MATRIX GEMINI LIMS AT WORK IN CANCER RESEARCH TRIALS

Executive Summary

The Roy Castle Lung Cancer Foundation (RCLCF) is a UK wide charity, dedicated to the defeat of lung cancer. It funds basic science research, tobacco control initiatives and work in lung cancer patient information, support and advocacy. RCLCF works towards defeating lung cancer through research, campaigning and education and gives practical and emotional support for patients and all those affected by lung cancer and smoking. It also enables children and young people to make informed decisions about smoking and the tobacco industry.

RCLCF funds a programme of research into the early detection of lung cancer. One of these projects is the Liverpool Lung Project which is a study researching the early diagnosis of lung cancer. The main aim of this research programme is to identify people who are at especially high risk of developing lung cancer by using molecular genetics technologies and epidemiology. The research team is led by Professor John Field.

Professor John Field

Background

Clinical trial research facilities like RCLCF and computer systems that involve the storage of Human Tissue Samples need to be compliant with the Human Tissue Act (2006). The competent auditing authority is the MHRA and the relevant statutes are the EU Clinical Trials Directive (20001/20/EC and 2005/28/EC) and subsequent UK laws (statutory Instrument 1031, 1928, 2984 and 2031) covering the conduct of clinical trials in accordance with Good Clinical Laboratory Practice (GCLP). Compliance with GCLP guidelines allows clinical laboratories to ensure the safety and efficacy of data and that it is repeatable, reliable, auditable and can be easily reconstructed and audited in a research setting.

Human Tissue Act 2004

Key Objectives for implementing a LIMS at RCLCF

- Comply with current and future regulatory requirements and associated audits
- Improve the method for booking in samples
- Logging of booked out samples and their usage
- User friendly system that makes sample editing and auditing easy to use
- Integration with IBM System Builder Database
- Select a system that can easily be configured to meet current and future needs
- Select a system with a track record of backward compatibility and ease of upgrade
- Purchase a compliant system that RCLCF staff could configure themselves from a reputable supplier

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Autoscribe Matrix LIMS Solution

Following detailed product demonstrations, Autoscribe's Matrix LIMS was chosen for tracking samples in storage at RCLCF. Autoscribe Matrix LIMS was installed at RCLCF in 2006 for use with the Liverpool Lung Project's samples. Currently there are more than 130,000 samples in storage at and every sample and aliquot can be tracked, traced and its movements fully audited thereby complying with regulatory requirements. The system was easily configured by RCLCF's staff as a compliant Sample Tracking System after completing Autoscribe's 3 day configuration training course. Matrix LIMS is FDA CFR21 Part 11 ready and facilitates regulatory compliance for laboratories that are governed by GCLP, FDA, GLP, cGMP, MHRA, UKAS, EU and National regulations.

Sample Types Stored

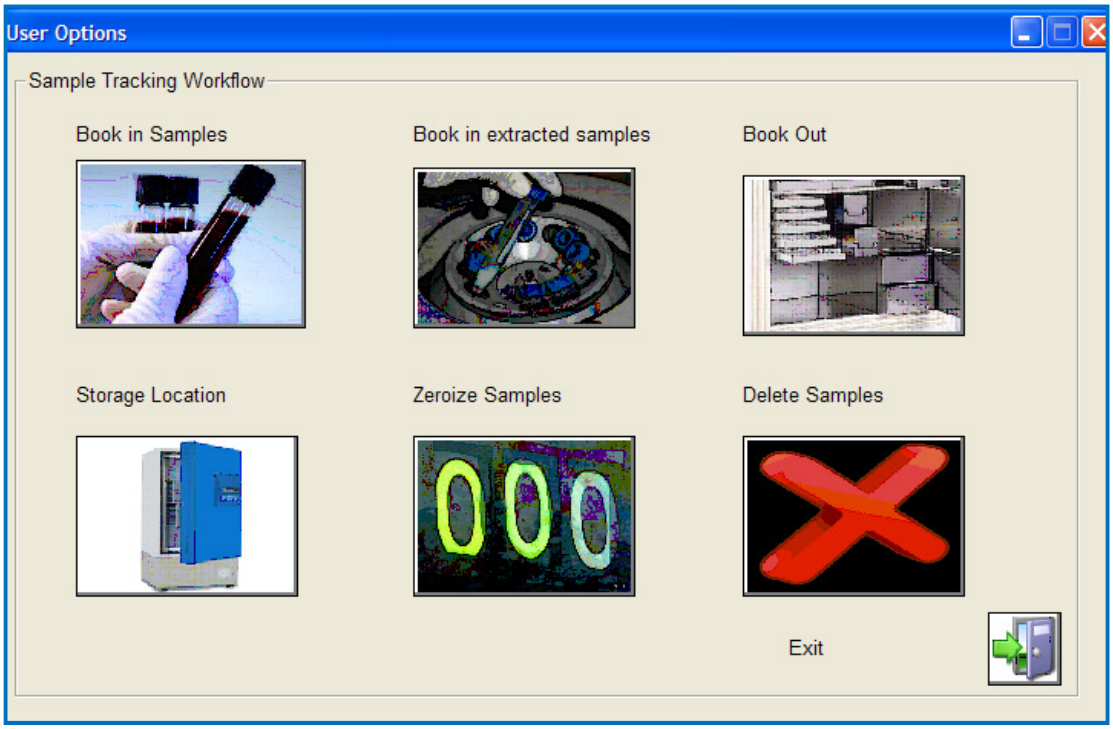
The types of samples stored include:

- Blood Plasma
- Blood Plasma Frozen
- Bronchial Washings
- Bronchial Washings Frozen
- Cheek Scrapings in RNA
- Cheek Scrapings in Saccamanno fixative
- FTA Cards
- Normal Frozen Tissue
- Normal Preserved Tissue
- Sputum Frozen
- Sputum Preserved
- Tumour Frozen
- Tumour Preserved
- White Blood Cell Pellet and Whole Blood

The list of sample types stored and storage locations can be readily altered and expanded upon with full audit trailing of any changes that are made to the system.

Main Roy Castle Sample Tracking Workflow

An intuitive graphical workflow was easily created by RCLCF staff using the Matrix LIMS configuration tools that gives easy and intuitive access to the major RCLCF sample tracking processes.



Main Roy Castle Sample Tracking Workflow

Storage/Freezer Lists

The creation and maintenance of Store and Freezer lists is an administrative function. Samples are stored in several storage locations: in Freezers, in the Specimen Store or in the Cold Room. Storage locations were readily configured into the system and different formats could be easily setup for each storage location.

See Appendix 1 for a detailed description of the configured RCLCF sample tracking workflow and processes. Appendix 1 also includes LIMS screenshots from the operational LIMS.

Conclusions

- Matrix LIMS at RCLCF complies with current regulatory requirements and associated audits
- Matrix LIMS configurability and complete version control and audit trailing will enable RCLCF to meet future regulatory requirements
- We now have a greatly improved method for booking in samples
- We now have completer control and traceability for logging the booking out samples and their usage
- Matrix LIMS configuration creates a very user friendly / intuitive system that makes sample editing and auditing much easier to use
- RCLCF staff easily Integrated Matrix LIMS with IBM System Builder Database
- Selection of Matrix LIMS by RCLCF gave us a system that can easily be configured to meet current and future needs
- RCLCF selected a system with a track record of backward compatibility and ease of upgrade
- RCLCF purchased a compliant system that RCLCF staff could configure themselves from a reputable supplier

User Quotes

- ✓ "We now have a much improved method for booking in samples. Booking in samples is much faster and simpler than the previous system."
- ✓ "We now have a booking out system that allows us to log where samples have been taken and used."
- ✓ "All samples from a subject can be listed and accessed from a single screen which makes editing & auditing much easier"
- ✓ "Integration into our IBM System Builder database allows researchers to see exactly what samples we have available for each subject."
- ✓ "A number of screens have been created especially to aid the auditing process. We can now quickly and easily update the database to reflect the true state of the tissue bank"

Matrix LIMS truly lives up to Autoscribe's claims that it is:

- Better by Design
- Faster to Implement
- Easier to Use and Support
- Designed for Business Change

About Autoscribe

Autoscribe Limited is a world leader in the development and supply of Successful Software Solutions for LIMS (Laboratory Information Management Systems) and the Scientific Laboratory and Business markets. Autoscribe pioneered the use of innovative configuration tools within the LIMS market and today our Matrix Gemini LIMS software is seen as the industry standard to which others aspire.

Autoscribe offers a wide portfolio of products and services including systems for LIMS, sample tracking, instrument calibration and maintenance, stability testing, customer complaints management, support management system, training records management and resource planning.

Founded in 1981, Autoscribe is a privately owned UK company. Worldwide we are represented by a network of business partners in regions including the USA, Canada, Europe, Indonesia, Malaysia, Thailand, Singapore, Vietnam, India, Kuwait, Pakistan, Australia, Kenya, East Africa, South Africa and Brazil.

Our organisation includes a dedicated team of developers, technical support specialists and sales & marketing professionals. Our customers include leading analytical, oil, pharmaceutical, biotechnology, chemical, nuclear, water, biotechnology, food and consumer products companies as well as academic research institutes, hospitals and many others.

For further information please contact Autoscribe quoting reference: RCLCF0909:

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Appendix 1

RCLCF LIMS Screenshots

Book in Samples

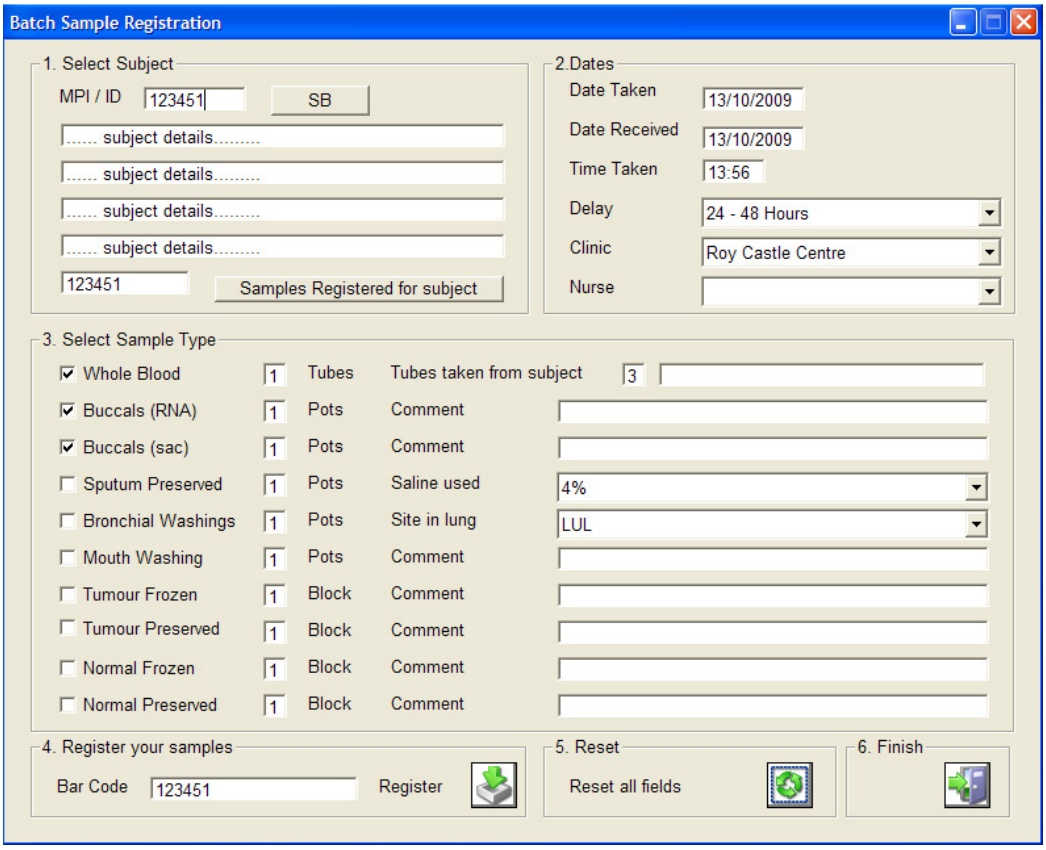
Blood samples are received in the sample reception area – see below photograph.

RCLCF Sample Reception Area

Sample storage locations include the specimen store where samples are stored at ambient temperature in boxes on shelves in a rack mounted system; in the cold room or in a series of -80C freezers (shown below).

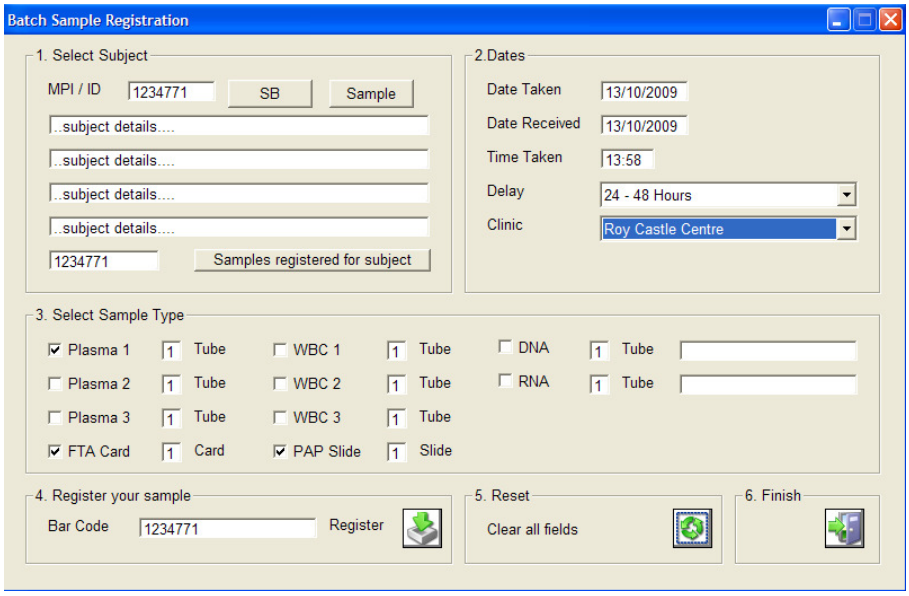
Sample Tracking / Storage Locations: -80C Freezers at RCLCF

Patient samples are booked in at RCLCF using the configured screen below. Access to the patient record is made via the SB button. No subject details have been shown for patient confidentiality reasons. Sample types, number and units are readily selectable.



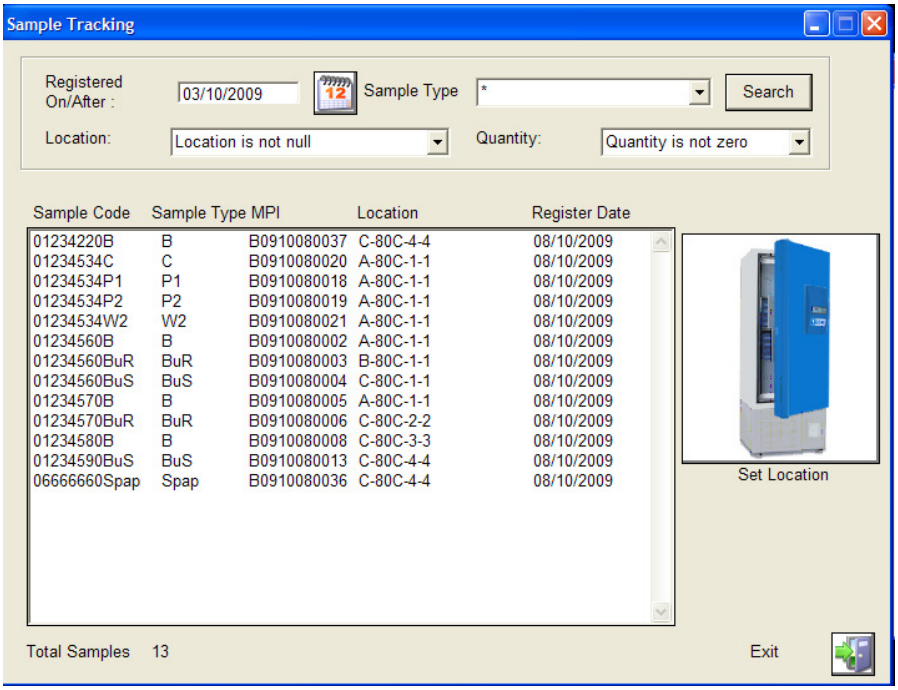
Booking in Samples

Matrix LIMS allows the use of multiple registration screens. A further screen (see overleaf) is used to register extracted samples with their specific sample types.



Booking in Extracted Samples

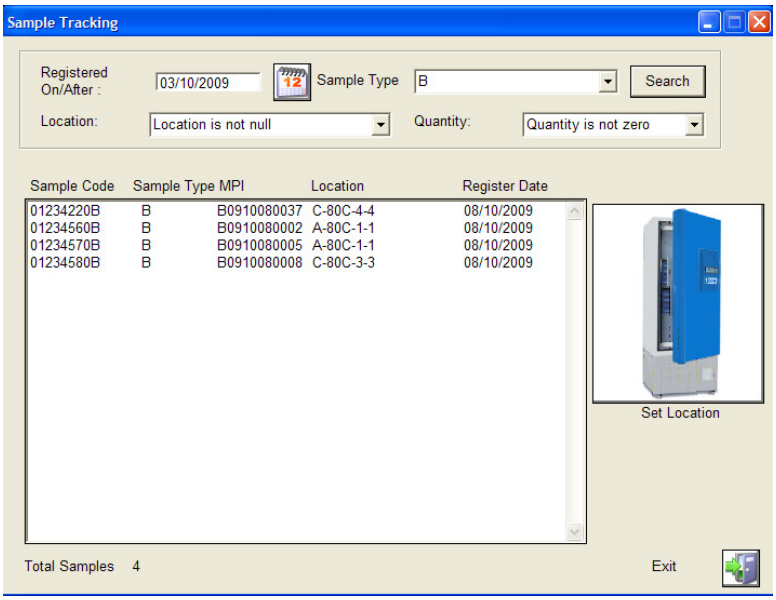
Once the samples have been logged into the system they are allocated storage space using the following screen.



Sample Tracking / Storage Locations

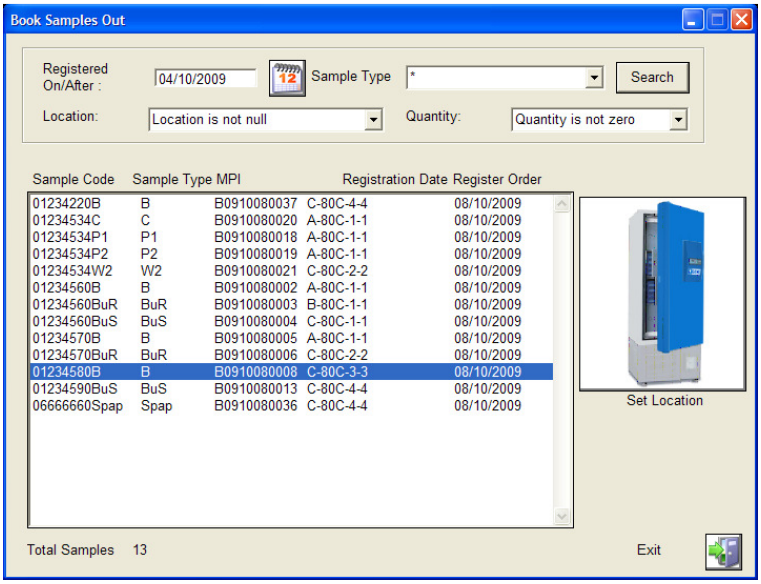
Using Screen Filters

Matrix LIMS screens can be configured with multiple filters for ease of finding and operating upon samples. The screen below shows 'B' sample types that have not yet been allocated storage.



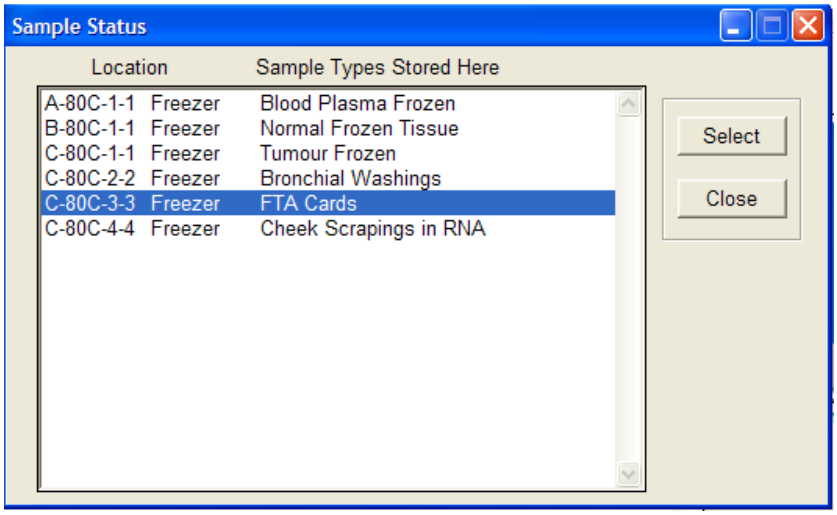
Screen Filters: Finding the "B" samples?

Samples in storage can be booked out to authorised users /researchers.



Booking Samples Out from Freezer C-80C, Shelf 3, Box 3

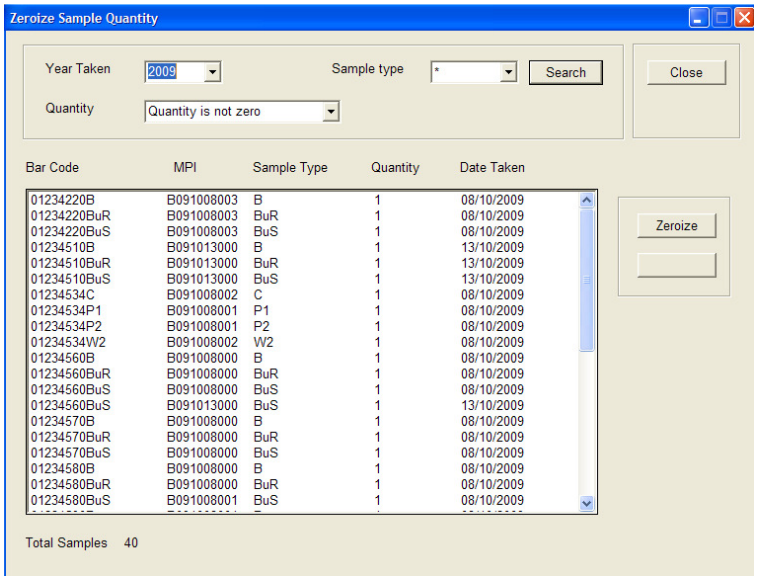
The user receives confirmation of the sample types held in the storage location for Freezer C-80C, Shelf 3, Box 3:



Selecting Sample(s) to Book Out

Zeroize Samples

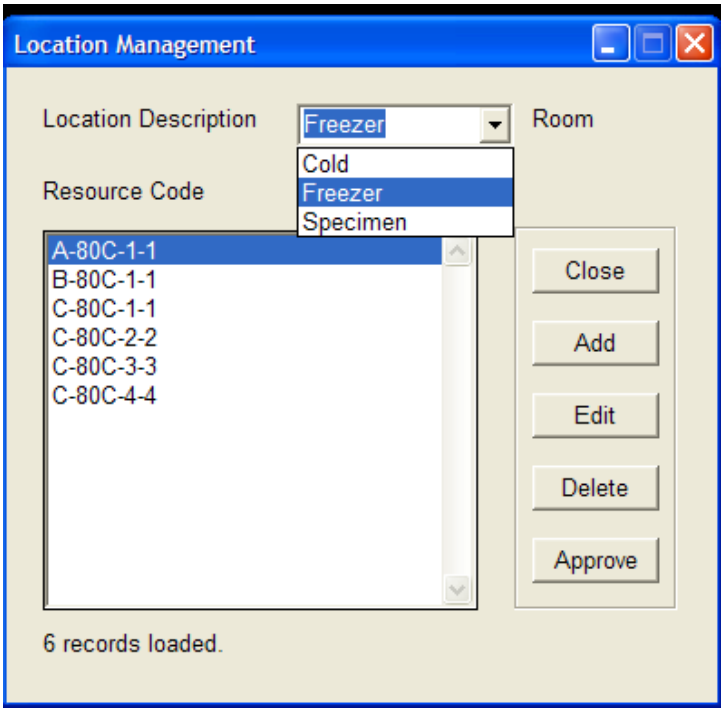
Zeroize Samples allows authorised users to list samples and allows those users to select several samples and then set their quantity to zero (eg where samples have been completely used up for research). Even then Matrix LIMS will maintain the full history and audit trail of the sample's lifetime in the system.



"Zeroize Sample Quantity

Storage/Freezer Lists

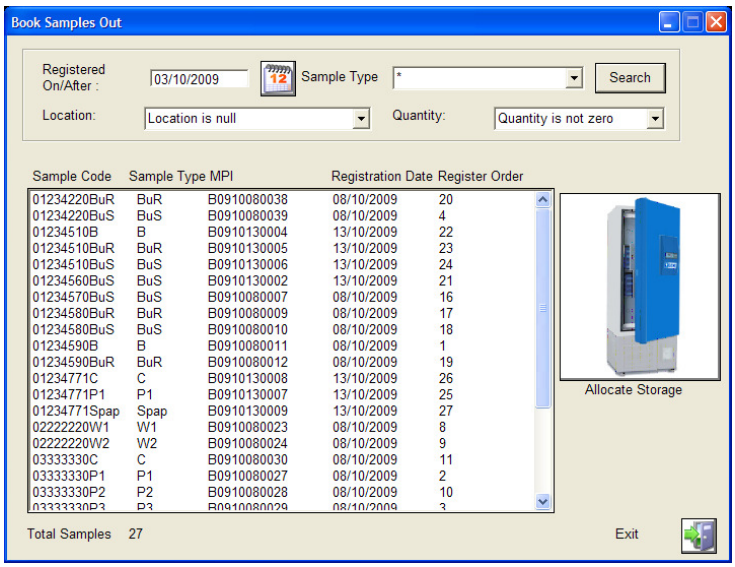
Storage/Freezer lists are created and accessed via the menu bar. This is an administrative function. Samples are stored in several storage locations: Freezers, in the Specimen store or in the Cold room. Storage locations were readily configured into the system and different formats were used for each storage location. reference is different for Freezers. For example: A freezer location defined as “A-1-2” means freezer “A”, Shelf “1” & Tray “2”.This method lets RCLCF easily find the tray where a sample is stored. Samples are filed sequentially in date & id number order so can be located easily.



Setting up Freezer, Specimen and Cold Room Storage Locations

Allocating storage location to samples

The screen below lists samples booked in (registered) “today” and makes it easy for users to see work that needs to be completed “today”.



Allocating storage location to samples

Users can select several samples at once, they then click the “set Location” button. Users then select a location reference from the list of available locations and appropriate options.

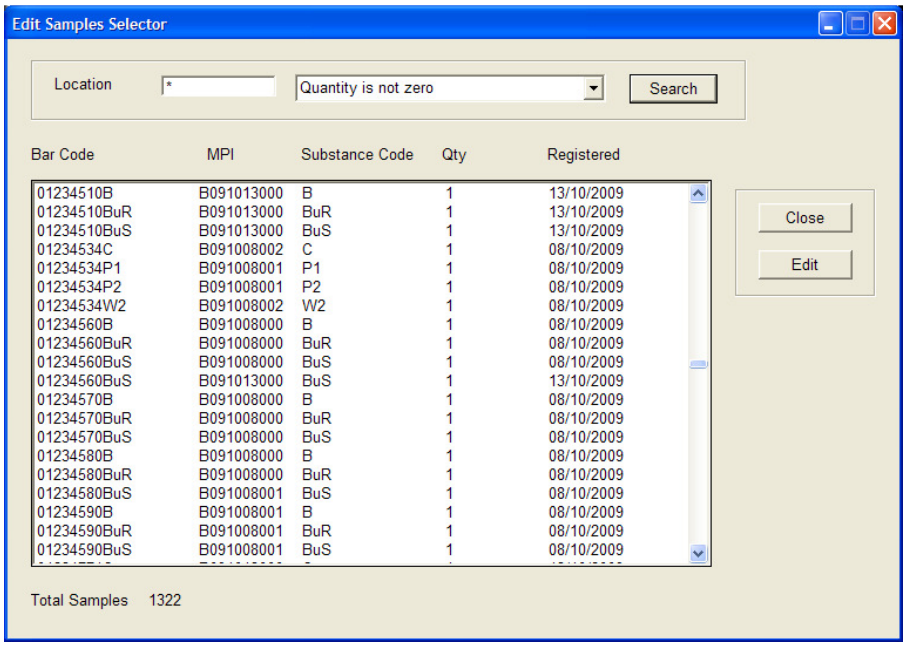
Freezer trays have a defined maximum capacity and may be partly filled, this screen checks that all of the selected items can fit into the tray.

Freezer Reconciliation

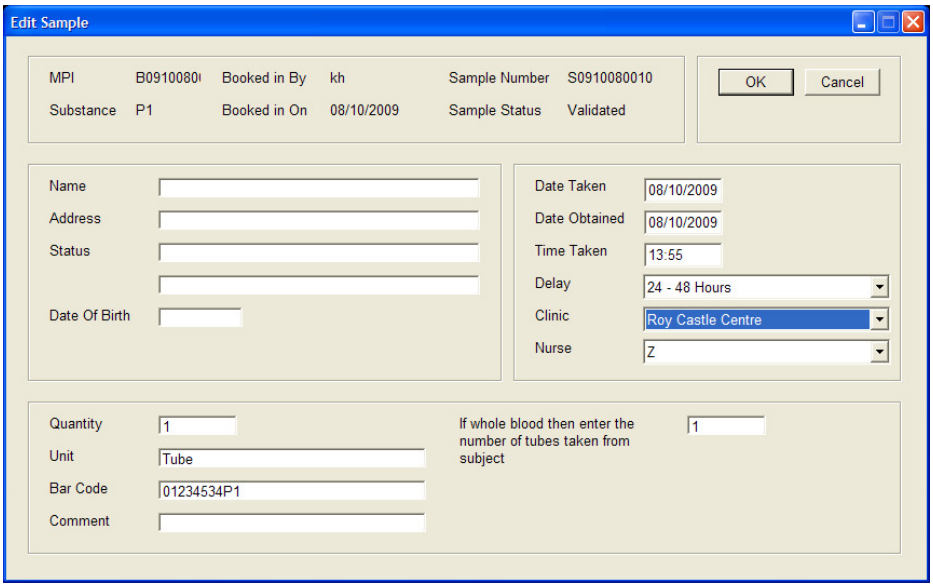
The Human Tissue Act entered the statute books in 2004 and came into force in 2006. Many samples stored by research units sample all over the world have been stored since the mid-1990’s under less stringent regulatory requirements. Freezers/sample contents are routinely to ensure that the patient information and sample storage / content information are up to date and correct.

Edit By Location

This menu item allows authorised users to list samples at a specific location and allows them to select and edit the samples / locations (auditing is by freezer and tray at a time).



Selecting Samples for Edit by Location



Editing Sample Details by Location

Change Location

Change Location lists samples at a specific location and allows authorised users to move to the sample to another location (ie move them to another freezer)

Delete by Location

Delete by location allows authorised users to list samples at a specific location and allows those users to select and delete those samples.

Reporting

Matrix LIMS provides for fully configurable reports using Crystal Reports. Users can easily access online reports to see storage lists and samples in a specific location for definable date ranges. This makes tracking and finding samples simple and easy to do. See below and overleaf for examples of storage reports that have been configured for end users.

Printed on: 13/10/2009 **Samples Registered on: 09/10/2009**

MPI	Received On	Type	Qty.	Units	Bar Code	Location
7231422	09/10/2009	P1	1	Tube	09.00369P1	D-1-11
	09/10/2009	P2	1	Tube	09.00369P2	D-1-11
	09/10/2009	P3	1	Tube	09.00369P3	D-1-11
	09/10/2009	C	1	Card	09.00369C	D-1-11
	09/10/2009	W1	1	Tube	09.00369W1	D-2-11
	09/10/2009	W2	1	Tube	09.00369W2	D-2-11
	09/10/2009	W3	1	Tube	09.00369W3	D-2-11
	09/10/2009	B	1	Tube	09.00369B	D-2-11
	09/10/2009	BuS	1	Pot	09.00369BuS	D-2-11
7234532	09/10/2009	BuS	1	Pot	09.00370BuS	D-1-11
	09/10/2009	B	1	Tube	09.00370B	D-1-11
	09/10/2009	P1	1	Tube	09.00370P1	D-1-11
	09/10/2009	P2	1	Tube	09.00370P2	D-1-11
	09/10/2009	P3	1	Tube	09.00370P3	D-1-11
	09/10/2009	C	1	Card	09.00370C	D-2-11
	09/10/2009	W1	1	Tube	09.00370W1	D-2-11
	09/10/2009	W2	1	Tube	09.00370W2	D-2-11
	09/10/2009	W3	1	Tube	09.00370W3	D-2-11

Patient samples listed by type, quantity and location

13/10/2009 **Storage Location List**

Location Type	Code	Samples Held	Capacity	Available
Cold				
	s01-b01-b99	Cheek Scrapings in RNA	210	0
	s01-b01-r01	Cheek Scrapings in Saccamanno	75	1
	s01-b01-r02	Bronchial Washings	210	0
	s02-b01-r01	Sputum Preserved	56	1
Freezer				
	1-1-10	White Blood Cell Pellet	333	0
	1-1-11	White Blood Cell Pellet	333	0
	1-1-12	White Blood Cell Pellet	333	0
	1-1-13	White Blood Cell Pellet	333	0
	1-1-14	White Blood Cell Pellet	333	0
	1-1-15	White Blood Cell Pellet	333	0
	1-1-16	White Blood Cell Pellet	333	0
	1-2-1	White Blood Cell Pellet	303	0

Storage Location List

Date: 13/10/2009 **Storage List – Samples at location: 2-3-16**

Sample ID	Qty.	Units	Type
009752P	1	Tube	P1
009752P2	1	Tube	P2
009752P3	1	Tube	P3
009753P1	1	Tube	P1
009753P2	1	Tube	P2
009753P3	1	Tube	P3
009754P1	1	Tube	P1
009754P2	1	Tube	P2
009754P3	1	Tube	P3
009755P1	1	Tube	P1
009755P2	1	Tube	P2
009755P3	1	Tube	P3
009757P1	1	Tube	P1
009757P2	1	Tube	P2
009757P3	1	Tube	P3

Storage List of Samples at a Location