s)**
By default, all Departments are selected. To view specific Department(s), select the Department(s) by clicking on the appropriate **Department**. Once the Department(s) has been selected, the **Test Name(s)** criteria box will populate with the associated Test Names of the chosen Department(s).
- **Test Criteria – Test Name(s)**
By default, all Test Name(s) are selected. If a Department(s) was selected then the Test Name(s) for that department will populate. To select specific Test(s), click on the associated **Test Name(s)**.
- **Test Criteria – Units of Measure**
By default, Conventional Units are the units of measure that the report will generate with. To change the units of measure to SI, click on the SI Units button.
- **Sort By**
The Sort By filter option allows the user to select how the report will be sorted. By default, the report is sorted in ascending order by

Department Name, then by Test Name. To change the sort order, click on the down arrow and select the field to sort by. Click the appropriate **Ascending** or **Descending** button to sort the selected field.

Once the filter selections have been made, click on the **Show Report** button to generate the report.

To make any changes to the filter selections that were chosen, use the **Reset** button to reset all of the filter choices that were previously selected. To deselect specific filter choices, use the up arrows to remove the selections, uncheck checked selections, or use the "Ctrl" key and click on the values that you want to deselect.

▪ **Subject Results Trend Report Description**

The Subject Results Trend report allows the user to view data that is presented in a format that can be used to trend subject lab data. This report also has a graphing capability, allowing the user to view trend data in a graphical format.

This report includes the following fields, as displayed in Figure H:

- Investigator Name
- Site #
- Subject ID
- Subject Initials
- Test Name
- Protocol-specific visits that the subject has received, excluding unplanned visits

To sort the report, click on the **Ascending** or **Descending** button and then click a column in the report.

To view a different page on the report, click on the appropriate page number. Page numbers are located at the bottom of the report.

Protocol: ICODEMO | Tests User | Account# User123 |

Your Filter Criteria
 Protocol: ICODEMO
 Subject ID: 6081

Subject Lab Results Trend Print Export

Ascending Descending

Investigator Name	Site#	Subject ID	Subject Initials	Department Name	Test Name	Units	SCREENING	BASELINE	DAY 7	WEEK 4	WEEK 8	WEEK 12	WEEK 16	WEEK 20	WEEK 24	WEEK 28	WEEK 32	WEEK 36	WEEK 40	WEEK 44	WEEK 48	WEEK 52
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	CHLORIDE	mEq/L	104	106	<u>103</u>		104			103				103				104
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	CHOLESTEROL, TOTAL	mg/dL	162	130	<u>235</u>		122			166				125				138
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	CREATININE	mg/dL	0.9	1.0	<u>1.1</u>		1.0			0.9				1.2				1.2
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	GLUCOSE, FASTING, SERUM	mg/dL	77		<u>105</u>		104							112				91
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	HDL - CHOLESTEROL	mg/dL	32	33	<u>49</u>		48			45				44				46
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	LDH	U/L	234	215	<u>217</u>		168			162				166				153
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	LDL-CHOLESTEROL	mg/dL	102	69	<u>152</u>		57			92				64				67
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	LDLCAHDL-C	RATIO	3.19	2.09	<u>3.10</u>		1.19			2.04				1.45				1.46
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	MAGNESIUM	mEq/L	1.5	1.5	<u>1.9</u>		1.5			1.4				1.4				1.5
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	PHOSPHATE	mg/dL	3.7	3.9	<u>4.7</u>		3.9			4.2				4.0				4.1
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	POTASSIUM	mEq/L	4.3	4.7	<u>4.7</u>		3.7			3.8				3.8				4.6
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	SODIUM	mEq/L	140	140	<u>141</u>		136			136				137				137
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	TOTAL BILIRUBIN	mg/dL	0.3	0.2	<u>0.2</u>		0.4			0.3				0.3				0.4
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	TOTAL PROTEIN	g/dL	8.3	8.6	<u>8.0</u>		8.9			8.2				8.6				8.5
Stevens, Paul MD	30402	6081	ALC	CHEMISTRY	TRIGLYCERIDES	mg/dL	179	192	<u>320</u>		127			188				120				146

Page 2 of 7

1 2 3 4 5 6 7

Figure H – Subject Lab Results Trend Report

Hovering Capability

This report has hover capabilities on the following fields:

- Investigator Name – Displays the investigator name, the investigator address and telephone number.
- Site # - Displays the shipping address.
- Subject ID – Displays the subject ID, subject screen ID, subject initials, gender, date of birth and the race code (If applicable).
- Test Result – If the Test Result is underlined, there is a test-specific comment associated with the test result. Hovering over the test result will display the test comment.

Graph Capability

This report has the ability to graph trends for a specific study subject and test. Clicking on the test name will generate the graph of the test results for that subject (To view graphs for the entire or a selected study population, use the Study Trend report). The graph will generate in Microsoft Excel® format (Figure I). The graph can only be displayed. It cannot be printed or exported into a spreadsheet application.

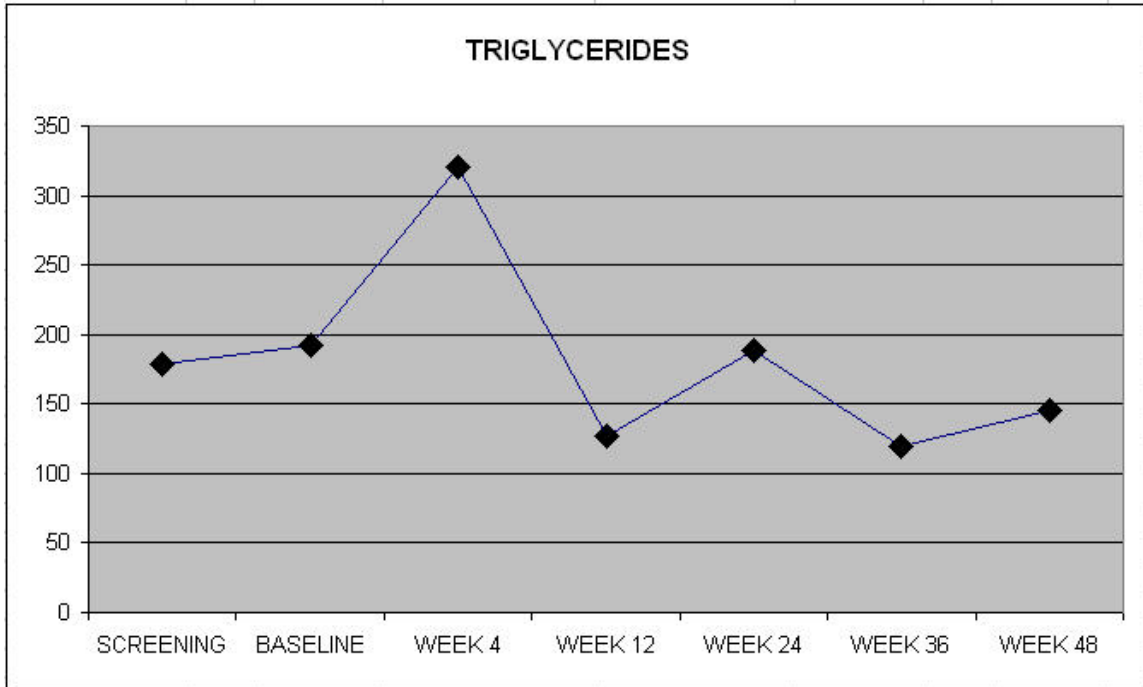


Figure I – A Graph Produced by Clicking on a Test Name in the Subject Trend Report

Print

Clicking on **Print** will generate the Print Preview page of the report. From this screen, clicking on the Printer icon will generate the Print dialog box. The report can also be saved as a PDF document from this screen by clicking on the Save icon.

NOTE: If the report’s width exceeds the standard 8.5” x 11” landscape page size, the report will generate the appropriate number of pages that is needed to display all data.

Export

Clicking on **Export** will open the File Download dialog box. The file can be opened or saved as a Microsoft Excel® comma separated file. If **Open** is chosen, without saving the report, Microsoft Excel® will auto format the report text. To keep the format the same, choose to **Save** the report as a .csv file and then import the .csv file into any spreadsheet application.

Your Filter Criteria

The box entitled Your Filter Criteria contains the filter criteria that were selected when the report generated.

7.4 Study Trend Report

- **Study Trend Report Filter Page**

- **Site Criteria – Investigator(s)**

- By default, all Investigators are listed alphabetically by last name then by first name and credentials. To sort by Investigator Number, click on **List by Number**. The default sort is ascending. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the

report will default to include all Investigators. To view specific Investigator(s), highlight the Investigator(s) and then click on the down arrow to select the highlighted Investigator(s). Once the Investigator(s) populate in the Selected box, the Site(s) box will populate with the corresponding Site Numbers associated with the selected Investigator(s).

- **Site Criteria – Site(s)**

The default sort for sites is in ascending alphanumeric order. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Sites. To view a specific Site(s), highlight the Site(s), and then click on the down arrow to select the highlighted Site(s). Once the Site(s) populate in the Selected box, the Investigator(s) box will populate with the corresponding Investigator Numbers associated with the selected Site(s)
- **Subject Criteria – Birth Date**

Enter a range of **Birth Dates** in DD-MMM-YYYY format in the **FROM** and **TO** fields.
- **Subject Criteria – Gender (If applicable)**

By default, both **Male** and **Female** are selected. To view only Male subjects, uncheck the **Female** checkbox. To view only Female subjects, uncheck the **Male** checkbox.
- **Subject Criteria – Race Code(s) (If applicable)**

By default, all race codes are selected. To view specific race code(s), select the **Race Code(s)** by clicking on the appropriate Race Code.
- **Test Criteria – Department(s)**

By default, **Department** is disabled for this report. This report allows only one test to be selected.
- **Test Criteria – Test Name(s)**

Select the **Test Name** of the test by clicking on the **Test Name**. This report allows only one test to be selected.
- **Test Criteria – Units of Measure**

By default, Conventional Units are the units of measure that will display on the screen and on reports. To change the units of measure to Standard International (SI) units, click on the **SI Units** button.
- **Sort By**

The Sort By filter option allows the user to select how the report will be sorted. By default, the report is sorted in ascending order by Investigator, then by Subject ID and chronologically by Visit Name. To change the sort order, click on the down arrow and select the field to sort by. Click the appropriate **Ascending** or **Descending** button to sort the selected field.

Once the filter selections have been made, click on the **Show Report** button to generate the report. Clicking on **Show Report** without making any filter selections will result in generating all laboratory results.

To make any changes to the filter selections that were chosen, use the **Reset** button to reset all of the filter choices that were previously selected. To deselect specific filter choices, use the up arrows to remove the selections,

uncheck checked selections, or use the “Ctrl” key and click on the values that you want to deselect.

- **Study Trend Report Description**

The Study Trend report allows the user to view laboratory result data for an entire or selected study population. This report also has a graphing capability, allowing the user to view trend data in a graphical format.

This report includes the following fields, as displayed in Figure J:

- Investigator Name
- Site #
- Subject ID
- Subject Initials
- Test Name
- Protocol-specific visits, excluding any unplanned visits

To sort the report, click on the **Ascending** or **Descending** button and then click a column in the report.

To view a different page on the report, click on the appropriate page number. Page numbers are located at the bottom of the report.

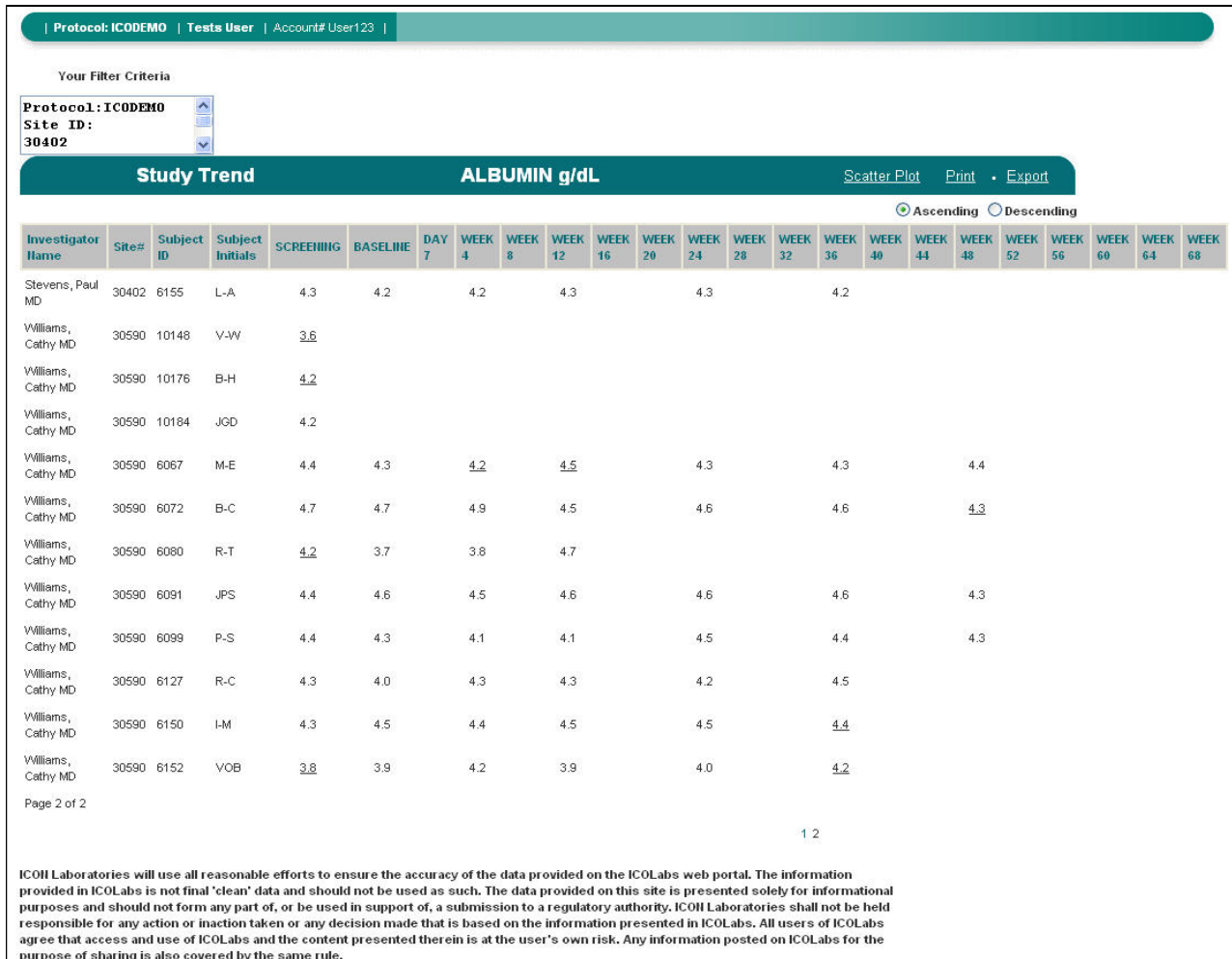


Figure J – A Study Trend Report for Albumin Test Results at a Specific Investigator’s Site

Hovering Capability

This report has hover capabilities on the following fields:

- Investigator Name – Displays the investigator name, the investigator address and telephone number.
- Site # - Displays the shipping address.
- Subject ID – Displays the subject ID, subject screen ID, subject initials, gender, date of birth and the race code (If applicable).
- Test Result – If the Test Result is underlined, there is a test-specific comment associated with the test result. Hovering over the test result will display the test comment.

Scatter Plot

Clicking on **Scatter Plot** will generate the scatter plot graph for the selected population and test. (Figure K) The visit names will not appear along the X-axis; however the visit name will appear when hovering over the point in the graph.

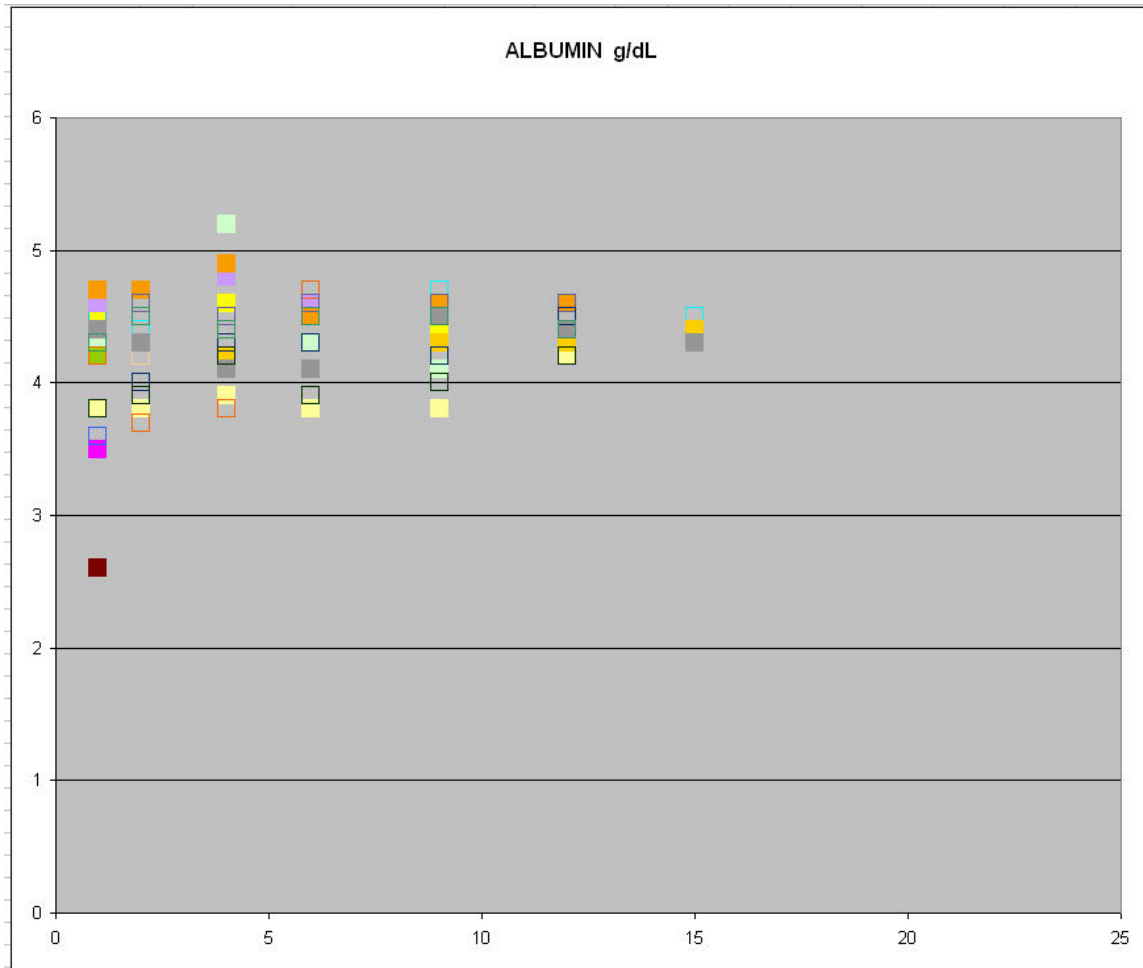


Figure K – A Scatter Plot of Albumin Results for a Selected Study Population

Print

Clicking on **Print** will generate the Print Preview page of the report. From this screen, clicking on the Printer icon will generate the Print dialog box. The report can also be saved as a PDF document from this screen by clicking on the Save icon.

NOTE: If the report's width exceeds the standard 8.5" x 11" landscape page size, the report will generate the appropriate number of pages that is needed to display all data.

Export

Clicking on **Export** will open the File Download dialog box. The file can be opened or saved as a Microsoft Excel® comma separated file. If **Open** is chosen, without saving the report, Microsoft Excel® will auto format the report text. To keep the format the same, choose to **Save** the report as a .csv file and then import the .csv file into any spreadsheet application.

Your Filter Criteria

The box entitled Your Filter Criteria contains the filter criteria that were selected when the report generated.

7.5 Enrollment Report

▪ Enrollment Report Filter Page

➤ Site Criteria – Investigator(s)

By default, all Investigators are listed alphabetically by last name then by first name and credentials. To sort by Investigator Number, click on **List by Number**. The default sort is ascending. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Investigators. To view specific Investigator(s), highlight the Investigator(s) and then click on the down arrow to select the highlighted Investigator(s). Once the Investigator(s) populate in the Selected box, the Site(s) box will populate with the corresponding Site Numbers associated with the selected Investigator(s).

➤ Site Criteria – Site(s)

The default sort for sites is in ascending alphanumeric order. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Sites. To view a specific Site(s), highlight the Site(s), and then click on the down arrow to select the highlighted Site(s). Once the Site(s) populate in the Selected box, the Investigator(s) box will populate with the corresponding Investigator Numbers associated with the selected Site(s).

➤ Units of Measure -

By default, Conventional Units are the units of measure that will display on the screen and on reports. To change the units of measure to Standard International (SI) units, click on the **SI Units** button.

➤ Sort By

The Sort By filter option allows the user to select how the report will be sorted. By default, the report is sorted in ascending order by Investigator Name, then by Site Number. To change the sort order, click on the down arrow and select the field to sort by. Click the appropriate **Ascending** or **Descending** button to sort the selected field.

Once the filter selections have been made, click on the **Show Report** button to generate the report. Clicking on **Show Report** without making any filter selections will result in generating all laboratory results.

To make any changes to the filter selections that were chosen, use the **Reset** button to reset all of the filter choices that were previously selected. To deselect specific filter choices, use the up arrows to remove the selections.

▪ Enrollment Report Description

The Enrollment report allows the user to view the number of subjects at a site who have completed specific visits. It also provides the user with a grand total

of all subjects at specific visits for the entire study. This report also has a drill down capability to the **Site Activity** report.

This report includes the following fields, as displayed in Figure L:

- Investigator Name
- Site #
- Protocol-specific Visit Names
- Total Visit Enrollment
- Grand Total Enrollment at Specific Visits
- Grand total for all visits

To sort the report, click on the **Ascending** or **Descending** button and then click a column in the report.

To view a different page on the report, click on the appropriate page number. Page numbers are located at the bottom of the report.

Protocol: ICODEMO | Tests User | Account# User123 |

Your Filter Criteria

Protocol: ICODEMO
 All Sites
 All Investigators

Enrollment Print Export

Ascending Descending

Investigator Name	Site#	SCREENING	BASELINE	DAY 7	WEEK 4	WEEK 8	WEEK 12	WEEK 16	WEEK 20	WEEK 24	WEEK 28	WEEK 32	WEEK 36	WEEK 40	WEEK 44	WEEK 48	WEEK 52	WEEK 56	WEEK 60	WEEK 64	WEEK 68	WEEK 72	WEEK 80	WEEK 88	WEEK 96	UNSC:TERM	Total	
Smith, Robert MD	12376	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1											15	
Stevens, Paul MD	30402	12	6	6	6	6	6	6	6	6	6	6	6	6	5	3	3										7	102
Tuckey, Debbie MD	19122	5	3	3	3	3	3	3	3	3	3	3	2	2	2	2	2	1	1	1							2	50
Walgreen, Shane MD	8773	4	4	4	4	4	4	4	4	4	4	3	3	3	3	2	2	1									1	58
Williams, Cathy MD	30590	11	8	8	8	8	8	8	7	7	7	7	7	6	6	4	3	1									4	118
Total	20	137	98	98	97	97	96	96	94	93	92	90	86	86	85	65	51	29	20	4	1					72	1587	

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1 2

ICON Laboratories will use all reasonable efforts to ensure the accuracy of the data provided on the ICOLabs web portal. The information provided in ICOLabs is not final 'clean' data and should not be used as such. The data provided on this site is presented solely for informational purposes and should not form any part of, or be used in support of, a submission to a regulatory authority. ICON Laboratories shall not be held responsible for any action or inaction taken or any decision made that is based on the information presented in ICOLabs. All users of ICOLabs agree that access and use of ICOLabs and the content presented therein is at the user's own risk. Any information posted on ICOLabs for the purpose of sharing is also covered by the same rule.

Figure L – An Enrollment Report Displaying Number of Visits Completed at All Study Sites

Hovering Capability

This report has hover capabilities on the following fields:

- Investigator Name – Displays the investigator name, the investigator address and telephone number.
- Site # - Displays the shipping address.

Drill Down Capability

This report has a drill down capability to view the **Site Status** report. Clicking on a clickable cell that contains a numeric value will drill down to the **Site Status** report for the specific cell. For Example, clicking on the cell for Site # 002 and Screening, will generate the **Site Activity** Report for all Site # 002

Screening visits. If the numeric value for that cell is 5, then the report will generate with the 5 subjects that have a Screening visit at Site # 002.

Print

Clicking on **Print** will generate the Print Preview page of the report. From this screen, clicking on the Printer icon will generate the Print dialog box. The report can also be saved as a PDF document from this screen by clicking on the Save icon.

NOTE: If the report's width exceeds the standard 8.5" x 11" landscape page size, the report will generate the appropriate number of pages that is needed to display all data.

Export

Clicking on **Export** will open the File Download dialog box. The file can be opened or saved as a Microsoft Excel® comma separated file. If **Open** is chosen, without saving the report, Microsoft Excel® will auto format the report text. To keep the format the same, choose to **Save** the report as a .csv file and then import the .csv file into any spreadsheet application.

Your Filter Criteria

The box entitled Your Filter Criteria contains the filter criteria that were selected when the report generated.

7.6 Site Activity Report

- **Site Activity Report Filter Page**
 - **Site Criteria – Investigator(s)**

By default, all Investigators are listed alphabetically by last name then by first name and credentials. To sort by Investigator Number, click on **List by Number**. The default sort is ascending. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Investigators. To view specific Investigator(s), highlight the Investigator(s) and then click on the down arrow to select the highlighted Investigator(s). Once the Investigator(s) populate in the Selected box, the Site(s) box will populate with the corresponding Site Numbers associated with the selected Investigator(s).
 - **Site Criteria – Site(s)**

The default sort for sites is in ascending alphanumeric order. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Sites. To view a specific Site(s), highlight the Site(s), and then click on the down arrow to select the highlighted Site(s). Once the Site(s) populate in the Selected box, the Investigator(s) box will populate with the corresponding Investigator Numbers associated with the selected Site(s).
 - **Subject Criteria – Subject ID(s)**

By default, all Subject IDs are listed alphabetically by Subject Initials – Subject ID. To sort by Subject ID, click on **List by Number**. The default sort is ascending. To sort in descending order, click on **Sort**

Desc. If a selection is not made, the report will default to include all Investigators. To view specific Subject(s), highlight the Subject ID(s), and then click on the down arrow.

- **Visit Criteria – Visit(s)**
By default all visits are selected. To view specific Visit(s), select the **Visit(s)** by clicking on the appropriate visit(s).
- **Visit Criteria – Collection Date**
Enter a range of **Collection Dates** in DD-MMM-YYYY format in the **FROM** and **TO** fields.
- **Sort By**
The Sort By filter option allows the user to select how the report will be sorted. By default, the report is sorted in ascending order by Investigator, then by Subject ID and chronologically by Visit Name. To change the sort order, click on the down arrow and select the field to sort by. Click the appropriate **Ascending** or **Descending** button to sort the selected field.

Once the filter selections have been made, click on the **Show Report** button to generate the report. Clicking on **Show Report** without making any filter selections will result in generating all laboratory results.

To make any changes to the filter selections that were chosen, use the **Reset** button to reset all of the filter choices that were previously selected. To deselect specific filter choices, use the up arrows to remove the selections, uncheck checked selections, or use the “Ctrl” key and click on the values that you want to deselect.

▪ **Site Activity Report Description**

The Site Activity report generates a summary of the site activity for specific or all sites. When used with filtering, this report allows the user to view activity for specific sites, subjects, visits and/or a range of collection dates. This report will also display if a visit is missed (not received), by displaying Visit Not Received in place of the visit name.

This report includes the following fields, as displayed in Figure M:

- Site #
- Investigator Name
- Subject ID
- Screen ID
- Subject Initials]
- Accession #
- Visit Name
- Collection Date

To sort the report, click on the **Ascending** or **Descending** button and then click a column in the report.

To view a different page on the report, click on the appropriate page number. Page numbers are located at the bottom of the report.

Protocol: ICODEMO | Tests User | Account# User123 |

Your Filter Criteria

Protocol: ICODEMO
 All Sites
 All Subjects

Print • Export

Ascending Descending

Site#	Investigator Name	Subject ID	Screen ID	Subject Initials	Accession #	Visit Name	Collection Date
5842	Bella, Nicole MD	6009	10014	JSJ	B342848	SCREENING	25-FEB-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B352158	BASELINE	16-MAR-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B356048	DAY 7	23-MAR-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B364378	WEEK 4	14-APR-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B373284	WEEK 8	10-MAY-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B383472	WEEK 12	08-JUN-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B391950	WEEK 16	02-JUL-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B400746	WEEK 20	02-AUG-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B409555	WEEK 24	31-AUG-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B418000	WEEK 28	28-SEP-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B427232	WEEK 32	27-OCT-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B436638	WEEK 36	29-NOV-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B444587	WEEK 40	21-DEC-2004
5842	Bella, Nicole MD	6009	10014	JSJ	B453992	WEEK 44	24-JAN-2005
5842	Bella, Nicole MD	6009	10014	JSJ	B462586	WEEK 48	22-FEB-2005
5842	Bella, Nicole MD	6009	10014	JSJ	B471405	WEEK 52	22-MAR-2005
5842	Bella, Nicole MD	6009	10014	JSJ	B481848	WEEK 56	26-APR-2005
5842	Bella, Nicole MD	6009	10014	JSJ	B487025	WEEK 60	12-MAY-2005
5842	Bella, Nicole MD	6009	10014	JSJ	B495286	WEEK 64	06-JUN-2005
5842	Bella, Nicole MD	6009	10014	JSJ	B488949	UNSC/ETERM	19-MAY-2005
5842	Bella, Nicole MD	6017	10010	CLH	B341390	SCREENING	23-FEB-2004
5842	Bella, Nicole MD	6017	10010	CLH	B355307	BASELINE	23-MAR-2004
5842	Bella, Nicole MD	6017	10010	CLH	B358772	DAY 7	30-MAR-2004
5842	Bella, Nicole MD	6017	10010	CLH	B366991	WEEK 4	21-APR-2004
5842	Bella, Nicole MD	6017	10010	CLH	B376528	WEEK 8	18-MAY-2004
5842	Bella, Nicole MD	6017	10010	CLH	B386484	WEEK 12	16-JUN-2004
5842	Bella, Nicole MD	6017	10010	CLH	B394832	WEEK 16	13-JUL-2004
5842	Bella, Nicole MD	6017	10010	CLH	B403334	WEEK 20	10-AUG-2004

Figure M – A Site Activity Report

Hovering Capability

This report has hover capabilities on the following fields:

- Investigator Name – Displays the investigator name, the investigator address and telephone number.
- Site # - Displays the shipping address.
- Subject ID – Displays the subject ID, subject screen ID, subject initials, gender, date of birth and the race code (If applicable).

Drill Down Capability

This report has a drill down capability when clicking on the Accession #. Clicking on this field will generate the General Lab and/or Micro Report associated with the Accession #. (Please refer to the General Lab and Micro Report in Sections 7.9 and 7.10 for report description.)

Print

Clicking on **Print** will generate the Print Preview page of the report. From this screen, clicking on the Printer icon will generate the Print dialog box. The report can also be saved as a PDF document from this screen by clicking on the Save icon.

Export

Clicking on **Export** will open the File Download dialog box. The file can be opened or saved as a Microsoft Excel® comma separated file. If **Open** is chosen, without saving the report, Microsoft Excel® will auto format the report text. To keep the format the same, choose to **Save** the report as a .csv file and then import the .csv file into any spreadsheet application.

Your Filter Criteria

The box entitled Your Filter Criteria contains the filter criteria that were selected when the report generated.

7.7 Specimen Storage Management Status Report

- **Specimen Storage Management Status Report Filter Page**
 - **Site Criteria – Investigator(s)**

By default, all Investigators are listed alphabetically by last name then by first name and credentials. To sort by Investigator Number, click on **List by Number**. The default sort is ascending. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Investigators. To view specific Investigator(s), highlight the Investigator(s) and then click on the down arrow to select the highlighted Investigator(s). Once the Investigator(s) populate in the Selected box, the Site(s) box will populate with the corresponding Site Numbers associated with the selected Investigator(s).
 - **Site Criteria – Site(s)**

The default sort for sites is in ascending alphanumeric order. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Sites. To view a specific Site(s), highlight the Site(s), and then click on the down arrow to select the highlighted Site(s). Once the Site(s) populate in the Selected box, the Investigator(s) box will populate with the corresponding Investigator Numbers associated with the selected Site(s).
 - **Subject Criteria – Subject ID(s)**

By default, all Subject IDs are listed alphabetically by Subject Initials – Subject ID. To sort by Subject ID, click on **List by Number**. The default sort is ascending. To sort in descending order, click on **Sort Desc**. If a selection is not made, the report will default to include all Investigators. To view specific Subject(s), highlight the Subject ID(s), and then click on the down arrow.
 - **Visit Criteria – Visit(s)**

By default all visits are selected. To view specific Visit(s), select the **Visit(s)** by clicking on the appropriate visit(s).
 - **Storage Criteria – Container Names**

By default, all container names are selected. To select and view a specific Container Name(s), click on the appropriate **Container Name**.

➤ **Storage Criteria – Status**

By default, all statuses are selected. To view a specific **Status**, select the **Status** by clicking on the appropriate status.

- **In Storage** – The sample is stored at ICON Laboratories.
- **Shipped Out** – The sample has been shipped out.
- **Transferred Out** – The sample has been transferred out, but ICON expects to store the sample in again.

➤ **Sort By**

The Sort By filter option allows the user to select how the report will be sorted. By default, the report is sorted in ascending order by Investigator, then by Subject ID and chronologically by Visit Name. To change the sort order, click on the down arrow and select the field to sort by. Click the appropriate **Ascending** or **Descending** button to sort the selected field.

Once the filter selections have been made, click on the **Show Report** button to generate the report. Clicking on **Show Report** without making any filter selections will result in generating all Specimen Storage samples.

To make any changes to the filter selections that were chosen, use the **Reset** button to reset all of the filter choices that were previously selected. To deselect specific filter choices, use the up arrows to remove the selections, uncheck checked selections, or use the “Ctrl” key and click on the values that you want to deselect.

▪ **Specimen Storage Management Status Report Description**

The Specimen Storage Management Status report allows the user to view the specimens that are being stored at ICON Laboratories. The user can view all samples that are stored, the type of samples and if or when the samples were shipped. This report includes the following fields, as displayed in Figure N:

- Investigator Name
- Site #
- Subject ID
- Subject Initials
- Accession #
- Visit Name
- Bar Code
- Container Name
- Shipment #
- Current Status
- Ship To
- Transaction Date

To sort the report, click on the **Ascending** or **Descending** button and then click a column in the report.

To view a different page on the report, click on the appropriate page number. Page numbers are located at the bottom of the report.

Specimen Storage Management Status											
Investigator	Site#	Subject ID	Subject Initials	Accession #	Visit Name	Bar Code	Container Name	Shipment #	Current Status	Ship To	Transaction Date
Bella, Nicole MD	5842	6009	JSJ	B352158	BASELINE	04410140026739	P-STR1	1	Shipped Out		16-APR-2004
Bella, Nicole MD	5842	6009	JSJ	B352158	BASELINE	00620140026739	PBMC	2	Shipped Out		24-MAY-2004
Bella, Nicole MD	5842	6009	JSJ	B352158	BASELINE	00640140026739	PLASMA		In Storage		19-MAR-2004
Bella, Nicole MD	5842	6009	JSJ	B352158	BASELINE	00640240026739	PLASMA		In Storage		19-MAR-2004
Bella, Nicole MD	5842	6009	JSJ	B356048	DAY 7	00640140026742	PLASMA		In Storage		26-MAR-2004
Bella, Nicole MD	5842	6009	JSJ	B356048	DAY 7	00640240026742	PLASMA		In Storage		26-MAR-2004
Bella, Nicole MD	5842	6009	JSJ	B364378	WEEK 4	00620140026748	PBMC	2	Shipped Out		24-MAY-2004
Bella, Nicole MD	5842	6009	JSJ	B364378	WEEK 4	04440140026748	PK		In Storage		16-APR-2004
Bella, Nicole MD	5842	6009	JSJ	B364378	WEEK 4	00640240026748	PLASMA		In Storage		16-APR-2004
Bella, Nicole MD	5842	6009	JSJ	B364378	WEEK 4	00640140026748	PLASMA		In Storage		16-APR-2004
Bella, Nicole MD	5842	6009	JSJ	B373284	WEEK 8	00640140121184	PLASMA		In Storage		12-MAY-2004
Bella, Nicole MD	5842	6009	JSJ	B373284	WEEK 8	00640240121184	PLASMA		In Storage		15-JUN-2004
Bella, Nicole MD	5842	6009	JSJ	B383472	WEEK 12	04410140130582	P-STR1	5	Shipped Out		15-JUN-2004
Bella, Nicole MD	5842	6009	JSJ	B383472	WEEK 12	00620140130582	PBMC	7	Shipped Out		25-JUN-2004
Bella, Nicole MD	5842	6009	JSJ	B383472	WEEK 12	04440140130582	PK		In Storage		10-JUN-2004
Bella, Nicole MD	5842	6009	JSJ	B383472	WEEK 12	00640240130582	PLASMA		In Storage		10-JUN-2004
Bella, Nicole MD	5842	6009	JSJ	B383472	WEEK 12	00640140130582	PLASMA		In Storage		10-JUN-2004
Bella, Nicole MD	5842	6009	JSJ	B391950	WEEK 16	00640140146706	PLASMA		In Storage		06-JUL-2004
Bella, Nicole MD	5842	6009	JSJ	B391950	WEEK 16	00640240146706	PLASMA		In Storage		06-JUL-2004
Bella, Nicole MD	5842	6009	JSJ	B400746	WEEK 20	04440140146707	PK		In Storage		04-AUG-2004
Bella, Nicole MD	5842	6009	JSJ	B400746	WEEK 20	00640140146707	PLASMA		In Storage		04-AUG-2004
Bella, Nicole MD	5842	6009	JSJ	B409555	WEEK 24	04410140146708	P-STR1	17	Shipped Out		02-SEP-2004
Bella, Nicole MD	5842	6009	JSJ	B409555	WEEK 24	00620140146708	PBMC	20	Shipped Out		20-SEP-2004
Bella, Nicole MD	5842	6009	JSJ	B409555	WEEK 24	00640240146708	PLASMA		In Storage		02-SEP-2004
Bella, Nicole MD	5842	6009	JSJ	B409555	WEEK 24	00640140146708	PLASMA		In Storage		02-SEP-2004
Bella, Nicole MD	5842	6009	JSJ	B418000	WEEK 28	00640140187230	PLASMA		In Storage		01-OCT-2004
Bella, Nicole MD	5842	6009	JSJ	B418000	WEEK 28	00640240187230	PLASMA		In Storage		01-OCT-2004
Bella, Nicole MD	5842	6009	JSJ	B427232	WEEK 32	00640140190459	PLASMA		In Storage		29-OCT-2004
Bella, Nicole MD	5842	6009	JSJ	B427232	WEEK 32	00640240190459	PLASMA		In Storage		29-OCT-2004
Bella, Nicole MD	5842	6009	JSJ	B436638	WEEK 36	04410140190460	P-STR1	29	Shipped Out		06-DEC-2004
Bella, Nicole MD	5842	6009	JSJ	B436638	WEEK 36	00620140190460	PBMC	34	Shipped Out		21-JAN-2005
Bella, Nicole MD	5842	6009	JSJ	B436638	WEEK 36	00640140190460	PLASMA		In Storage		01-DEC-2004
Bella, Nicole MD	5842	6009	JSJ	B436638	WEEK 36	00640240190460	PLASMA		In Storage		01-DEC-2004
Bella, Nicole MD	5842	6009	JSJ	B444587	WEEK 40	00640140222358	PLASMA		In Storage		23-DEC-2004

Figure N – A Specimen Storage Management Report

Hovering Capability

This report has hover capabilities on the following fields:

- Investigator Name – Displays the investigator name, the investigator address and telephone number.
- Site # - Displays the shipping address.
- Subject ID – Displays the subject ID, subject screen ID, subject initials, gender, date of birth and the race code (If applicable).

Print

Clicking on **Print** will generate the Print Preview page of the report. From this screen, clicking on the Printer icon will generate the Print dialog box. The report can also be saved as a PDF document from this screen by clicking on the Save icon.

Export

Clicking on **Export** will open the File Download dialog box. The file can be opened or saved as a Microsoft Excel® comma separated file. If **Open** is chosen, without saving the report, Microsoft Excel® will auto format the report text. To keep the format the same, choose to **Save** the report as a .csv file and then import the .csv file into any spreadsheet application.

Your Filter Criteria

The box entitled Your Filter Criteria contains the filter criteria that were selected when the report generated.

7.8 Kit Inventory Report

▪ **Kit Inventory Report Filter Page**

➤ **Site Criteria – Investigator(s)**

By default, all Investigators are listed alphabetically by last name then by first name and credentials. To sort by Investigator Number, click on **List by Number**. The default sort is ascending. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Investigators. To view specific Investigator(s), highlight the Investigator(s) and then click on the down arrow to select the highlighted Investigator(s). Once the Investigator(s) populate in the Selected box, the Site(s) box will populate with the corresponding Site Numbers associated with the selected Investigator(s).

➤ **Site Criteria – Site(s)**

The default sort for sites is in ascending alphanumeric order. To sort in descending order, click on **Sort Desc**. If a specific selection is not made, the report will default to include all Sites. To view a specific Site(s), highlight the Site(s), and then click on the down arrow to select the highlighted Site(s). Once the Site(s) populate in the Selected box, the Investigator(s) box will populate with the corresponding Investigator Numbers associated with the selected Site(s).

➤ **Sort By**

The Sort By filter option allows the user to select how the report will be sorted. By default, the report is sorted in ascending order by Investigator, then by Visit Type. To change the sort order, click on the down arrow and select the field to sort by. Click the appropriate **Ascending** or **Descending** button to sort the selected field.

Once the filter selections have been made, click on the **Show Report** button to generate the report. Clicking on **Show Report** without making any filter selections will result in generating an all-site kit inventory.

To make any changes to the filter selections that were chosen, use the **Reset** button to reset all of the filter choices that were previously selected. To deselect specific filter choices, use the up arrows to remove the selections.

▪ **Kit Inventory Report Description**

The Kit Inventory report allows the user to view the inventory of all kits for all or specific sites. The user will be able to determine the number of visit-

specific kits available at each investigator site. This report also has a drill down capability to view the **Kit Inventory Detail** report that lists the kits and their expiration date.

This report includes the following fields, as displayed in Figure O:

- Investigator Name
- Site #
- Kit Type
- Total Sent
- Total Returned to ICON Central Laboratories
- Total Expired
- Total Expiring in 0 – 30 Days
- Total Expiring in 31 to 60 days
- Total Available

NOTE: Statistics provided on the Kit Inventory Report are based upon ICON Laboratories' records of kits sent to and received from each investigator site. Please note that a number of factors can affect the accuracy of the information provided on this report, including:

- Use of kits by site personnel to obtain replacement supplies, thereby rendering the kit unusable;
- Site use of the wrong kit for a visit;
- Site use of kits for testing outside the protocol;
- Kits damaged or lost in shipping;
- Kits destroyed/discarded on site for any reason;
- If a protocol is configured to receive GenKits, the report will display Total Sent, however, it will not calculate Total Returned, and therefore Total Available will not be accurate. Please contact your ICON Project Manager for this information.

To sort the report, click on the **Ascending** or **Descending** button and then click a column in the report.

To view a different page on the report, click on the appropriate page number. Page numbers are located at the bottom of the report.

Protocol: ICODEMO Tests User Account# User123								
Your Filter Criteria								
Protocol: ICODEMO								
All Sites								
All Investigators								
Kit Inventory Summary								
Print • Export								
<input checked="" type="radio"/> Ascending <input type="radio"/> Descending								
Investigator Name	Site#	KitType	Total Sent	Total Returned to ICON Labs	Total Expired	Total Expiring in 0-30 days	Total Expiring in 31-60 days	Total Available
Smith, Robert MD	12376	SCREENING	5	1	4	0	0	0
Smith, Robert MD	12376	BASELINE	4	1	3	0	0	0
Smith, Robert MD	12376	DAY 7	4	1	3	0	0	0
Smith, Robert MD	12376	WEEK 4	4	1	3	0	0	0
Smith, Robert MD	12376	WEEK 8	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 12	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 16	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 20	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 24	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 28	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 32	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 36	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 40	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 44	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 48	1	1	0	0	0	0
Smith, Robert MD	12376	WEEK 52	1	0	1	0	0	0
Smith, Robert MD	12376	WEEK 56	1	0	1	0	0	0
Smith, Robert MD	12376	WEEK 60	1	0	1	0	0	0
Smith, Robert MD	12376	WEEK 64	1	0	1	0	0	0
Smith, Robert MD	12376	UNSC/ETERM	5	0	5	0	0	0
Site Total	12376		37	15	22	0	0	0
Correa, Gerald MD	13006	SCREENING	8	3	5	0	0	0
Correa, Gerald MD	13006	BASELINE	7	3	4	0	0	0
Correa, Gerald MD	13006	DAY 7	6	3	3	0	0	0
Correa, Gerald MD	13006	WEEK 4	6	3	3	0	0	0
Correa, Gerald MD	13006	WEEK 8	6	3	3	0	0	0

Figure O - A Kit Inventory Report

Hovering Capability

This report has hover capabilities on the following fields:

- Investigator Name – Displays the investigator name, the investigator address and telephone number.
- Site # - Displays the shipping address.

Drill Down Capability

This report has a drill down capability to view the Kit Inventory Detail report. This report lists the Kit Type, Lab Code and Expiration Date. Clicking on a clickable cell that contains a numeric value will generate the Kit Inventory Detail report. For example, clicking on a cell for Site # 123, Visit 1, and Total Expired cell will generate the Kit Inventory Detail report listing all expired Visit 1 kits for that specific site. (Figure M)

The screenshot displays two windows from the ICODEMO software. The left window shows the 'Kit Inventory Summary' table with columns for Investigator Name, Site#, KitType, Total Sent, Total Returned to ICON Labs, Total Expired, and Total. The right window shows the 'Kit Inventory Detail' report for a specific kit, listing Kit Type, Lab Code, and Expiration Date. A red arrow points from a cell in the summary table to the detail report.

Investigator Name	Site#	KitType	Total Sent	Total Returned to ICON Labs	Total Expired	Total
Smith, Robert MD	12376	SCREENING	5	1	4	0
Smith, Robert MD	12376	BASELINE	4	1	3	0
Smith, Robert MD	12376	DAY 7	4	1	3	0
Smith, Robert MD	12376	WEEK 4	4	1	3	0
Smith, Robert MD	12376	WEEK 8	1	1	0	0
Smith, Robert MD	12376	WEEK 12	1	1	0	0
Smith, Robert MD	12376	WEEK 16	1	1	0	0
Smith, Robert MD	12376	WEEK 20	1	1	0	0
Smith, Robert MD	12376	WEEK 24	1	1	0	0
Smith, Robert MD	12376	WEEK 28	1	1	0	0
Smith, Robert MD	12376	WEEK 32	1	1	0	0
Smith, Robert MD	12376	WEEK 36	1	1	0	0
Smith, Robert MD	12376	WEEK 40	1	1	0	0
Smith, Robert MD	12376	WEEK 44	1	1	0	0
Smith, Robert MD	12376	WEEK 48	1	1	0	0
Smith, Robert MD	12376	WEEK 52	1	0	0	0
Smith, Robert MD	12376	WEEK 56	1	0	0	0
Smith, Robert MD	12376	WEEK 60	1	0	0	0
Smith, Robert MD	12376	WEEK 64	1	0	1	0
Smith, Robert MD	12376	UNSCITEERM	5	0	5	0
Site Total	12376		37	15	22	0

Figure P – Clicking on a Cell Produces A Kit Inventory Detail Report

Print

Clicking on **Print** will generate the Print Preview page of the report. From this screen, clicking on the Printer icon will generate the Print dialog box. The report can also be saved as a PDF document from this screen by clicking on the Save icon.

Export

Clicking on **Export** will open the File Download dialog box. The file can be opened or saved as a Microsoft Excel® comma separated file. If **Open** is chosen, without saving the report, Microsoft Excel® will auto format the report text. To keep the format the same, choose to **Save** the report as a .csv file and then import the .csv file into any spreadsheet application.

Your Filter Criteria

The box entitled Your Filter Criteria contains the filter criteria that were selected when the report generated.

7.9 General Laboratory Report

The General Laboratory Report (Figure P) can be accessed through standard reports containing the Accession # field (with the exception of the Specimen Storage Management report). The General Lab Report contains data that are formatted to resemble the actual Lab Report that is faxed to the sites from ICON Central Laboratories. This report is not intended to replace the actual lab report, but rather to display data in the same format as the Lab Report received by the site.

Displaying and/or Printing General Laboratory Reports

When displaying or printing a General Laboratory Report that contains Test comments, this information will appear under the associated test result. If a

General Laboratory Report contains Additional Information (Visit and/or Container specific), this information will appear after all of the Test Results under the heading of “Additional Information”.

NOTE: Clicking on Accession # will generate the associated General and / or Microbiology report(s) with the exception of the New/Amended Laboratory Report that has one column for General Lab report and one for the Microbiology report.

The following standard reports contain drill down capability to the General Laboratory Report:

- New/Amended Laboratory Report
- Selected Laboratory Results
- Site Activity

If the user chooses to, this report can be marked as reviewed by clicking on **Click Here to Mark Report as Reviewed**. When clicked, a message will appear indicating that the Accession # has been reviewed. To continue, click **OK**. This action will close the report window and mark the report as "reviewed". If the report was previously marked as "reviewed," the **Click Here to Mark Report as Reviewed** option will not display.

ICON
A Symbol of Excellence
Central Laboratories

123 Smith Street
Farmingdale, NY 11735
Tel: 631.777.8833
Fax: 631.777.8842

South County Business Park
Leopardstown, Dublin 18
Tel: 353.1.218.1100
Fax: 353.1.218.1201

PROTOCOL # ICODEMO
SUBJECT VISIT # SCREENING

[Click Here to Mark Report as Reviewed](#)

SITE #	INVT	INV TEL#	INV FAX#	COLLECTION DATE/TIME	RECEIVED DATE/TIME	REPORT DATE/TIME
30402	30402	(305) 555-5621	(305) 555-3005	28-APR-2004 10:45:00	29-APR-2004 13:43:05	04-MAY-2004 10:43:00

**I
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Stevens, Paul MD
University Of Miami School Of Medicine
Infectious Diseases Clinical Research
200 NW 8th FL WW, Miami FL 33136

S U B J E C T

#	INITIALS	SEX	BIRTHDATE
6081	ALC	M	21-OCT-1942

ACCESSION #	LABORATORY #	SCREEN #
B369475	40097363	10106

LAB USE ONLY

[Click to Mark Report as Reviewed](#)

Comments
*AMENDED REPORT*CHG PT GENDER FROM FEMALE TO MALE PER SANDRA MERCADO AT SITE*

LABORATORY REPORT Page 1 of 3

TEST NAME	RESULT	FLAGS	ABNORMAL	UNITS	REFERENCE RANGE
---CHEMISTRY---					
ALBUMIN	4.3			g/dL	3.7 - 4.9
ALKALINE PHOSPHATASE	94			U/L	40 - 135
ALT	17			U/L	0 - 47
AMYLASE		H	108	U/L	28 - 100
AST	25			U/L	0 - 37
BICARBONATE	26			mEq/L	20 - 31
CALCIUM	9.1			mg/dL	8.5 - 10.2
CHLORIDE	104			mEq/L	95 - 113
CHOLESTEROL, TOTAL	162			mg/dL	0 - 199
CREATININE	0.9			mg/dL	.6 - 1.4
GLUCOSE, FASTING, SERUM	77			mg/dL	70 - 112
HDL - CHOLESTEROL		L	32	mg/dL	GREATER OR = 40
LDH	234			U/L	110 - 250
LDL-CHOLESTEROL		H	102	mg/dL	LESS THAN 100
LDL/HDL		H	3.19	RATIO	LESS THAN 3.0
MAGNESIUM	1.5			mEq/L	1.4 - 2.1
PHOSPHATE	5.7			mg/dL	2.4 - 4.5
POTASSIUM	4.3			mEq/L	3.5 - 5.2
SODIUM	140			mEq/L	134 - 146
TOTAL BILIRUBIN	0.3			mg/dL	0 - 1.1
TOTAL PROTEIN		H	8.3	g/dL	6.1 - 7.9
TRIGLYCERIDES		H	179	mg/dL	LESS THAN 150
UREA (BUN)	15			mg/dL	9 - 24
URIC ACID	8.3	G1		mg/dL	3.1 - 8.8
---FLOW CYTOMETRY---					
CD-3 %	75			%	58 - 84
CD-3 ABS	1475			cells/uL	594 - 1992
CD-3/4 %		L	1	%	29 - 59
CD-3/4 ABS		L	10	cells/uL	356 - 1351
CD-3/8 %		H	71	%	19 - 48
CD-3/8 ABS		H	1401	cells/uL	282 - 999
CD-4/8 RATIO		L	0.0	RATIO	.6 - 3
CD3/16+56 %	12			%	7 - 34
CD3/16+56 ABS	239			cells/uL	102 - 511
CD3/19 %	16			%	7 - 23
CD3/19 ABS	309			cells/uL	109 - 532
---HEMATOLOGY---					
ABS BASOPHILS	0.08			x10 ⁹ /L	0 - .2

Figure P – Example General Laboratory Report

7.10 Microbiology Laboratory Report

The **Microbiology Laboratory Report** (Figure Q) can be accessed through standard reports containing the **Accession #** field. The **Microbiology Report** contains data that are formatted to resemble the actual Microbiology Report that is faxed to the sites from ICON Central Laboratories. This report is not intended to replace the actual microbiology report, but rather to display data in the same format as the Lab Report received by the site.

NOTE: Clicking on **Accession #** will generate the associated **General and / or Microbiology report(s)** with the exception of the **New/Amended Laboratory Report** which has one column for **General Lab report** and one for the **Microbiology report**.

The following standard reports contain drill down capability to the **Microbiology Report**:

- New/Amended Laboratory Report
- Selected Laboratory Results
- Site Activity

If the user chooses to, this report can be marked as reviewed by clicking on **Click Here to Mark Report as Reviewed**. When clicked, a message will appear indicating that the Accession # has been reviewed. To continue, click **OK**. This action will close the report window and mark the report as “reviewed”. If the report was previously marked as “reviewed,” the **Click Here to Mark Report as Reviewed** option will not display.


		123 Smith Street Farmingdale, NY 11735 Tel: 631.777.8933 Fax: 631.777.8942	South County Business Park Leopardstown, Dublin 18 Tel: 353.1.216.1100 Fax: 353.1.216.1201	PROTOCOL # ICODEMO SUBJECT VISIT # SCREENING																																		
Click Here to Mark Report as Reviewed																																						
<table border="1"> <tr> <th>SITE #</th> <th>INVT #</th> <th>INV TELE</th> <th>INV FAX#</th> <th>COLLECTION DATE/TIME</th> <th>RECEIVED DATE/TIME</th> <th>REPORT DATE/TIME</th> </tr> <tr> <td>30402</td> <td>30402</td> <td>(305) 555-5621</td> <td>(305) 555-3005</td> <td>28-APR-2004 10:43:00</td> <td>29-APR-2004 13:43:05</td> <td>05-MAY-2004 13:31:06</td> </tr> </table>	SITE #	INVT #	INV TELE	INV FAX#	COLLECTION DATE/TIME	RECEIVED DATE/TIME	REPORT DATE/TIME	30402	30402	(305) 555-5621	(305) 555-3005	28-APR-2004 10:43:00	29-APR-2004 13:43:05	05-MAY-2004 13:31:06	<table border="1"> <tr> <th colspan="4">S U B J E C T</th> </tr> <tr> <td>#</td> <td>INITIALS</td> <td>SEX</td> <td>BIRTHDATE</td> </tr> <tr> <td>6081</td> <td>ALC</td> <td>M</td> <td>21-OCT-1942</td> </tr> <tr> <td>ACCESSION #</td> <td>LABORATORY #</td> <td colspan="2">SCREEN #</td> </tr> <tr> <td>B369475</td> <td>40097363</td> <td colspan="2">10106</td> </tr> </table>		S U B J E C T				#	INITIALS	SEX	BIRTHDATE	6081	ALC	M	21-OCT-1942	ACCESSION #	LABORATORY #	SCREEN #		B369475	40097363	10106		LAB USE ONLY	
SITE #	INVT #	INV TELE	INV FAX#	COLLECTION DATE/TIME	RECEIVED DATE/TIME	REPORT DATE/TIME																																
30402	30402	(305) 555-5621	(305) 555-3005	28-APR-2004 10:43:00	29-APR-2004 13:43:05	05-MAY-2004 13:31:06																																
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ACCESSION #	LABORATORY #	SCREEN #																																				
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INVESTIGATOR Stevens, Paul MD University Of Miami School Of Medicine Infectious Diseases Clinical Research 200 NW 5th FL WW, Miami FL 33136																																						
Comments																																						
Page 1 of 2																																						
MICRO REPORT																																						
HIV GENOTYPE SPECIMEN NUMBER: 0403498 SPECIMEN SETUP: 04-May-2004 10:45:54 CULTURE SOURCE: PLASMA REPORT STATUS: FINAL																																						
Relevant RT Mutations NO RELEVANT MUTATIONS DETECTED.																																						
NUCLEO RT INHIB RESISTANCE INTERPRETATION																																						
zidovudine No Evidence of Resistance																																						
didanosine No Evidence of Resistance																																						
zalcitabine No Evidence of Resistance																																						
lamivudine No Evidence of Resistance																																						
stavudine No Evidence of Resistance																																						
abacavir No Evidence of Resistance																																						
tenofovir No Evidence of Resistance																																						
NonNUCL RT INHIB RESISTANCE INTERPRETATION																																						
nevirapine No Evidence of Resistance																																						
delavirdine No Evidence of Resistance																																						
efavirenz No Evidence of Resistance																																						
Relevant Protease Mutations																																						
LOP																																						
PROTEASE INHIB RESISTANCE INTERPRETATION																																						
zalcitabine No Evidence of Resistance																																						
didanosine No Evidence of Resistance																																						
zidovudine No Evidence of Resistance																																						
lamivudine No Evidence of Resistance																																						
stavudine No Evidence of Resistance																																						
abacavir No Evidence of Resistance																																						
didanosine No Evidence of Resistance																																						
zidovudine No Evidence of Resistance																																						
zalcitabine Insufficient Evidence																																						
COMMENT: TRUGENE HIV Resistance Report sent under separate cover via fax. Test Method: Bayer TruGene HIV-1 Assay Results obtained with different assay methods should not be used interchangeably.																																						

Figure Q –Example of a Microbiology Report

7.11 Sample Inventory Management Reports (SIMS)

What is SIMS?

- SIMS is an interactive reporting module in ICOLabs for use by Sponsors and study teams.
- SIMS provides near real-time, high-level traceability of all patient samples in a clinical trial (utilizing ICON barcodes) as they move from accessioning through disposition.
- SIMS provides detailed sample inventory reports and graph/table based summaries of sample status and location with drill down capabilities.

ICOLabs Website Link


<https://rda-fed.ICOLabs.com/iconstudyreporter/>

What are the benefits of SIMS?

- SIMS proprietary design enables rapid insight into specimen status and location for all samples managed by ICON. This includes a unique mechanism to provide visibility of specimens assumed to be at sites and third party laboratories.
- SIMS data will help to locate samples more rapidly, in particular at critical study junctures like interim analysis and database lock.
- SIMS provides valuable information for monitoring result status. Use cases include monitoring samples required for enrolment purposes and samples tested at third party laboratories.

1. Report Navigation

When logged into ICOLabs, select the protocol to review from the drop down list.



Select the SIMS Report from the Standard Reports menu.

1 Site ID(s)
Sort Desc

0001
0521
0522
4400
4423
7002

Selected

2 Subject Number(s)
Sort Desc

0001 -
0201 -
0201 -
0202 -
0231 -
0231 -
0324 -
0324 -

Selected

3 Visit Name(s)
Sort Desc

DAY 1
OUT OF PROTOCOL
PT Prem Disc
PT WK104
PT WK12
PT WK156
PT WK24
PT WK260

Selected

4 Sample Name(s)
Sort Desc

ALTARCH
CHEM
HCV/CAPLOG
HCV/CAPTAQ
HCV/SUBTYPE
HEMO
Req

5 Sample Type(s)
Sort Desc

Plasma EDTA K2
Serum
Serum w/Gel
Whole Blood

6 Site Country(s)
Sort Desc

USA

7 Primary Location(s)
Sort Desc

Farmingdale

include for All Users

8

9

10

Show Referral Lab samples
 Show Third Party samples
 Show Assumed to be At Site samples

– There are 10 different filter criteria categories to choose from.

– If no filter is selected, the report will generate all data for the selected study.

– **Click Show Report to load your samples**

2. Report Features

1. Sample Inventory Log/Raw Data

Report Detail:

- Complete listing of all samples that exist/existed for the selected study, with chain of custody information on each sample, including the current status and location.
- Data columns will populate where applicable for each sample. Users also have options to search and filter for specific values within each category in the report.

2. Five Summary Reports

- A. Summary of Current Samples
- B. Summary of Total Study
- C. Summary by Sample Name
- D. Summary by Site & Country
- E. Summary for Receipt Status

Report Detail: The report detail for each summary report is located under the report heading. Please see example below for the Summary of Current Samples Report.

SUMMARY OF CURRENT SAMPLES

- **Report Detail:** Quantity of samples currently available for the study e.g. samples in testing, in storage, assumed to be at site.; Sorted by sample location.
- Please take study configuration into account when reviewing this report e.g some samples may appear counted in two categories if the sample has both storage and testing services set up as part of your study.

3. Summary Reports Details

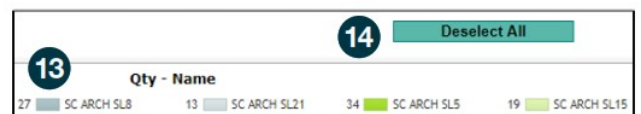
Each Summary Report takes the data from the Sample Inventory Log and summarizes it in different ways. The data is then displayed as follows:

- 11** In the form of an interactive bar chart with hover-over data point information and drill down capabilities.
- 12** In table form with drill down capabilities underneath the chart.



12 Chart Data		
Sample Location - Status	# Of Samples	# Of Samples on Hold
ICON Farmingdale Pending Results From - Testing	44	105
Assumed to be at Site	48	0
Total Samples	92	105

- 13** The legend is also interactive and allows users to remove a specific sample type from the bar chart by clicking on the box beside that sample name e.g. 'SC Arch SL8'.
- 14** Users may also choose to Deselect All groups from the legend if they wish to build their own bar chart from scratch.



4. Important Reminders/Tips

- ☆ All Sponsors must sign our ICOLabs Set-up Worksheet if they wish to have access to SIMS at a study level. Subject demographics are blinded by default in SIMS, but the Sponsor has the option to unblind this information at a user level if required within the ICOLabs Set-up Worksheet.
- ☆ For scenarios when no component of a visit is received at ICL, e.g. if the entire visit is shipped directly from site to Third Party Lab, there is the option to set up visits with virtual accessioning for visibility purposes so that these samples are included in the SIMS report.
- ☆ **Downloading vs Exporting Capabilities**
 - When a user clicks Download Report, all Sample Inventory Reports and graphs will download and export to Excel, based on the selected filter criteria.
 - When a user clicks Export, only the selected single report will export to Excel.
- ☆ Please note that some assumptions are made with this data e.g. samples assumed to be at site. Also note scenarios where no assumptions can be made e.g. if a visit is missed/skipped/not collected at all.

8.0 Custom Searches

ICOLabs has the capability to save a standard report applying user's filter selections. Once a user selects a standard report and applies filter criteria to the report, the report generates. Once the report has generated, the filter page for the report will enable the "Save Filter as Custom Search" field (Figure R). To save the search criteria, enter the desired name of the report and click on "Save Filter as Custom Search". The custom search will save and can be accessed in the Custom Search drop down bar.

Please note the following about Custom Searches:

- Custom Searches only save the filter criteria of a standard report, not the actual report data.
- There is no limit to the number of Custom Searches that can be saved.
- Custom Searches must have a unique name. If a duplicate name is entered, the user will be prompted to select a different name.
- Custom Searches can be renamed or deleted from the Manage Custom Searches screen.
- Custom Search names can be added as part of the title name for those reports that are generated from the saved custom searches.

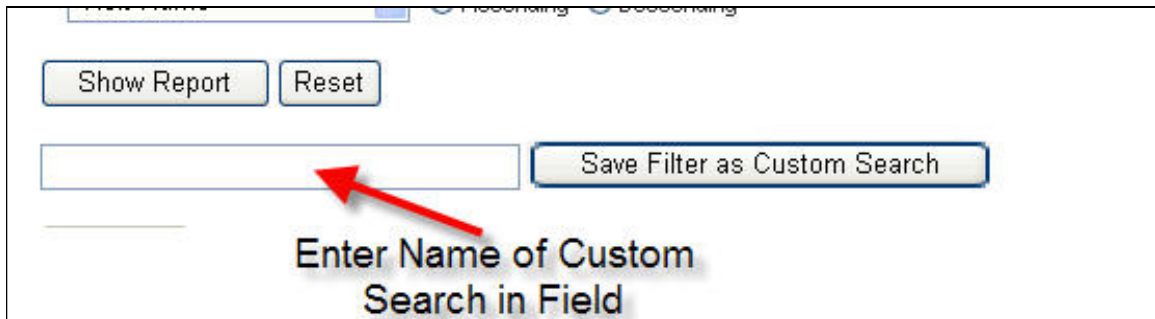


Figure R – Saving A Custom Search

9.0 Manage Profile

Users have the ability to customize their ICONtrol Panel and change their password through the Manage Profile screen (Figure S). To access this screen, click on the **Manage Profile** link.

To change the password, click on the **Change User Password** button. If this is selected, the Password Change screen will appear. Enter the new password twice and click on **Update Password**.

To configure **Favorite Reports**;

1. In the Favorites section a custom search can be set as a favorite report by choosing the custom search from the drop down bar.
2. Up to 5 custom searches can be set up as **Favorite Reports**. The number located next to the Favorite Search represents the order of the reports appearing on the ICONtrol Panel from left to right.
3. Once satisfied with the selection(s), click on **Save Changes** to update the Favorite Reports.

To configure **Key Indicators**:

1. The user can set Key Indicators by selecting the **Key Indicators** from the drop down bars.
2. Up to four Key Indicators can be selected. The number located next to the Key Indicator represents the order in which the Key Indicators appear on the ICONtrol Panel, from top to bottom.
3. Once satisfied with the selection(s), click on **Save Changes** to update the Key Indicators.

The screenshot displays the 'User Maintenance' interface for 'User : Tests User'. It includes a 'Change User Password' button, a 'Save Changes' button, and two sections: 'FAVORITES' and 'KEY INDICATORS'. The 'FAVORITES' section lists five custom searches with dropdown menus for selection. The 'KEY INDICATORS' section lists four indicators with dropdown menus for selection. Red arrows and text annotations highlight the 'Change User Password' button, the 'Save Changes' button, and the dropdown menus for selecting favorite reports and key indicators.

Figure S – Changing the User Profile

10.0 Manage Custom Searches

The Manage Custom Searches screen (Figure T) allows the user to rename, delete and/or change the order of their Custom Search listing. To access this screen, select a protocol and click on the **Manage Custom Searches** link. The screen will populate with the list of Custom Searches that the user has created for the selected protocol.

To change the order of the Custom Search listing, click on **Custom Search** and use the arrows to move the Custom Searches up or down.

To rename a Custom Search, click on specific Custom Search to be renamed, and then type the new desired name of the Custom Report in the space above the **Save Rename** button. Once satisfied with the Custom Search name, click on the **Save Rename** button.

To delete a Custom Search, click on the specific Custom Search to be deleted and then click on the **Delete** button.

Once all changes have been made, click on **Close** button to return to the Home Page.

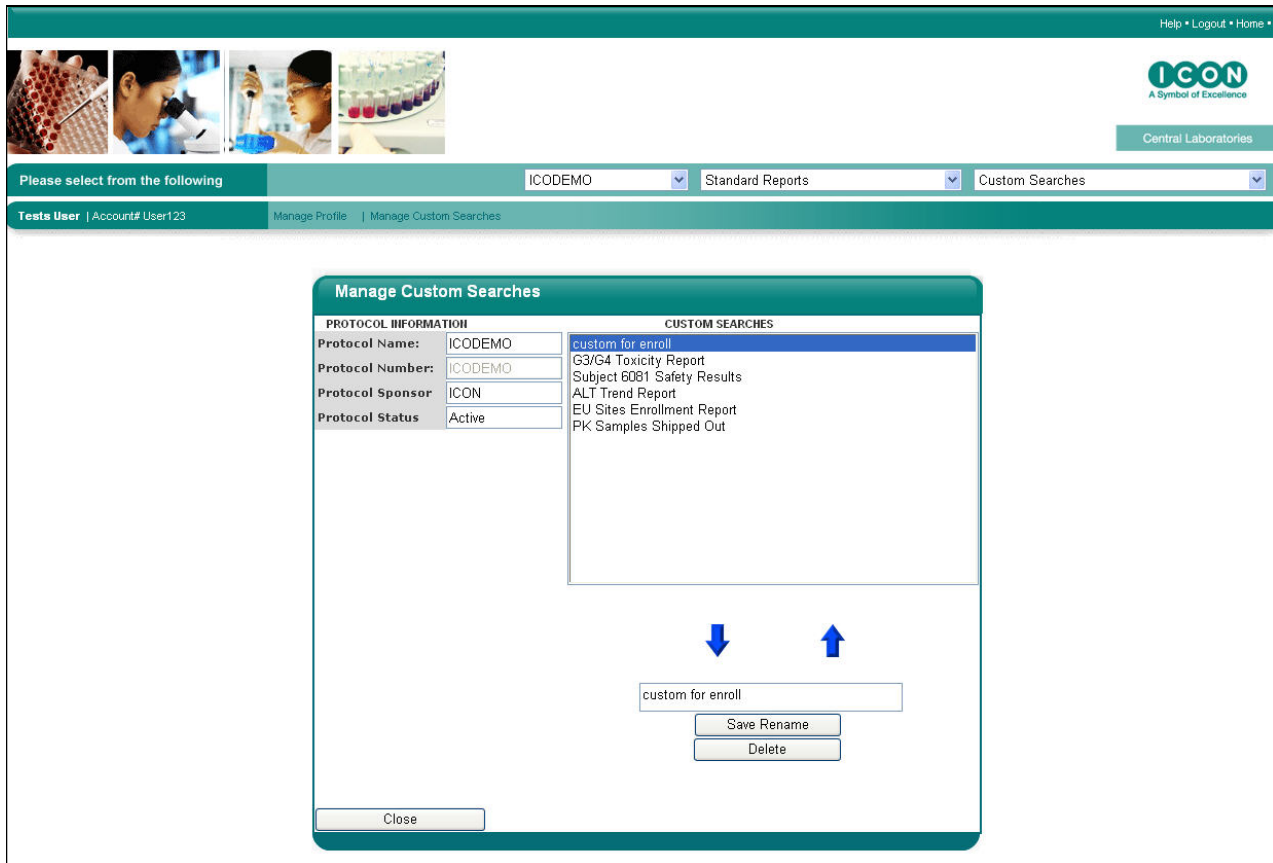


Figure T – Modifying and Deleting Custom Searches

11.0 ICONtroll Panel

The ICONtroll Panel (Figure B) is a customizable home page that allows the user to have quick and easy access to the most pertinent study data for each assigned protocol.

The ICONtroll Panel consists of five favorite reports, four key indicators, and the list of standard reports.

11.1 Favorite Reports

Favorite Reports are Custom Searches that the user has defined through the Manage Profile feature. To set up the Favorite Reports:

1. Choose the protocol from the protocol drop down bar.
2. Click on the **Manage Profile** link.
3. In the Favorites section a custom search can be set as a favorite report by choosing the custom search from the drop down bar.
4. Up to 5 custom searches can be set up as Favorite Reports. The number located next to the Favorite Search represents the order of the reports appearing on the ICONtroll Panel from left to right.
5. Once selections have been made, click on **Save Changes** to update the Favorite Reports and then click on **Home** to return to the ICONtroll Panel.

11.2 Key Indicators

Key Indicators provide summary information for a specific protocol. The user can choose up to four **Key Indicators** to display on the ICONtroll Panel. The user can choose their Key Indicators from the Manage Profile page. The following are the Key Indicators that are available:

- **Total Number of Abnormal Results** – This Key Indicator will display the total number of Abnormal results for the entire study population.
- **Total Number of Active Sites** – This Key Indicator will display the total number of active sites. A site is considered “active” when ICON Central Laboratories has received specimens for at least one subject visit.
- **Total Number of Delta Values** – This Key Indicator will display the total number of results that have a Delta Flag. (If applicable to protocol)
- **Total Number of Exclusions** – This Key Indicator will display the total number of results that have been flagged as exclusions. (If applicable to protocol)
- **Total Number of New/Amended Laboratory Reports** – This Key Indicator will display the number of New/Amended Laboratory reports that are in the queue awaiting review.
- **Total Number of Newly Activated Sites in the Past 7 Days** – This Key Indicator will display the number of sites that have their first subject visit within 7 days.
- **Total Number of Panic Values** – This Key Indicator will display the number of results that have a panic result flag. (If applicable to protocol)

- **Total Number of Subjects Enrolled** – This Key Indicator will display the number of Subjects that have been enrolled. This number is based on the number of subjects that have had the visit that is specified as the enrollment visit as per the ICOLabs CLW. (If applicable to protocol)
- **Total Number of Subjects Screened** - This Key Indicator will display the number of study subjects that have been screened. This number is based on the number of subjects that have completed the visit that is specified as the “screening visit,” per the ICOLabs CLW. (If applicable to protocol)

To select the Key Indicators:

1. Choose the protocol from the protocol drop down bar.
2. Click on the **Manage Profile** link.
3. Set the Key Indicators by selecting the specific **Key Indicators** from the drop down bars.
4. Up to four **Key Indicators** can be selected. The number located next to Indicator, represents the order of the **Key Indicators** appearing on the ICONtrol Panel, from left to right.
5. Once selections have been made, click on “Save Changes” to update the **Key Indicators** and then click on **Home** to return to the ICONtrol Panel.

12.0 Frequently Asked Questions

Q: How do I get an ICOLabs account?

A: Please contact your ICON Laboratories Project Manager to request access.

Q: Do I need to download any applications to my PC?

A: No. ICOLabs was designed to be completely web based. Consequently, the only requirement is the ability to access the Internet. However, in order to export reports, Microsoft Excel® must be installed since the export is in Microsoft Excel® format.

Q: How can I view subject results?

A: Subject results can be viewed in many different formats using the standard reports. To generate one of the standard reports, choose the report from the Standard Report drop down bar or from the ICONtrol Panel.

Q: I logged into ICOLabs, but everything is disabled. What's wrong?

A: If your account is assigned to more than one protocol, then you must select the protocol to work with from the Select Protocol. Once a protocol has been selected, then the ICONtrol Panel will become enabled.

Q: How can I review new data?

A: New data can be reviewed by generating the New/Amended Laboratory Report report, or by using the Selected Laboratory Results report and selecting "Not Reviewed" on the report filter page.

Q: How can I change my Favorite Reports and Key Indicators?

A: Favorite Reports and Key Indicators can be changed in the Manage Profile screen. To access this screen, click on the **Manage Profile** link.

Q: I created a custom search and would like other users on my team to use this report. How can I do that?

A: Your ICON Central Laboratories RDAS Specialist can create a custom search that is available to all users. Please contact the RDAS Specialist to discuss the report that you would like created for team-wide access.

Q: How can I change my password?

A: Passwords can be changed from the Manage Profile screen. To access this screen, click on the Manage Profile link and select "Change Password". You will be prompted to change your password.

Q: What does LOCKED mean in my reports?

A: When a subject visit is received with missing or discrepant demographic or collection information, ICON Central Laboratories "locks" the visit. This action prevents reporting to the site and inclusion of the questionable data in data transmissions to the client until there is resolution to the missing or discrepant information. All testing is performed as usual, unless the missing information prevents the proper testing from being performed. In addition, any panic, exclusion, and other client-defined abnormal values requiring site notification are called to the site as usual and without delay. However, no lab report is faxed or mailed to the site until the missing or discrepant information is resolved.

Q: How can I contact support?

A: ICOLabs Support can be contacted via email at ICOLabsSupport.Support@iconplc.com or by phone Telephone: + (1) 919-674-5474

Q: I forgot my password and/or my account is locked, who do I contact to unlock it?

A: Contact ICOLabs support via email at ICOLabsSupport.Support@iconplc.com or by phone Telephone: + (1) 919-674-5474

Find a toll free number for your location:

Argentina	0-800-222-2602
Australia	1800881823
Austria	0800-295306
Belgium	0-800-74-152
Brazil	8008921061
Chile	1230-020-4346
China - North	10-800-713-1446
China - South	10-800-1301-406
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