

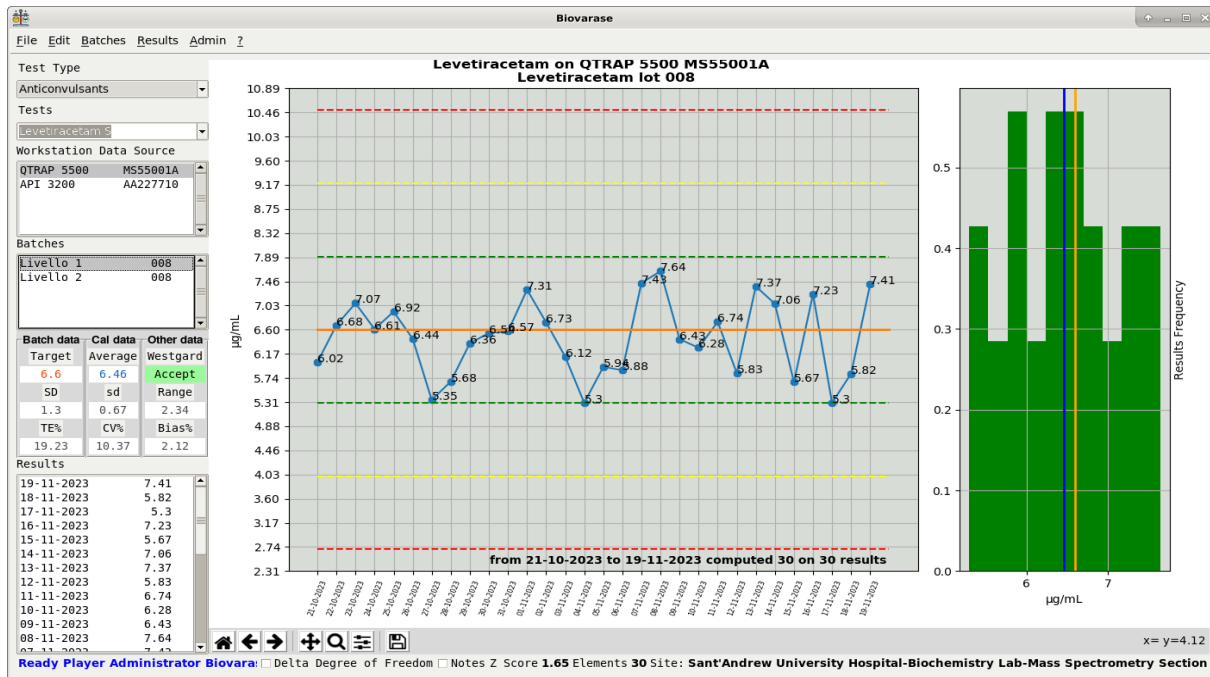
The Biovarase User Manual

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Introduction



Biovarase is an application for managing the internal quality control of a clinical laboratory.

This program allows the monitoring of internal quality control, IQC, through the calculation of the following parameters:

- standard deviation, sd
- coefficient of variation cv%
- range
- Bias
- Westgard's rules
- Levey-Jennings graphs
- Youdent's test

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In addition, based on the use of data reported by the article "Current Databases on biologic variation: pros, cons and progress." Scand J Clin Lab Invest 1999;59:491-500 (updated version 2014)

the program is able to calculate the TEa (total allowable error), and the critical difference (Dcr), of some analytes, allowing to define the laboratory's analytical goals.

Logical organization of the Biovarase program.

In Biovarase each test must be associated with an analytical method, and this is because a test could be performed with different analytical methods.

In addition, each test must be assigned to an analytical section and a workstation on which it is run.

A workstation is defined as the physical instrument where the test is performed.

To use a test for IQC, you must first create it, then assign it a method; a test can have from 1 to n associated methods. Then you have to associate the test-method with the section that runs it and also with the workstation where it is dosed.

You also have to create a control and its batches and assign these batches to the workstations and its tests.

Analytical sections are created from the sites. Site means the facility, usually a hospital within which there are departments, laboratories, in which there are specialized sections, for example, Hematology or Mass Spectrometry that perform tests to which IQC is submitted.

The samples used for IQC are associated with various batches normally supplied by firms outside the laboratory that certify the values for the target and standard deviation, which are to be calculated from the maximum and minimum values given on the control package inserts.

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Start application

Biovarase is developed on Debian 10 with Python 3.7.3

Biovarase use Tkinter patch level 8.6.9 as gui.

Biovarase use Sqlite3 as database.

Before launching the program make sure you have installed the following libraries

- matplotlib
- xlwt
- numpy

To launch the application, you must locate the file named `biovarase.py` in the folder where the Biovarase files reside and run it.

On windows systems it will be enough to invoke it from the command line. You could also compile the program using Pyinstaller.

On Linux systems you will need to make the file executable by typing the command "`chmod +x filename`" basically do something like this

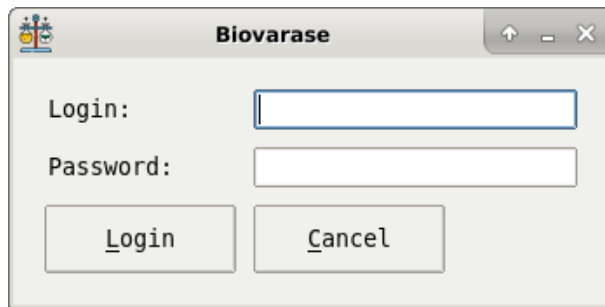
- `bc@hal9000:~$ cd Documents/Biovarase-master/`
- `bc@hal9000:~/Documents/Biovarase-master$ chmod +x biovarase.py`
- `bc@hal9000:~/Documents/Biovarase-master$./biovarase.py`

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Log into application

Once the application is launched, the login mask will open.

To log in you can use the credentials "adm" as the user and "adm" as the password.

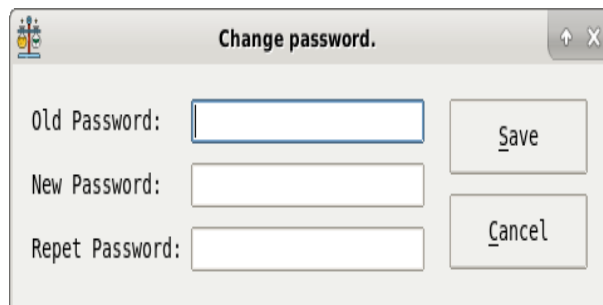


Change password

To change the password, you must go from the menu bar to the File item and then at the bottom click on the "Change Password" item.

Fill in all the fields and save the data.

The next time you open the application you will be able to use the new password.



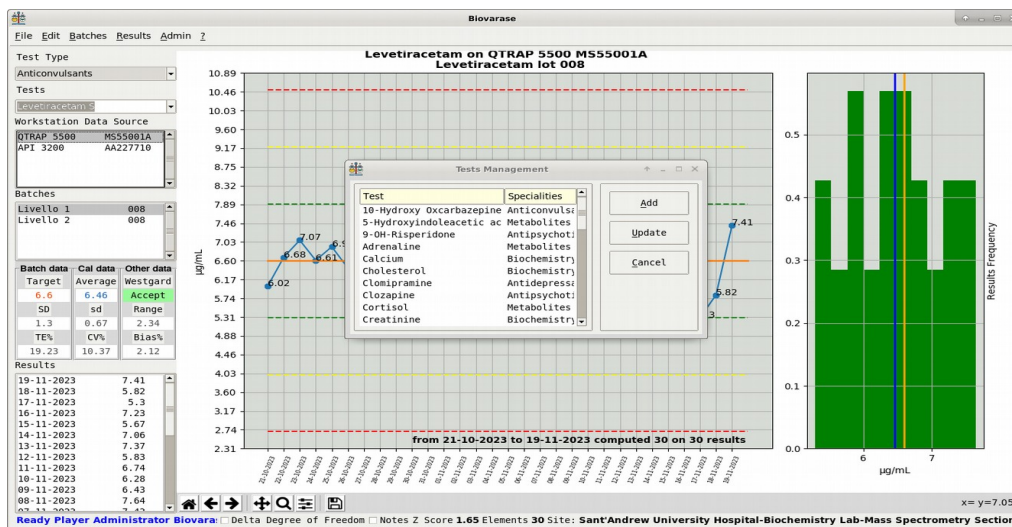
If the logged-in user has set administrator credentials, he can reset another user's password from the user management mask, see the appropriate chapter.

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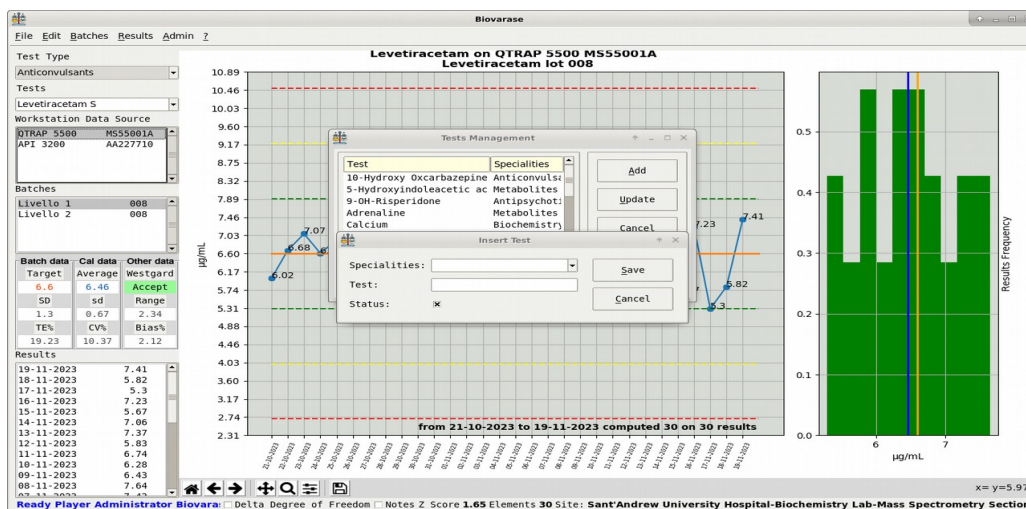
Manage Tests

Creating a test

From the menu bar, select the Edit item and then the Tests item.



In the window that opens press the Add button and in the mask that opens fill in the two fields assigning a specialty and a name to the test.

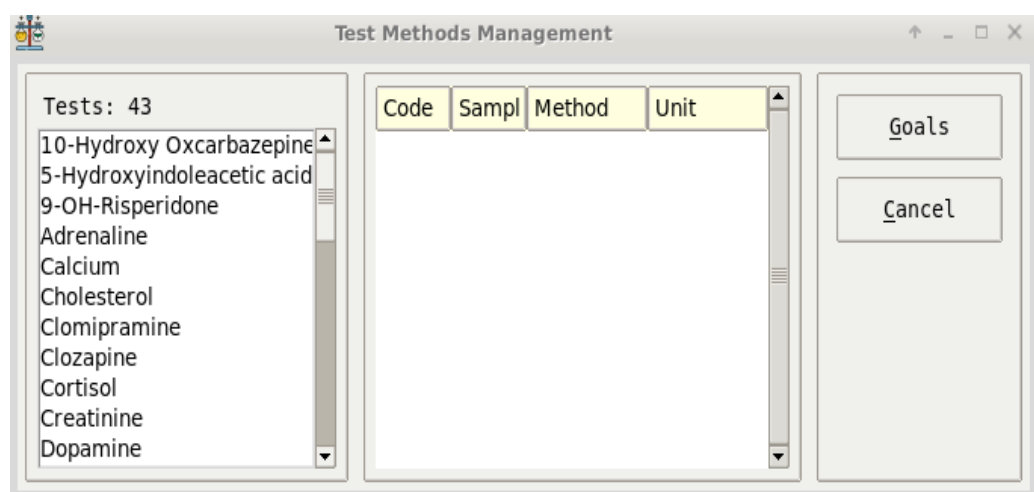


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Associate a test to a method

To use a test, it is not enough to create it but you will need to associate with it a method.

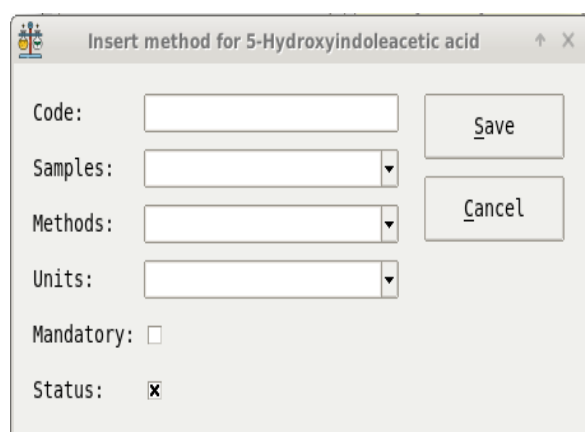
From the menu bar select the Edit item and then the Tests Methods item.



In the window that opens locate on the left list the test you entered.

Click on it twice. In the window that opens fill in all fields and save.

Remember that the code field must be unique.

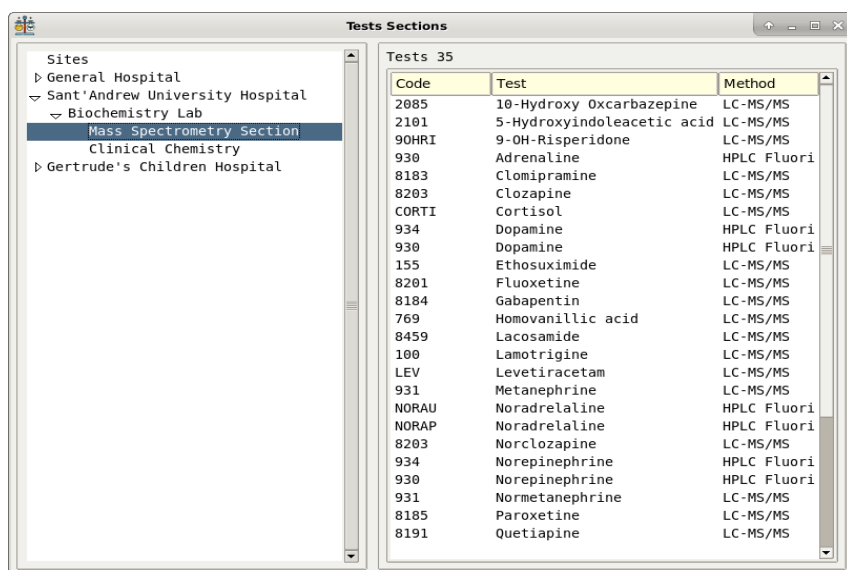


The mandatory field is used to highlight the test when exporting the IQC data if there are no results for the test.

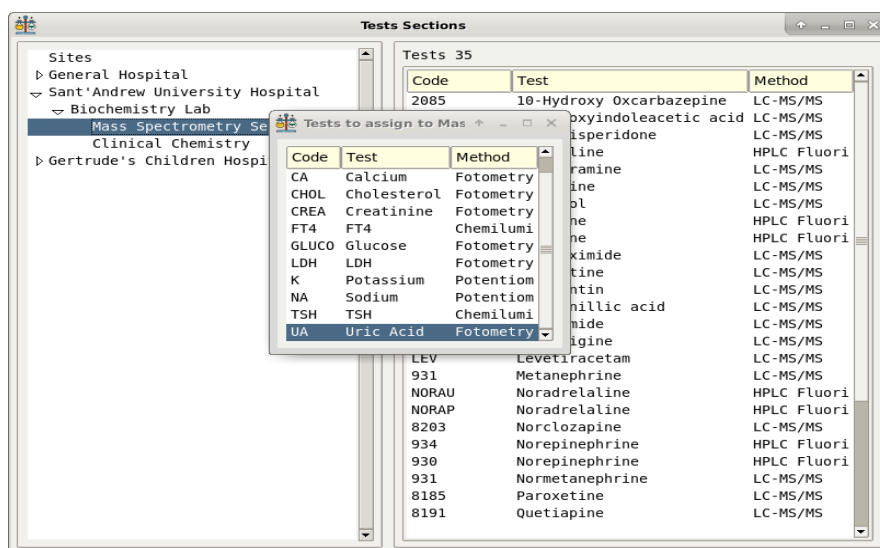
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Assign a Test Method to a section

Now assign the test to the section(s) running it by opening the Tests Sections mask from the edit item on the menu bar. When you open the Tests Sections mask open the tree list on the left until you locate the section to which you want to assign the test.



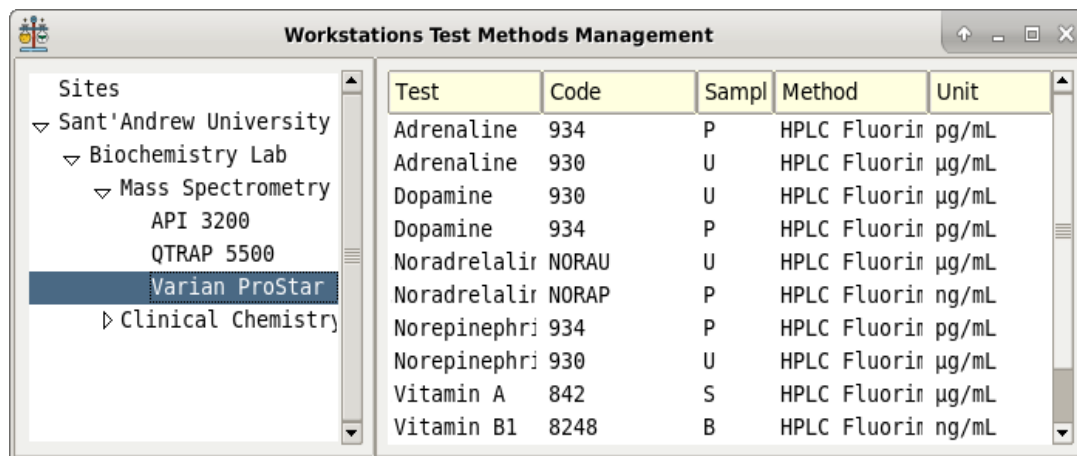
Double-click on it, locate on the list that opens the test you want to assign and double-click on it to assign it to the section, the assignment can be seen because the test appears in the list on the right that represents the executed tests of the section.



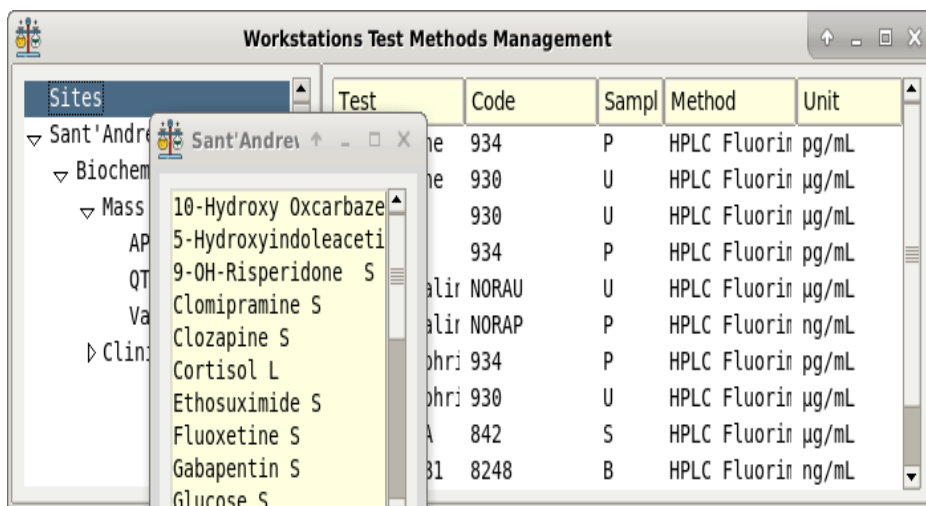
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Assign the test to a workstation

Tests have to be assigned both to the sections that run them but also to the workstations on which they are run. To do this you must first create the workstations, see the dedicated chapter to understand how to do this. Opening the Workstation Tests Methods window from the edit item on the menu bar.



Locate from the left list the workstation to be assigned a test and click on it twice. Select the test on the window that opens and double-click on it to assign it to the workstation. The test will appear in the right-hand list and disappear from the left-hand list.



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Manage Workstations

A workstation physically represents, an equipment model, on which tests are run. So, we may have more than one workstation of the same type i.e. of the same model. For example, we may have more than one Advia 1800 that is a Siemens equipment on which we run the cholesterol test.

So, to create a workstation we must first create the equipment that is the model and then the actual workstation that will be assigned to a given section.

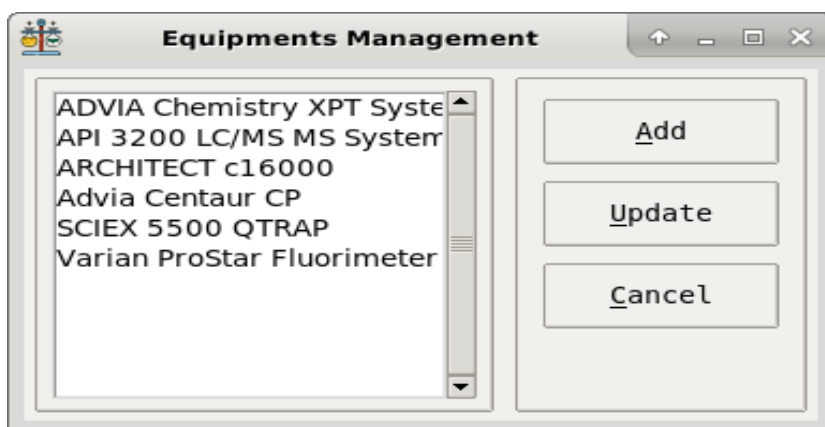
This workstation will be characterized by its serial number and device id which is a parameter that uniquely identifies it and will soon be used to interface Biovarase to the various workstations in a laboratory.

Creating an equipment.

Opening the Equipment's window from the Edit item on the menu bar.

Uses left buttons to add or update an equipment.

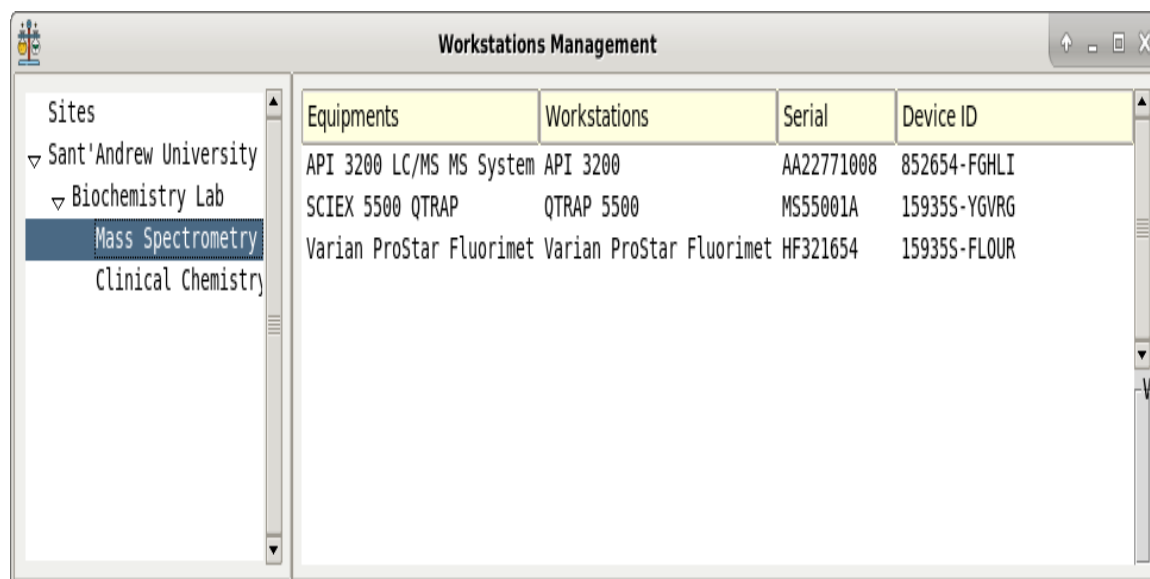
Remember that an equipment is a general model of a workstation.



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Creating a workstation

Opening the Workstations window from the Edit item on the menu bar.



Select a section from the left-hand list and double-click on it to open the mask for creating a new workstation.

The screenshot shows the 'Insert workstation' dialog box. It contains several input fields and two buttons: 'Save' and 'Cancel'.

Equipments: [dropdown menu]
Device id: [text field]
Description: [text field]
Serial: [text field]
Sections: [Mass Spectrometry Section] [dropdown menu]
Rank: [0] [text field]
Status: ☒

Fill in all fields and save. Remember that the device id field must be unique from other entries.

The rank field represents the order in which the workstation is displayed in the main window.

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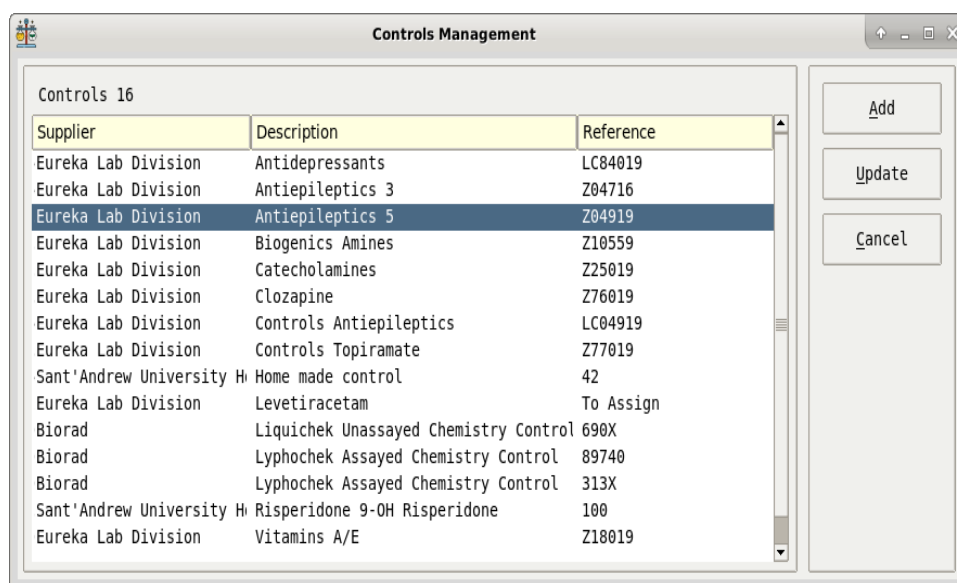
Manage Controls

This type of functionality is accessible only to users who have set the level to a value other than 2.

Creating a control

To insert a control, locate the Controls windows found on the menu bar under Edit.

Open it and enter from the Add button the data for the new control.



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Creating a batch

A batch represents a production of a control with its expiration date and the values, target, maximum and minimum values, associated with the tests that can be performed with that specific batch.

Enter the batches of the controls.

From the menu bar locate the Edit item and then Data.

Click on Data to open the corresponding form.

Test	S	Metho	Unit
10-Hydroxy (S	LC-MS	µg/mL
5-Hydroxyinc	U	LC-MS	mg/L
9-OH-Risperi	S	LC-MS	ng/mL
Clomipramine	S	LC-MS	ng/mL
Clozapine	S	LC-MS	ng/mL
Cortisol	L	LC-MS	µg/dL
Ethosuximide	S	LC-MS	µg/mL
Fluoxetine	S	LC-MS	ng/mL
Gabapentin	S	LC-MS	µg/mL
Homovanilli	U	LC-MS	mg/L
Lacosamide	S	LC-MS	µg/mL
Lamotrigine	S	LC-MS	µg/mL
Levetiracet	S	LC-MS	µg/mL
Metanephri	U	LC-MS	µg/L
Norclozapine	S	LC-MS	ng/mL
Normetanephi	U	LC-MS	µg/L
Paroxetine	S	LC-MS	ng/mL
Quetiapine	S	LC-MS	ng/mL
Sertraline	S	LC-MS	ng/mL
Topiramate	S	LC-MS	µg/mL
Vanillylman	U	LC-MS	mg/L

Control	Lot	Description	Expiration	Target
Antidepress: 002	L1		31-07-202	75.2
Antidepress: 002	L2		31-07-202	260.1
Antidepress: 002	L3		31-07-202	545.8

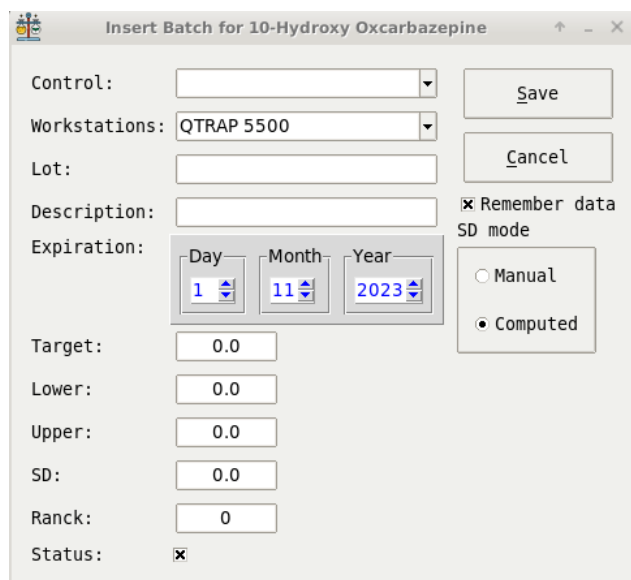
Results: 31	
19-11-2023	65.62
18-11-2023	70.13
17-11-2023	81.22
16-11-2023	76.91
15-11-2023	88.91
14-11-2023	72.66
13-11-2023	65.73
12-11-2023	74.27
11-11-2023	79.91
10-11-2023	66.66
09-11-2023	70.57
08-11-2023	83.73
07-11-2023	81.44
06-11-2023	88.71
05-11-2023	68.66
04-11-2023	83.01
03-11-2023	68.59
02-11-2023	71.5
01-11-2023	63.07
31-10-2023	79.31
30-10-2023	71.42
29-10-2023	76.89
28-10-2023	80.96
27-10-2023	60.75
26-10-2023	66.36
25-10-2023	81.49
24-10-2023	61.56
23-10-2023	81.39
22-10-2023	64.64
21-10-2023	81.36
20-10-2023	79.99

Locate on the left list the workstation on which you are running the test and select it. In the list next to it appears the list of tests you are running on the selected workstation.

Double-click on the test to which you want to assign a control batch.

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In the window that opens fill in all the fields assigning a control, the batch, a description, usually it is Level 1 or Level 2, the expiration date, and the target.



The screenshot shows a dialog box titled "Insert Batch for 10-Hydroxy Oxcarbazepine". It contains the following fields and controls:

- Control:** A dropdown menu.
- Workstations:** A dropdown menu with "QTRAP 5500" selected.
- Lot:** A text input field.
- Description:** A text input field.
- Expiration:** A date picker with "Day" (1), "Month" (11), and "Year" (2023) components.
- Target:** A text input field with "0.0".
- Lower:** A text input field with "0.0".
- Upper:** A text input field with "0.0".
- SD:** A text input field with "0.0".
- Ranck:** A text input field with "0".
- Status:** A checkbox that is checked.
- Buttons:** "Save" and "Cancel" buttons.
- Options:** A checked checkbox "Remember data SD mode" and two radio buttons: "Manual" (unselected) and "Computed" (selected).

If you enter the minimum and maximum value the program will calculate the standard deviation if computed is selected in the "SD mode" options otherwise if manual is selected you can enter the data without any calculation being done.

Note that each batch must be assigned a control and a workstation.

The rank field represents the order in which the batch is displayed in the main window.

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Manage Results

Adding a result

Control results can be entered in two ways. If the user has a level other than 2 from the Data window while for any level from the main program window.

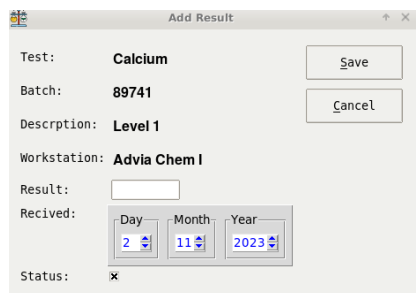
To enter a result referring to a given test, for a given batch run on a given workstation on the main window you must first select the test type from the combo at the top left, then select the test in the combo just below.

By selecting the test, you will see in the list under "Workstation data source" appear the list of workstations associated with the selected test.

Selecting the workstation on which the test was run will cause the list of batches associated with the selected test and workstation to appear in the list below.

Selecting a batch further will cause the results entered previously for the selected batch to appear, if any, and the related levey jennings graph will be drawn.

To enter a new result, make double click on his batch, enter the result in the window that opens and press Save button.



The screenshot shows a window titled "Add Result". It contains several input fields and two buttons. The fields are: "Test:" with the value "Calcium", "Batch:" with the value "89741", "Description:" with the value "Level 1", "Workstation:" with the value "Advia Chem I", "Result:" which is an empty text box, and "Received:" which consists of three spinners for "Day", "Month", and "Year" with values 2, 11, and 2023 respectively. At the bottom left is a "Status:" field with a small 'x' icon. On the right side are "Save" and "Cancel" buttons.

The value will be loaded into the database and consequently onto the graphs. On entering a new result, the current day's date is proposed. If you want to edit a result you can double-click on it.

It will open the same window used in the insertion phase but with the fields filled.

If the user has a level equal to two he can edit the data and also make the result inactive by removing the check on the "Status" control which will cause the result not to be used for the calculation of quality control data or even to make the related graphs. If the user has a level greater than 2 he will also be able to delete the result, the "Delete" button will appear.

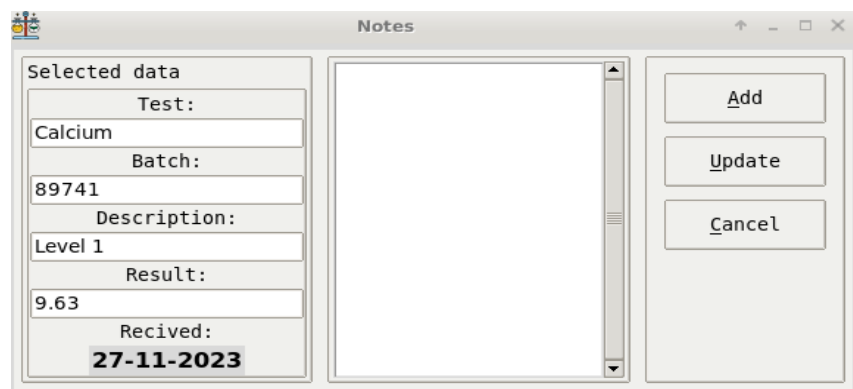
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Adding a note to a result

Sometimes you want to add a comment on an entered or edited value.

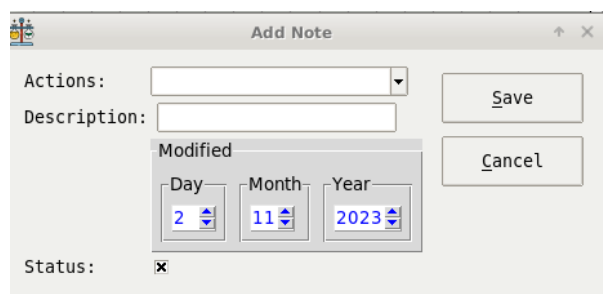
You can do this by putting a check mark on the Notes command on the status bar and then double-click on the result to which you want to add a note.

The following window will open.



The 'Notes' dialog box is shown. It has a title bar with standard window controls. On the left, under 'Selected data', there are fields for 'Test:' (Calcium), 'Batch:' (89741), 'Description:' (Level 1), 'Result:' (9.63), and 'Recived:' (27-11-2023). In the center is a large empty text area for notes. On the right are three buttons: 'Add', 'Update', and 'Cancel'.

By pressing the "Add" button we can add a note.



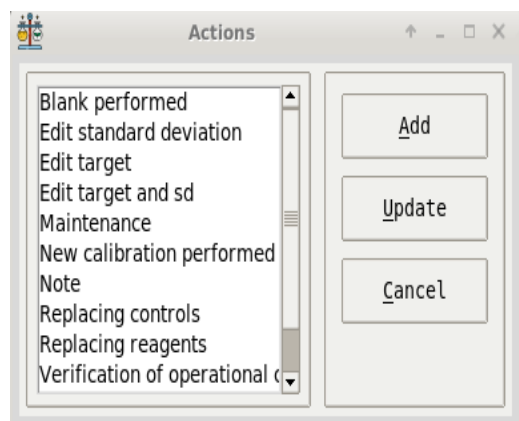
The 'Add Note' dialog box is shown. It has a title bar with standard window controls. It contains a dropdown menu for 'Actions:', a text field for 'Description:', and a date picker for 'Modified' with fields for Day (2), Month (11), and Year (2023). At the bottom left is a 'Status:' field with a checkbox. On the right are 'Save' and 'Cancel' buttons.

We select a preset action, add a comment and save.

We could then later extract this data by exporting it from the appropriate function invocable from the menu bar under File then under Export by clicking on the Notes item. Comments can be exported, in excel format starting from a given date

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Preset actions are managed from the Actions window that can be opened from the menu bar under "Edit"



Manage Users

Users are managed from the Users mask found from the menu bar by clicking on the Adm item and then the Users item.

Only an enabled user can access this window, which means that the user must have set the "level" value to zero.

Once this mask is open, users can be added or modified. You can also reset a user's password by selecting it from the list and then pressing the "Reset" button.

By doing so, the password will be set as "pass".

Assigning the value 0 to a user's rule entry is equivalent to making him or her an administrator and thus giving him or her access to all program features.

Assigning the value 1 means allowing him to edit all menu voices except for the administrator voices.

Assigning the value 2 means allowing him to enter only the results, edit them but not delete them.

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Manage Sites

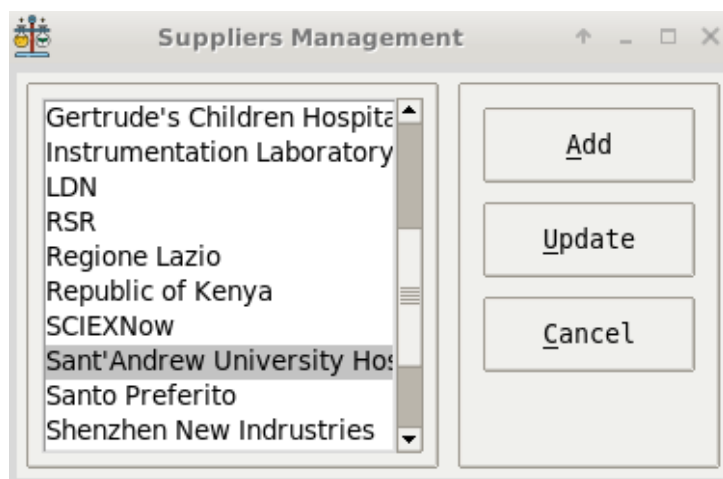
The management of the sites is reserved to the users with preset level to 0 that is that of administrator.

Biovarase is a multi-site application that is able to manage data from different workstations in different clinical laboratories.

For example, it is able to manage the results associated with a particular batch for the cholesterol test coming from different laboratories located in different places and involving different hospitals

To do this you must first of all create references to sites. For example, a hospital will be headed by a private company or a government agency, at least here in Italy it is.

So to create the site "Sant' Andrew University Hospital" we should include in the window Suppliers that is located under Admin voices of the menu bar a voice with "Sant' Andrew University Hospital" and another as "Lazio Region" as this hospital is a public hospital and depends on the Lazio region



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Creating site

Then open the window "Sites" always under Admin and pressing the Add key will open the following window

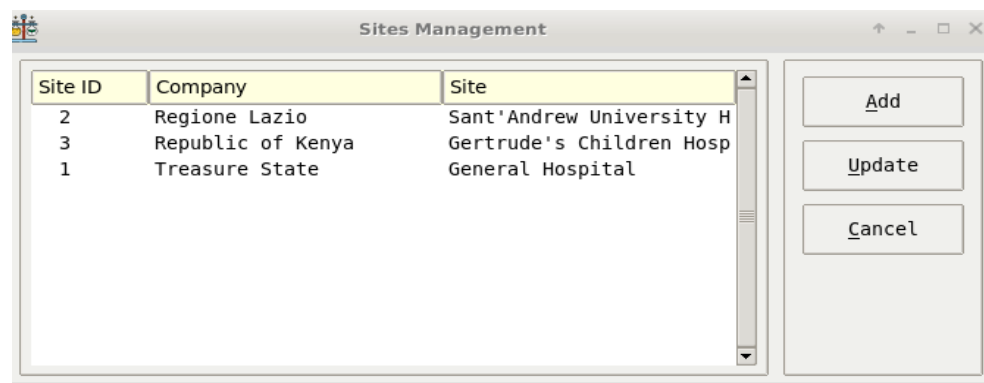


The "Insert Site" dialog box contains three input fields on the left and two buttons on the right. The first field is labeled "Companies:" and is a dropdown menu. The second field is labeled "Sites:" and is also a dropdown menu. The third field is labeled "Status:" and contains a checked checkbox. The buttons are labeled "Save" and "Cancel".

Companies:	<input type="text"/>	<input type="button" value="Save"/>
Sites:	<input type="text"/>	
Status:	<input checked="" type="checkbox"/>	<input type="button" value="Cancel"/>

The first field "Company" represents the parent company while the second "Site" the daughter company.

We can thus add to the same mother other daughter companies



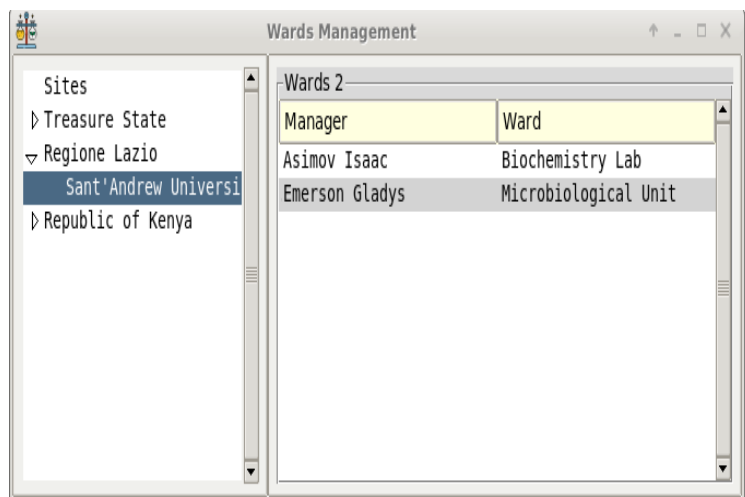
The "Sites Management" window displays a table with three columns: Site ID, Company, and Site. The table contains three rows of data. To the right of the table are three buttons: Add, Update, and Cancel.

Site ID	Company	Site
2	Regione Lazio	Sant'Andrew University H
3	Republic of Kenya	Gertrude's Children Hosp
1	Treasure State	General Hospital

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Once we have created the site we have to create the wards, that is, the laboratories of the site.

To do this we open from Admin the window "Wards"



From the list on the left we want to add a section by clicking on it twice and fill in the fields in the window that opens.

To update a ward, make double click on it row on the right list.

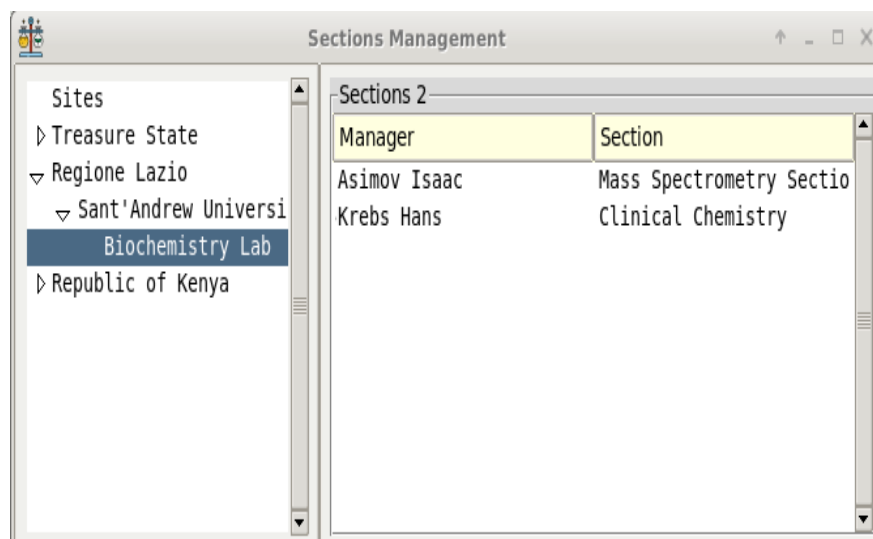
Once created the wards cannot be deleted but only disabled by setting the value of "Status".

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Creating sections

Once we have created the wards we have to create the sections, that is, the laboratory section such as Biochemistry or Emetology or Mass Spectrometry etc. etc. where workstation stay.

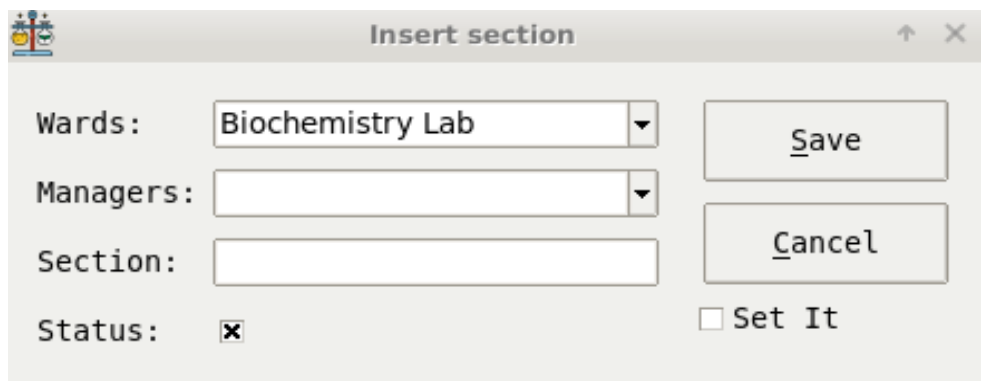
To do this we open from Admin the window "Sections"



Locate on the left list the ward previously created and where you want to create a section and click on it twice to open the data entry window

Fill in all fields and save.

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Insert section

Wards: Biochemistry Lab

Managers:

Section:

Status: ☒

☐ Set It

The field "Set It" if activated will cause the program will point to the data in this section.

In the program directory there is a file called "section_id" where the section id set with "Set It" is written.

To update a section, make double click on it row on the right list.

Once created the sections cannot be deleted but only disabled by setting the value of "Status".

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Plots

Biovarase can generate the following graphs

Levey Jennings

The Levey Jennings chart that is always shown in the main window but can be generated separately, after selecting a workstation on the main window and then clicking on the item in the menu bar under File and then Plots.

This generates a chart summarizing the active plots for the selected workstation,

Youden

The Youden graph can be generated only if you select two batches of the same test and an eworkstation provided that the two batches have the same number of results.

After selecting a workstation on the main window and then

two batches clicking on the item in the menu bar under File and then Youden is generated this type of chart.

TEA

This type of graph can only be generated if the selected test is adsorbed to the data for the analytical goals.

Export data

Biovarase can export the results data in excel format. From the menu bar select the Export item on the File item. Choose an item and click on it.

Analytical Goals

To manage analytical goals, we need to assign values, if any, of CVw, CVb, Imp%, Bias%, TEa% to a test on the mask for assigning methods to tests.

To do this, once a method has been assigned to the test from the Test Methods Management mask, press the Goals button and fill in the fields with the required data.

Enable the export of the test by enabling the check field named "To export"

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Quick data analysis

Selecting this item opens a window that asks for the date of the data to be exported.

By default, the current date is set. Clicking on Export are exported all the IQC data performed on the selected day referable to the section set on the program.

Counts

Export the number of checks performed for tests

Controls list

Shows the list of controls used with expiration dates and supplier

Database operations

From the menu bar select the Database item on the File voices.

Now you can execute a vacuum of the SQLite 3 or a dump of the database. Dumping the database generate a text file in the application directory named as `yyymmddhhmmss.sql`, something like `20231101133155.sql`