This document describes (with screen-shots) each of the modules that were developed to produce the BikaBiobank LIMS namely (1) Kit assembly, (2) Shipping, (3) Storage management, (4) Inventory management, , (5) Freezer Management, (6) Sample storage management, (7) Biospecimen registration and (8) Analysis request by a client

Supplementary Figures S1-S24:

1. Kit Assembly:

The following kit attributes are maintained with a kit template:

- Kit Name
- Kit Type/Class
- Labelling requirements
- Assembly SOP
- Component list (Select from components available in the Database)
- Packaging outline
- User Instructions on packaging of kits, shipping and completion of compulsory forms.
- Temperature monitors depending on sample type and shipment type.

Other required regulatory documentation that accompanies all shipments may be loaded to LIMS prior to shipments or are emailed to receiving laboratory or biobanks. These include the ethic approval documentation; the biospecimens deposit material transfer agreement andpermits. Submission sites also have to notify the receiving laboratory and biobank of incoming shipments and prepare the following required forms prior shipment. A shipment checklist is completed by the submission site and is for internal use only. The shipment manifest/notification and the shipment receipt confirmation and query form should be send by email to the receiving site at the time of shipment. The courier’s waybill number and copies of commercial invoice and permits must also be send with shipment.

1.1 Kit assembly:

The submission sites (the biobank's clients) orders kits from the biobank based on a particular project to be carried out on a specific case study. For example blood samples are to be collected to carry out DNA extraction and subsequent analysis on a group of participants. The lab manager navigates to "Kits" and select a list of pre-packed/designed kits which is mostly use in the field from the LIMS system. Many variations can be created for the DNA blood sampling kit dependent on the required collection tubes that are needed which is dependent on the downstream applications that would be performed. If the appropriate kit template is not available, then the lab manager can create the desired kit with the appropriate collection tubes. The kit template consists of a list of components the client needs for sample collection and subsequent shipment. Figure S1 shows a DNA blood sampling kit template with two components: one pair glove and two blood tubes.

The kit template is used to avoid the recurring selection of components during kit assembly. The kit template which consists of components is imported once for every number of kits to be assembled. In the kit assembly form (Figure S3), the selected kit template will define the components to put in each kit and their quantities. The biobank staff member will select the specific kit template from a drop down menu (Figure S3) and also the total number of kits to prepare (based on the client's requirements).

The kit assembly form inform the biobank workers which stored stock-items to use for the assembly of the kit from the specified list of stock-item storages which underlies the inventory management system. The latter track and audit the number of consumables that are required for the kit assembly. This also allows flags biobank staff when consumable are running low and needed to be re-stocked to ensure that there are always consumables available when kits needed to b assembled.

Once the kits are assembled, the biobank staffs store them in the selected kit's storages under the correct condition prior shipments to clients (Figure S2).

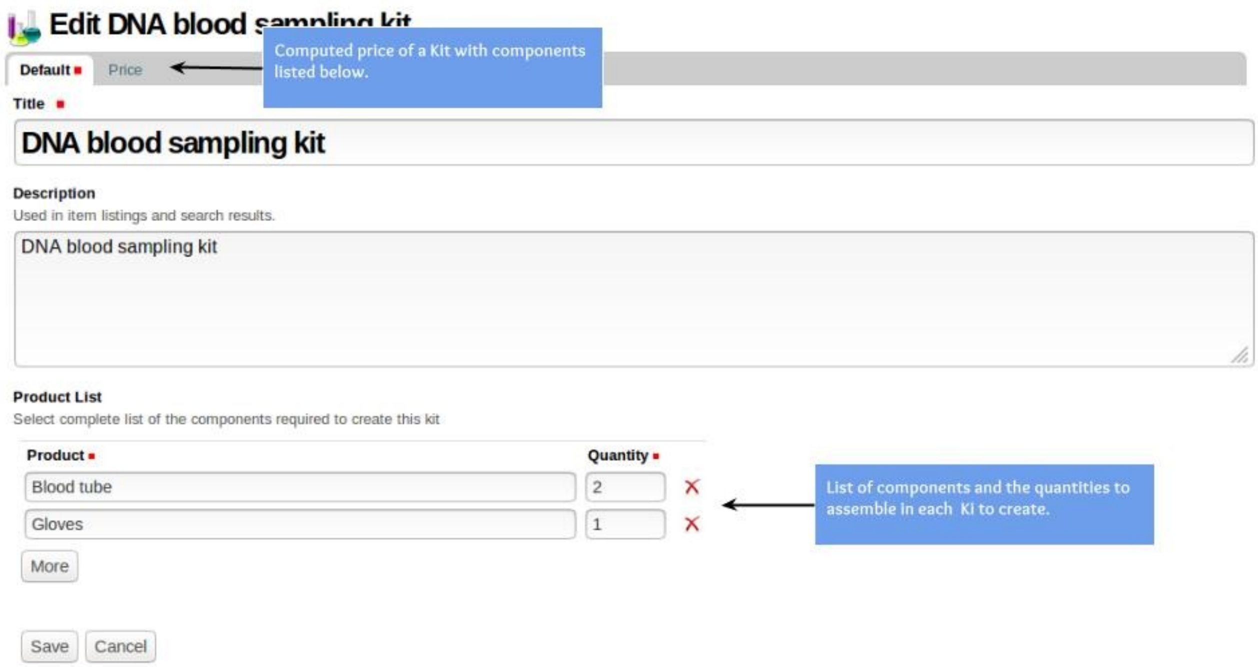


Figure S1: Creation of a DNA Blood sampling Kit.

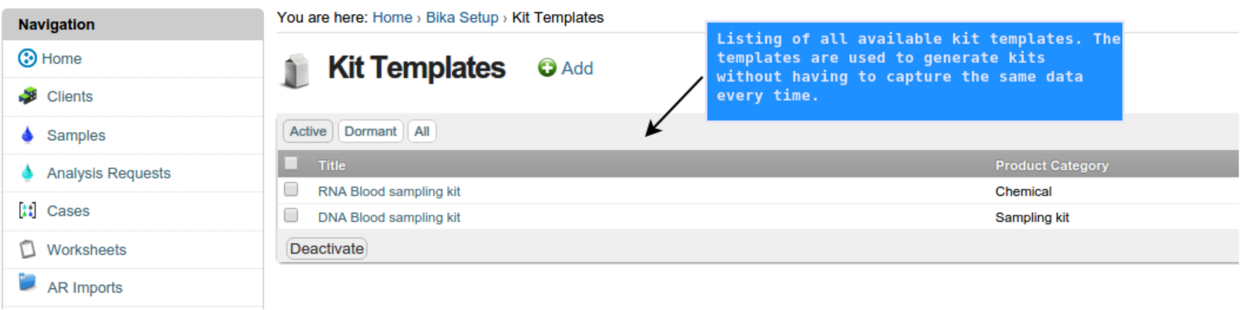


Figure S2: The list of kits available in BikaBiobank LIMS

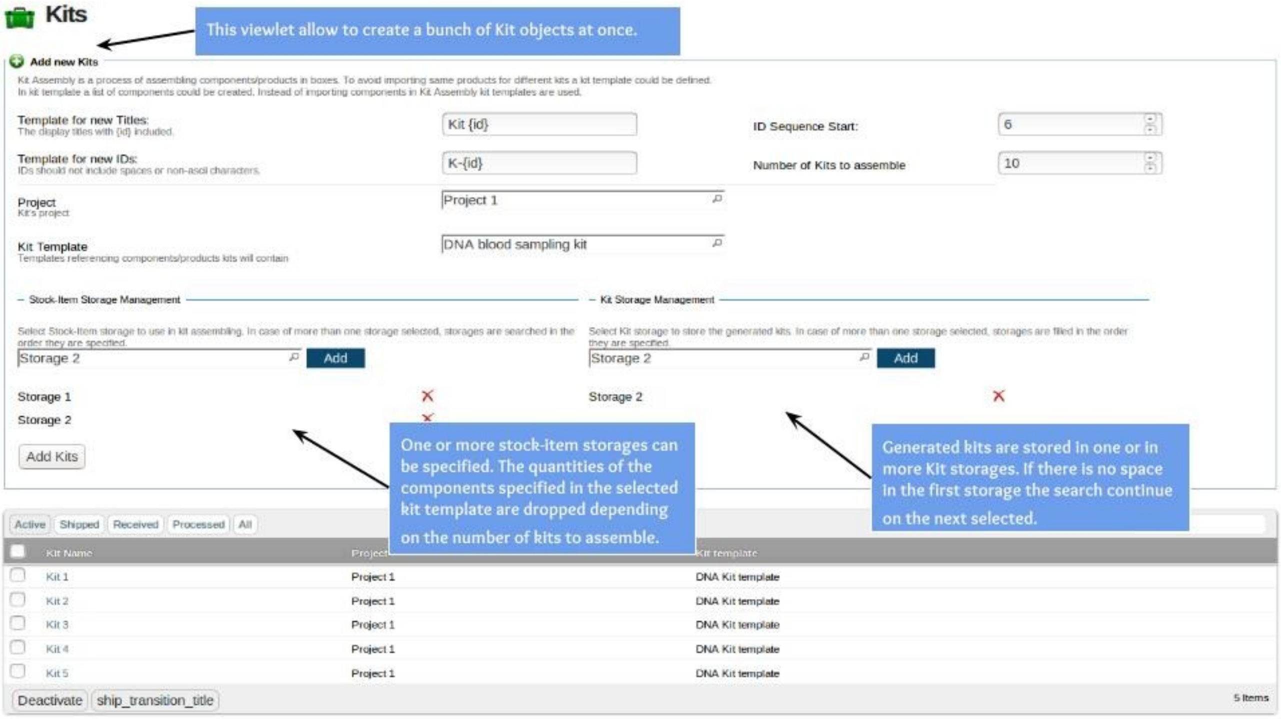


Figure S3: Kits creation. The specific Kit template (DNA blood sampling Kit) is selected other details added. This information is then ready for someone to physically collect materials from the storage room. Consumables are scanned in order to tell inventory system that a number of consumables have been released for kit assembly.

2. Shipping:

The Biobank in consultation with the client defines the appropriate containers to ship to the client. The kits are assembled as per section 1 (above). In our example below, one kit was prepared containing one pre-designed barcoded ACD collection tube with a assigned function associated with the label in a size appropriate styrofoam box (Figure S4). The collection tubes are secured with laboratory tape with barcoded label facing down. An absorbent material is placed within the cavity of the box and covers all components. A lid is added and waterproof tape are used to seal the lid to the body of the box. The sealed styrofoam box are placed in a press-lock plastic bag The plastic sealed kit are placed within a corrugated shipping carton box (Figure S5) with associated manifest (Figure 6) in the pockets of the plastic bags. The courier waybill, commercial invoices, and permits if applicable are placed on the outside of courier box not covering the markings on the box. Prior shipments to biobank, the shipping notification/manifest (Figure 6) and the confirmation and query forms are send to the biobank to notify biobanks of incoming shipments

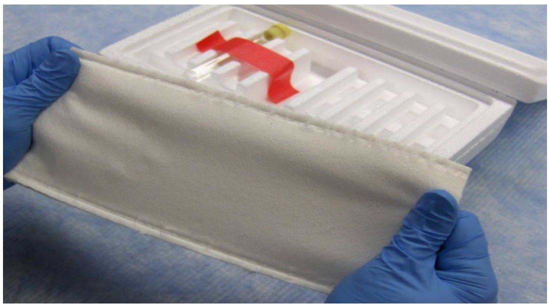


Figure S4: A kit comprising of collection tube and the associated components prepared for one patient or individual.

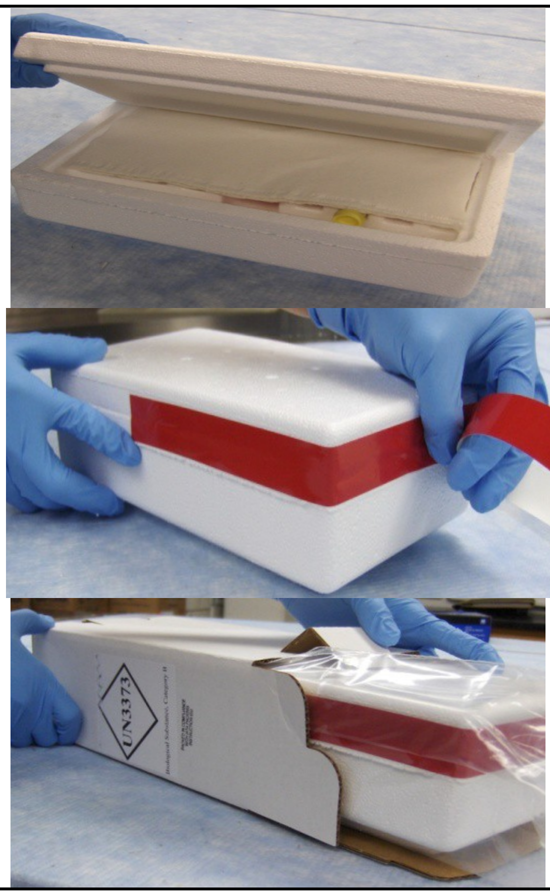


Figure S5: Kit assembly instructions shows packaging of kit according to IATA standards and assembly into a corrugated shipping box with the correct markings.

NSB
NHLS-Stellenbosch University Biobank

SHIPMENT MANIFEST

NSB Form 002
Edition 01

TO BE COMPLETED BY THE SAMPLE SUBMISSION SITE BEFORE SHIPMENT AND RECEIPT BIOREPOSITORY AFTER RECEIPT OF SHIPMENT

SHIPMENT SENT BY		**SHIPMENT RECEIVED BY**	
Study Name:	I-HAB	H3A Biorepository:	NSB
Type of Study:	PILOT (BIOREPOSITORY)		RM 2201, 10TH FLOOR, GREEN AVENUE
Address:	MILLENIUM BUILDERS PLAZA	Address:	TYGERBERG HOSPITAL
	PLOT 252 HERBERT MACAULAY,		FRANCIE VAN ZYL DRIVE TYGERBERG 7505
	CENTRAL BUSSINESS DISTRICT		CAPE TOWN
	ABUJA		
Country:	NIGERIA	Country:	SOUTH AFRICA
Contact Person:	TIMOTHY REID	Contact Person:	CARMEN SWANEPOEL
Phone#:	234 8033770440/ 234 8055306670 treid@sun.ac.za	Phone#:	+27 0219384103/4204 carmens@sun.ac.za
E-Mail: 1.		E-Mail:	

Number of Specimens		**Batch#**	**Number of Specimens**		**Batch#**
Plasma	0		Plasma		
DNA	0		DNA		
Urine	0		Urine		
Whole Blood DNA Collection Kit	1		Whole Blood DNA Collection Kit		
Shipment Conditions			**Shipment Conditions**		
Ambient	Yes		Ambient		
Frozen	N/A		Frozen		
Shipping Date	12/05/2016		Shipping Date received		
Additional Comments:			Additional Comments:		

Dry Ice "Fill" Information				
Biospecimen Submission Site *Record date, amount (kg)and time first Dry Ice Fill started*		**Host Biorepository** *Was the Dry Ice in Good condition upon receipt of shipment?*		
Date:	……………………… Kg Dry Ice: N/A	Yes	No	(Please tick one)
Signature:		Date		
		Signature		

Figure S6: A shipping manifest**.** This form is included in the assembled kits. The Client completes this form before shipping the biospecimens to the biobank.

2.1 Shipping instructions from the Biobank:

The "shipments" page (Figure S7) shows the list of shipment instructions including those that are pending (see tab in top lend hand corner). The "Add" button (Figure S7) pops up a new window (Figure S8) with a form that captures all the instructions to ship an assembled kit to the client. The fields in this form include the details of the courier company, a Kit-ID (defined for the assembled kit) (Figure S9), the date of shipping to the client, the person giving the shipping instructions and to whom the kits will be shipped. Following the request, the biobank calls the courier company to make arrangements for them to come and fetch the assembled kits.

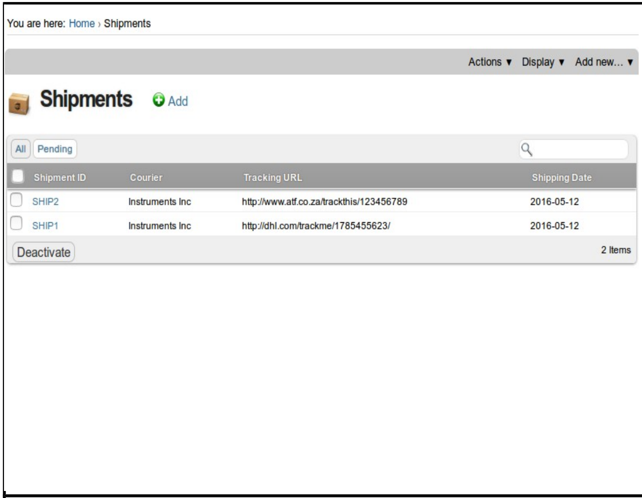


Figure S7: Summary of shipments. The “add” button (Fig. S8ii) provides a new form (Fig. S9) to activate the shipping instructions for an assembled Kit.

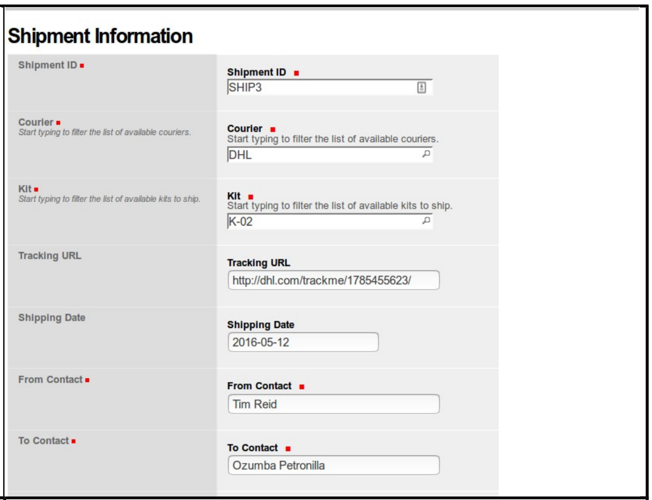


Figure S8: Shipping information. The assembled kits are specified in this shipping form together with the details of the courier. This form must be completed before calling the courier company.

2.2 Shipping instructions from the Client:

The assembled kits are delivered to the client and biospecimens (blood, urine etc) are collected in pre-labelled tubes according to the kits that were assembled (i.e. one kit per patient). The client logs into the LIMS system and use the shipping module to inform the biobank that the kits are ready to be shipped. An email is automatically generated and the Biobank is notified that the incoming kits are to be expected. The biobank contacts the courier to collect the biospecimens from the client or the shipper calls the courier as the shipment has been pre-arranged by the biobank.

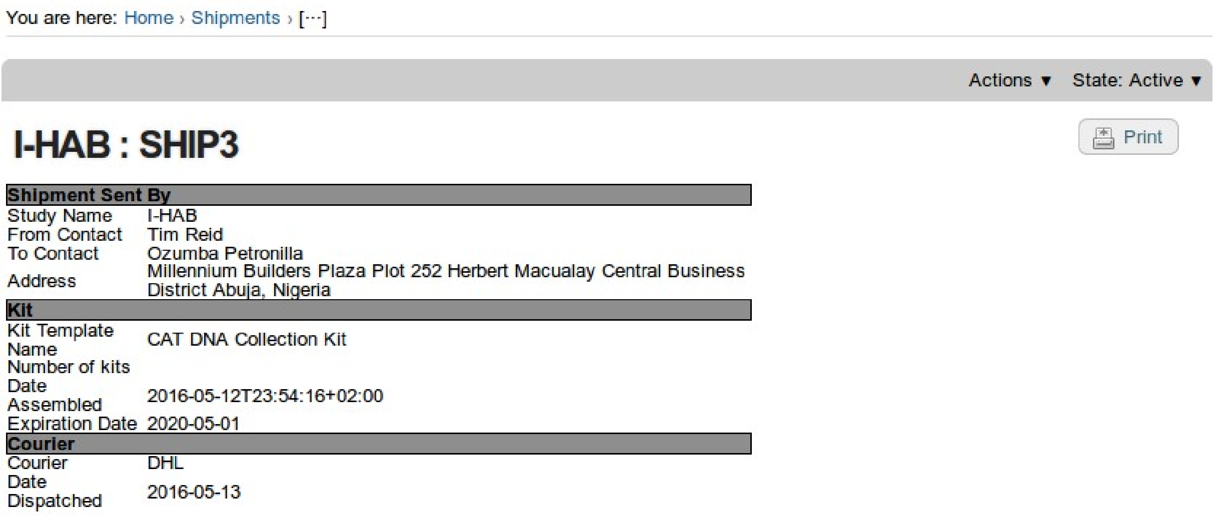


Figure S9: Summary window for a shipping instruction. The summary show in this figure reflects the shipping instructions as defined in Figure 5. This information is for record keeping and represents the information needed for the couriers to collect the biospecimens.

3. Storage management:

Figure S10 shows the form for storage creation. The form contains three tabs: Storage units, Managed storage and unmanaged storage.

3.1- Storage units:

These sections are used for creating the structure that matches the physical storage. Storage unit can contain more storage units as well as managed or unmanaged storages, but items cannot be stored directly in storage units. Room, Freezer, Shelf are storage units (Figure S10).

3.2- Managed storage:

This section contains a set number of positions for storing objects, e.g. boxes that can store 36 tubes each, or shelves that can store stock items. Once all positions are occupied, the storage itself will be flagged as occupied, and when a position next becomes available the storage becomes available too. Items can be stored in specific positions, or the storage itself can be selected, in which case a position is chosen automatically, useful in case many items to store (Figure S11).

3.3- Unmanaged storage:

This section does not restrict the number of items which can be stored. These storages will be available for selection until they are manually flagged as occupied (Figure S12).

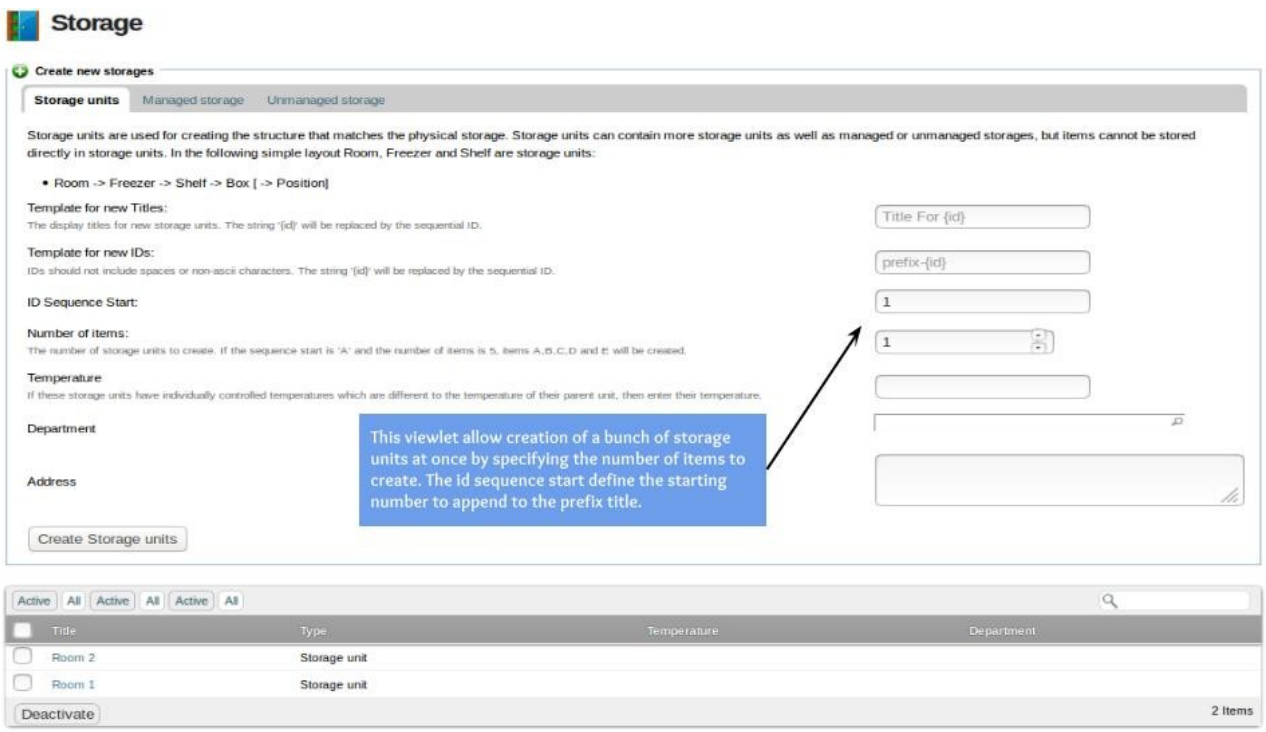


Figure S10: Form for creating storage units.

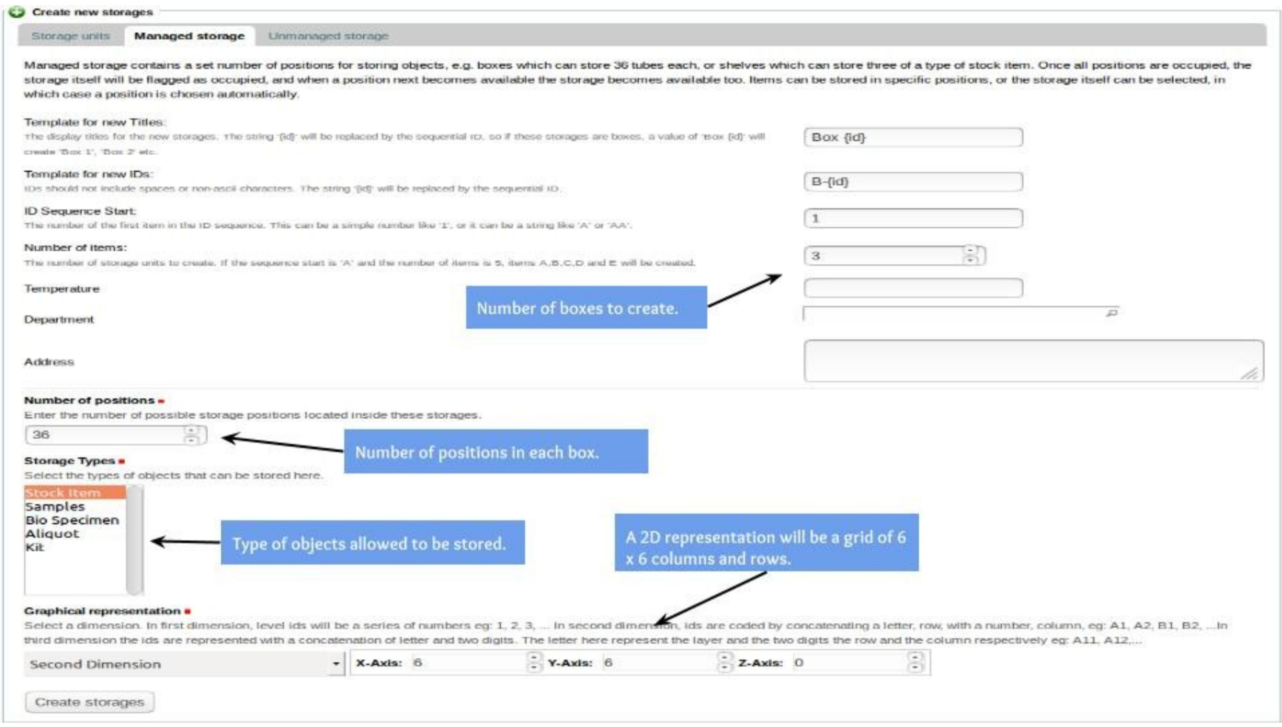


Figure S11: Storage management. A number of positions in each storage must be set.

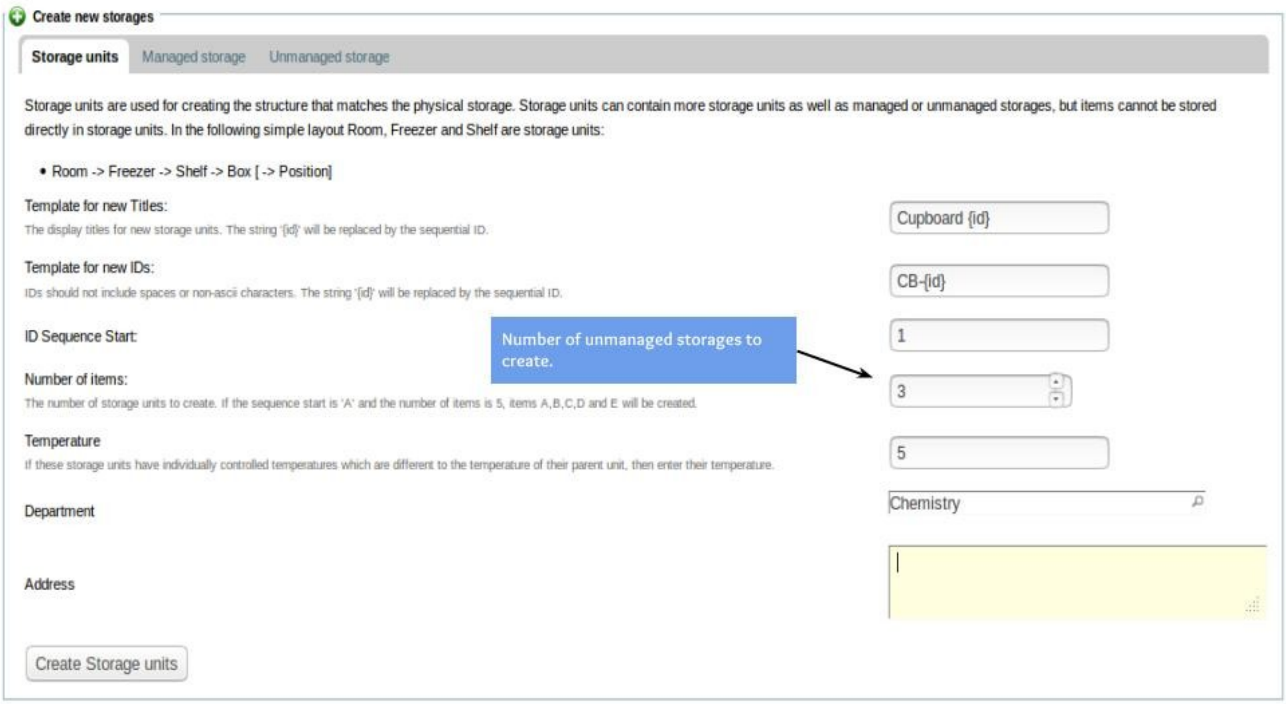


Figure S12: Unmanaged storage. No need for specifying the number of positions. The storage can only be manually set to fully occupied.

4. Inventory management:

Stock-items (products) and kit components can be stored in managed or unmanaged storage. Figure S13 shows an example of managed storage created for storing stock-items. At the creation the storage positions are all free and are shown in green color in the layout. Attributing positions for ordered products will change the positions to occupied and are shown in red color (see next section).

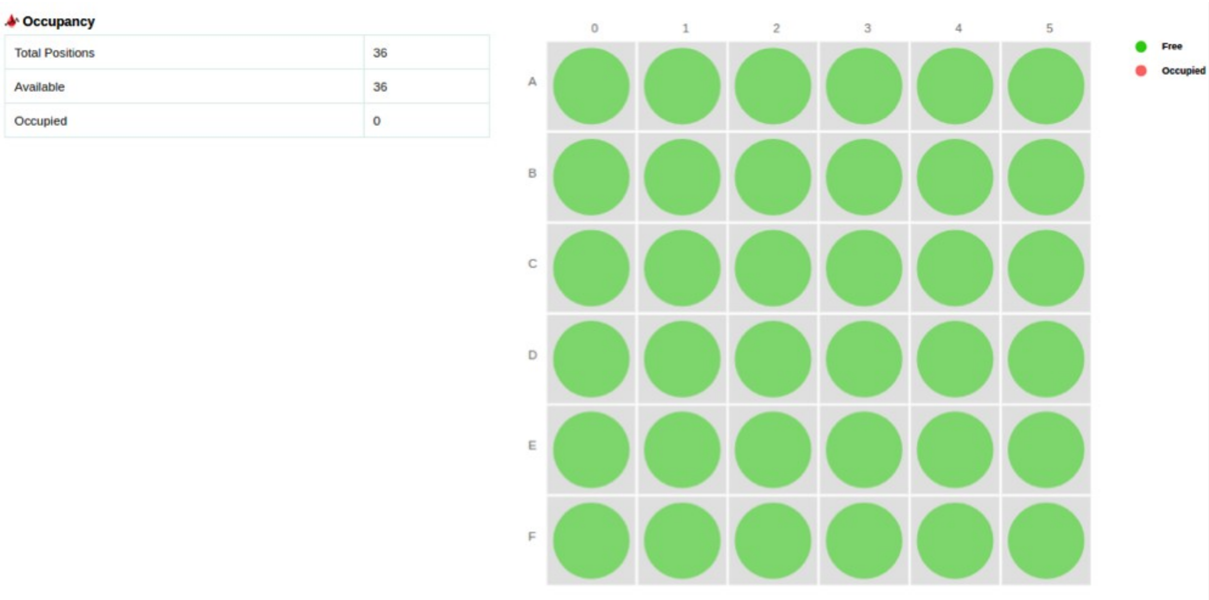


Figure S13: Graphical representation of a storage with 36 positions.

4.1 Stock orders from suppliers:

Stock and products should be provided before a KIT is created and assembled. Specific products are ordered from a supplier. Figure S14 shows the list of products that are available for a supplier called “Instruments Inc”. An order is placed for 5 quantities of “Blood tubes” and three quantities of “pipette” and depicted in Figure S15.

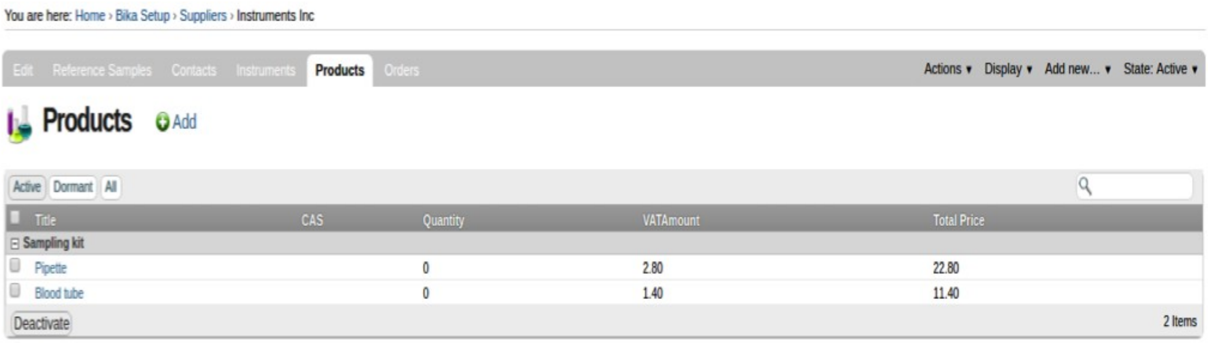
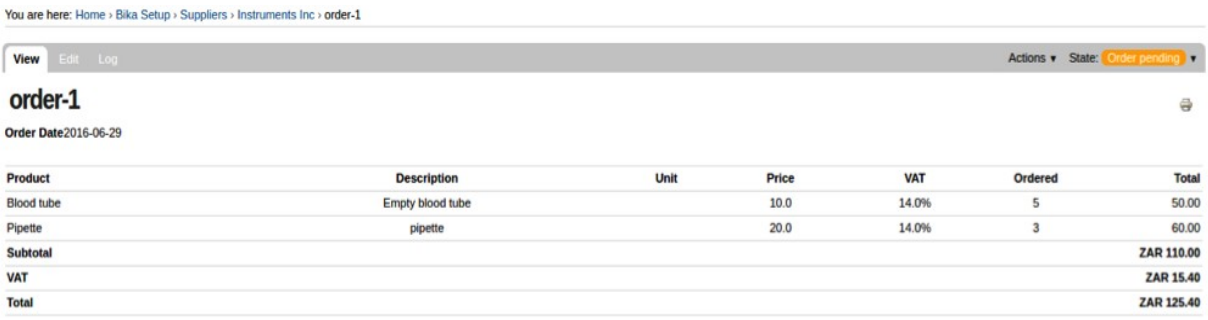


Figure S14: Products available for a supplier.



You are here: Home › Bika Setup › Suppliers › Instruments Inc › order-1

View | Edit | Log — Actions ▾ State: Order pending ▾

order-1

Order Date2016-06-29

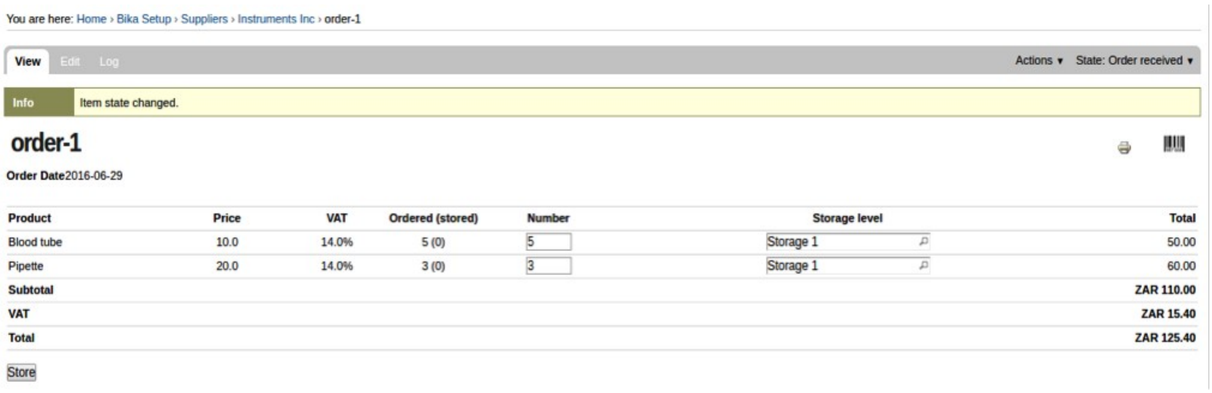
Product	Description	Unit	Price	VAT	Ordered	Total
Blood tube	Empty blood tube		10.0	14.0%	5	50.00
Pipette	pipette		20.0	14.0%	3	60.00
Subtotal						**ZAR 110.00**
VAT						**ZAR 15.40**
Total						**ZAR 125.40**

Figure S15: An order submitted to supplier (Instruments Inc)

4.2 Create stock-items for storages:

The products are automatically created as stock-items after they are received from the suppliers. At this point the stock-items are ready for storage in the location defined in the next form (Figure S16).

Figure S16 shows the precedent order when products are received. In that state, user will be able to select the quantity and the storage location. There are scenarios where the quantities received are more than the available positions in the location selected. The system will only store the number of stock-items equivalent to the number of available positions. Note that if the user can select other locations if exist. The order will be on state Stored only when all stock-items are stored.



You are here: Home › Bika Setup › Suppliers › Instruments Inc › order-1

View | Edit | Log — Actions ▾ State: Order received ▾

Info Item state changed.

order-1

Order Date2016-06-29

Product	Price	VAT	Ordered (stored)	Number	Storage level	Total
Blood tube	10.0	14.0%	5 (0)	5	Storage 1	50.00
Pipette	20.0	14.0%	3 (0)	3	Storage 1	60.00
Subtotal						**ZAR 110.00**
VAT						**ZAR 15.40**
Total						**ZAR 125.40**

Store

Figure S16: The order in which stock items are stored

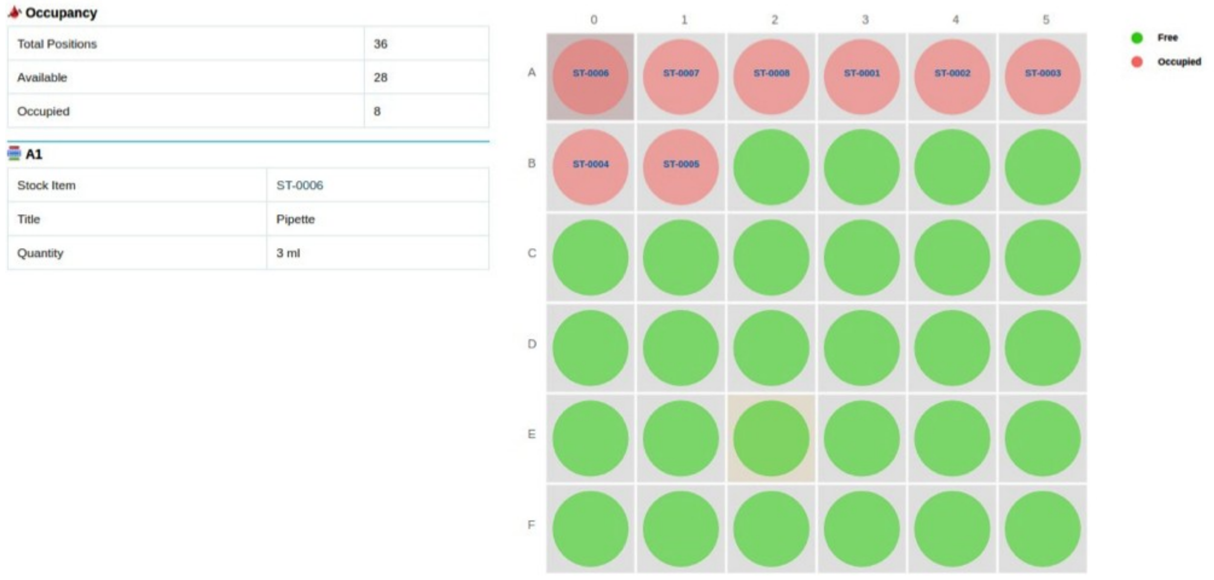


Figure S17: Storage after ordering

5.Freezer management:

In opposite to inventory management, freezer management follow a certain structure and order for creation. This order can be get only with using Managed storage (Figure S11).

5.1 Storage Position Engine:

Three classes (Content types) were used to design the Freezer management module (Figure 18) namely: Storage Unit (room), Storage Level (Freezer, Shelf and Box), and Storage Location (positions inside Box).

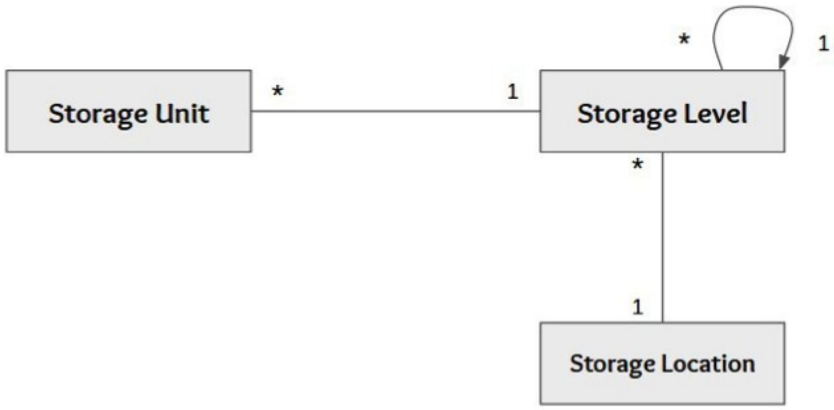


Figure S18: Freezer management relational diagram. Depicted in this diagram are: Storage Unit: room; Storage Level: Freezer, Shelf and Box and Storage Location: positions inside Box

Use case, Freezer configuration:

Plone and Zope frameworks use ZODB, an object database for storing records (objects). Objects, by following class inheritance concept, could be represented as a tree where a given object should have a parent. Figure S19 shows an example for how storage is represented.

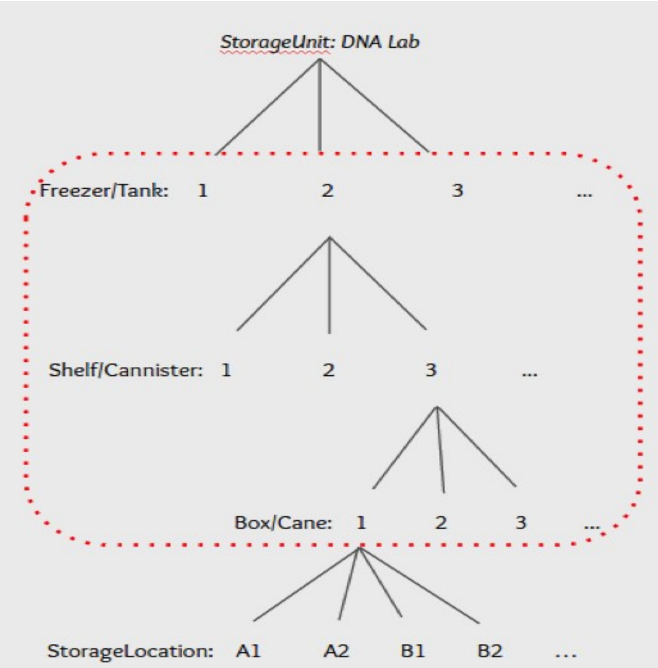


Figure S19: Freezer storage tree representation.

5.2 Storage Configuration:

For both Sample Storage and Inventory management, positions are set up once for every Freezer, or Cupboard and Room, during system configuration and only again when new freezers arrive or older ones are decommissioned.

6. Sample storage management:

Following the structure described in the precedent section, samples which can be biospecimens or aliquots are stored in position within boxes created using Managed storage form (Figure S11).

6.1 Graphical representation:

The different storage positions for samples are graphically depicted in Figure S20. Each circle represents an object position. A state of a position could be “Free”, “Reserved” or “Occupied”. A colour with a different color represents each state: Free=green; Reserved=blue and Occupied=Red.

Figure S20: Graphical representation. The different storage positions for biospecimens or aliquots are graphically depicted in Figure S21. Each circle represents an object position. A state of a position could be "Free", "Reserved" or "Occupied". A colour with a different color represents each state: Free=green; Reserved=blue and Occupied=Red.

6.2 Sample Storage Workflow:

The following workflow was implemented to keep track of the storage position's status: First, the position created will have "Free" state. When creating a sample, if a position is defined this position will change state to "Reserved". Now if the sample is physically stored, then position's state change automatically to "Occupied" (Figure S21).

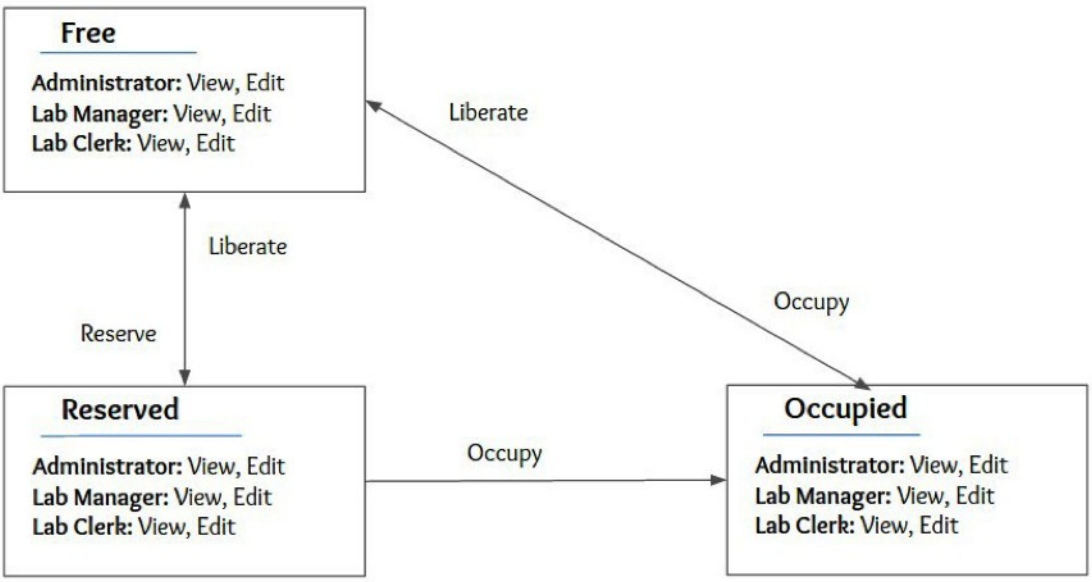


Figure S21: Storage location workflow.

7. **Biospecimen Registration**

Clients send back the kits received from the biobank for collection, but this time with biospecimens inside. A biospecimen is a material taken from human body, such as tissue, blood, plasma, stool and urine that can be used for diagnosis and analysis. The biobank staff member open the kits and register the biospecimens information into the system using the form shown in Figure S22: title, id, type, volume and storage location.

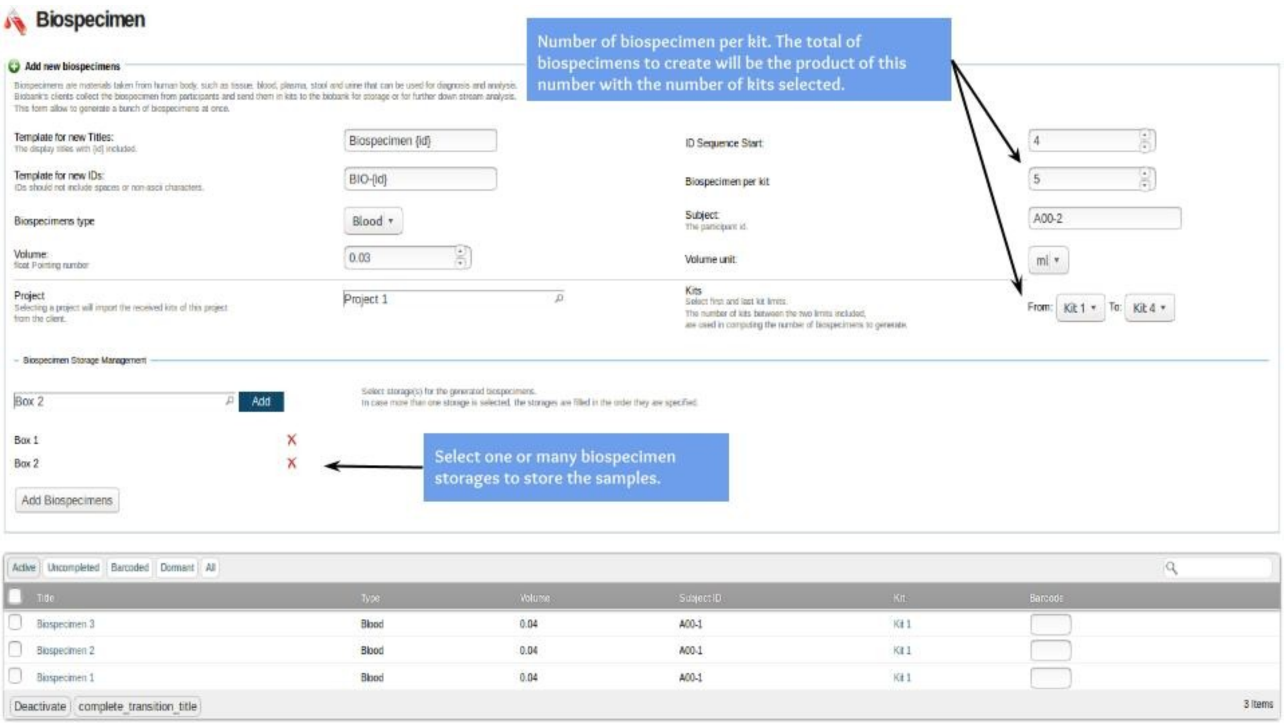


Figure S22: Biospecimen registration.

8. **Analysis Request by Client:**

The clients request for analysis to be carried out on specific biospecimens based on the case study on a particular project. The form to use for creating AR is shown in Figure S23. The biobank staff member select the biospecimen and the analysis services to use in the downstream analyses. The analyst perform the predefined analyses physically in the lab using lab instruments and the results are then captured (Figure S24).

NB: The module Analysis request is being updated with a release in October 2016.

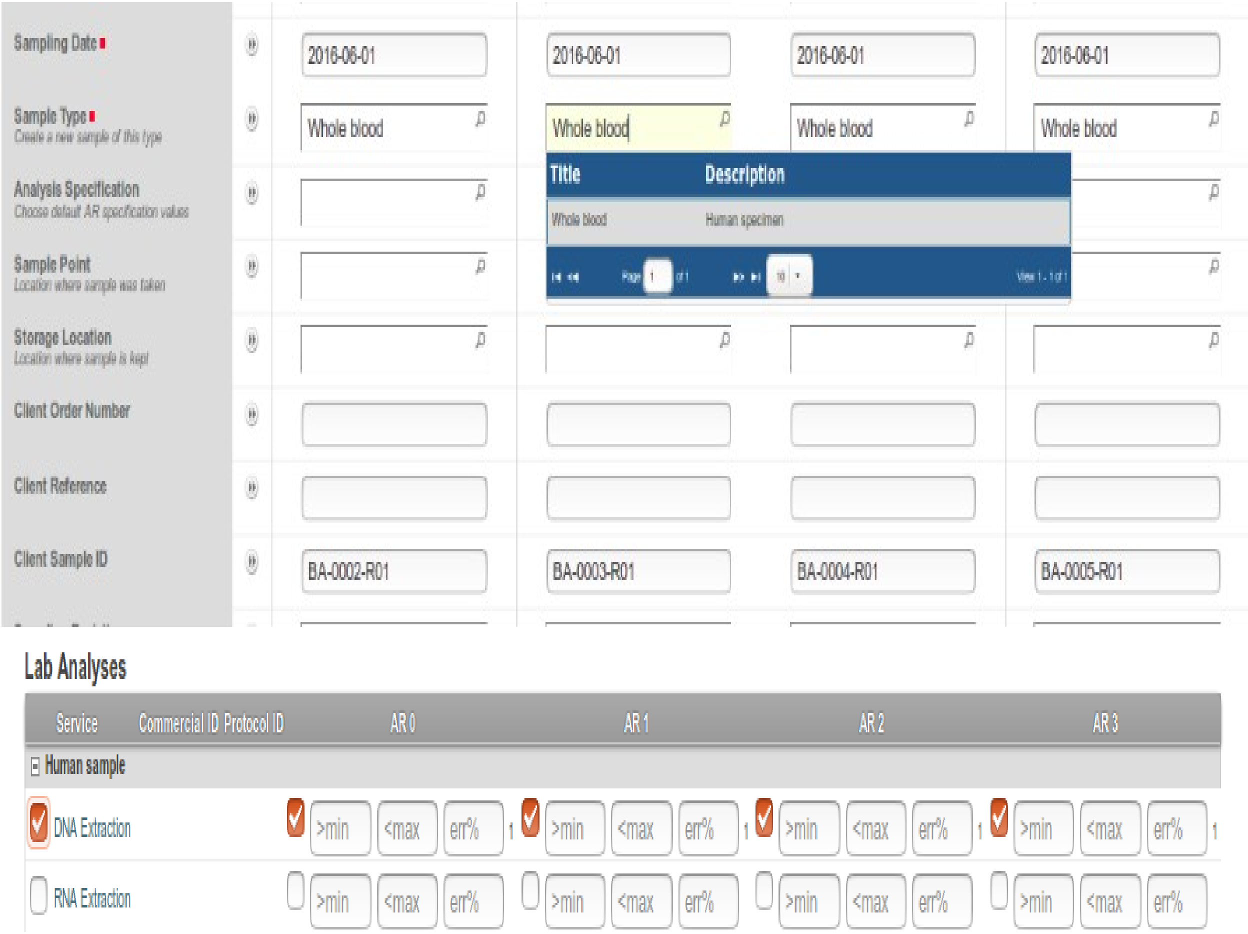


Figure S23: Analyses request form, indicating the essential fields that must completed by the clients requesting for analyses to be carried out on human specimen

8.1 Creating an instrument import interface for BioDrop µLITE and Qubit® 3.0 Fluorometer

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We identified two instruments that are key to human biobank and are lacking in BIKA LIMS namely BioDrop µLITE and Qubit Fluorometric instrument import interfaces for importing DNA/RNA analyses for utility in a biomedical laboratory. A template was created for BioDrop µLITE and Qubit Fluorometric instrument interface for analyses import form. This manages the submission of results files generated by instruments into LIMS, which automatically import the data after upload to avoid any form of transcription error. BioDrop µLITE and Qubit Fluorometric instrument result files are in CSV format. The user can uploads the generated instrument results files and import it into the LIMS by clicking on the submission button after uploading. This will significantly decrease the turnaround time and enhance results accuracy (Figure S24).

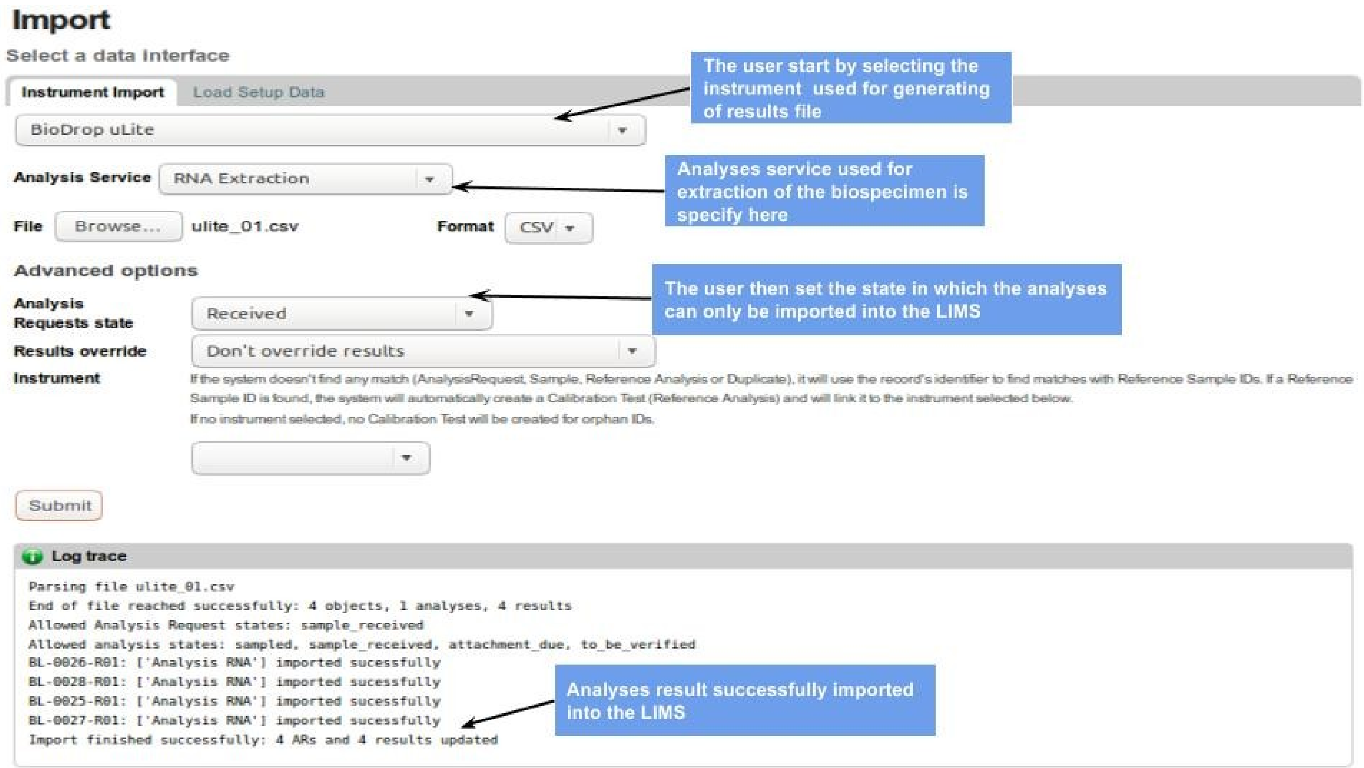

Figure S24: Selection of life technology instrument import interface and specifying of the necessary analyses done, and uploading of the required file to be imported into the LIMS. The results for DNA analysis sucessfully imported into the LIMS