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

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.

Biovarase also allows calculation of the accuracy of two sets of results from different workstations.

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Logical organization of Biovarase

Biovarase makes it possible to manage the internal quality control data of a clinical laboratory.

Thus it allows a given result to be associated with a given test performed on a given workstation present in a given laboratory

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==3.0.2
- numpy==1.16.2
- scipy==1.1.0
- xlwt==1.3.0

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 make from a cmd shell something like

py -m PyInstaller --windowed --name = biovarase.py

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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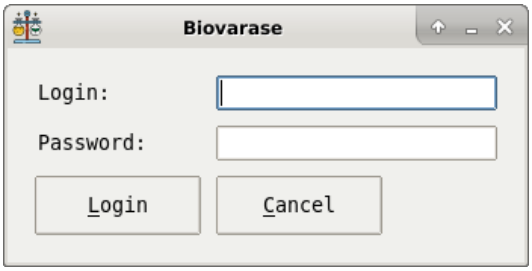
Log into application

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

To log in, at the first time, you can use the credentials "adm" as the user and "adm" as the password.

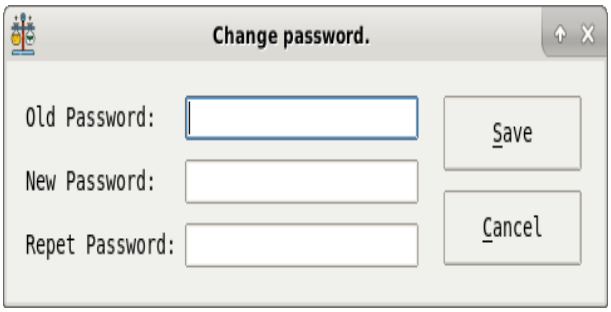


How to change password

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.



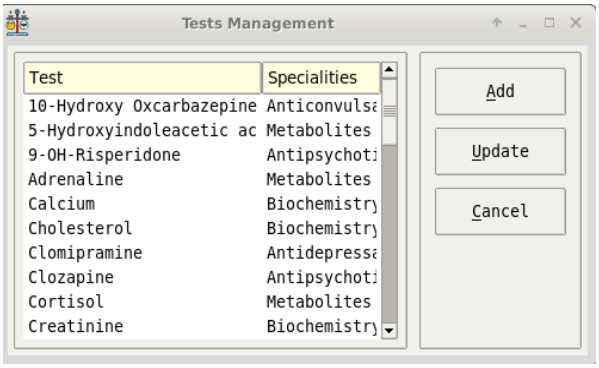
Manage tests

Creating a test

Only a user with administration rights can create or modify a test.

To create a test from the menu bar, select the *Admin* item and then the *Tests* item.

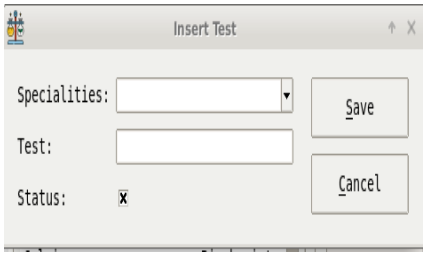
In the window that opens press the *Add* button.



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

In the *Specialities* combo are the values that will be used to search for the test in the main window in the combo named Test Type.

Press *Save*.



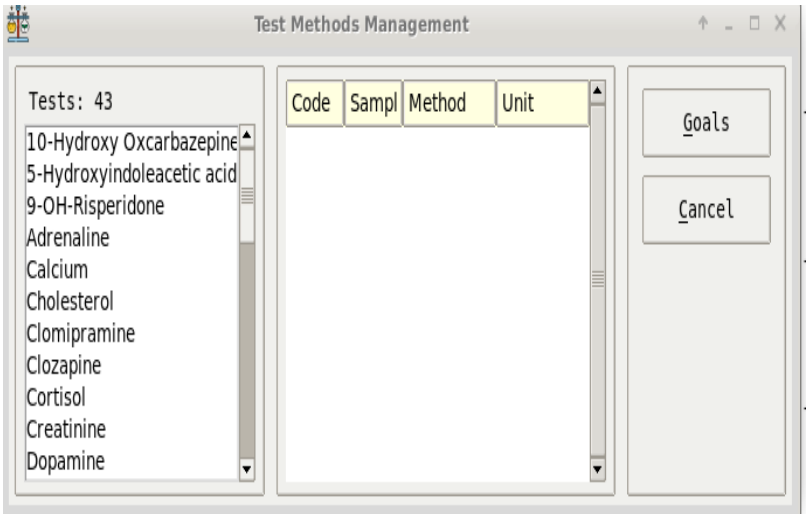
Associate a test to a method

To use a test you 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.

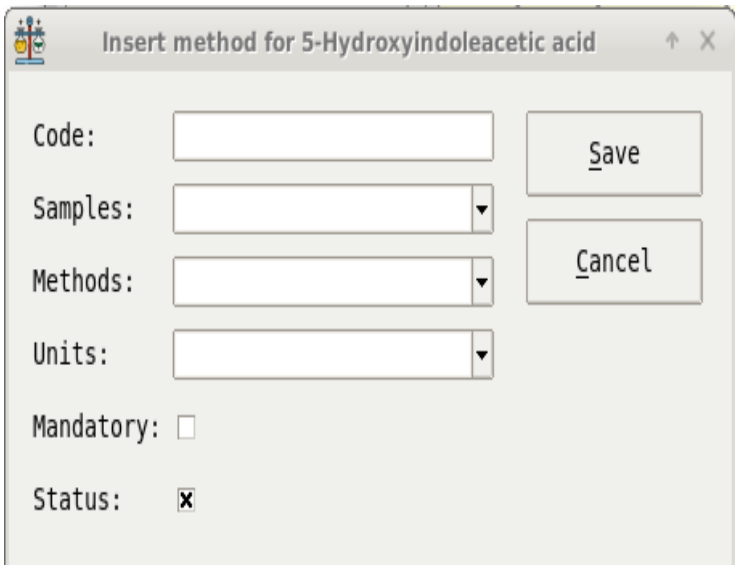
Click on it twice.



In the window that opens fill in all fields and save.

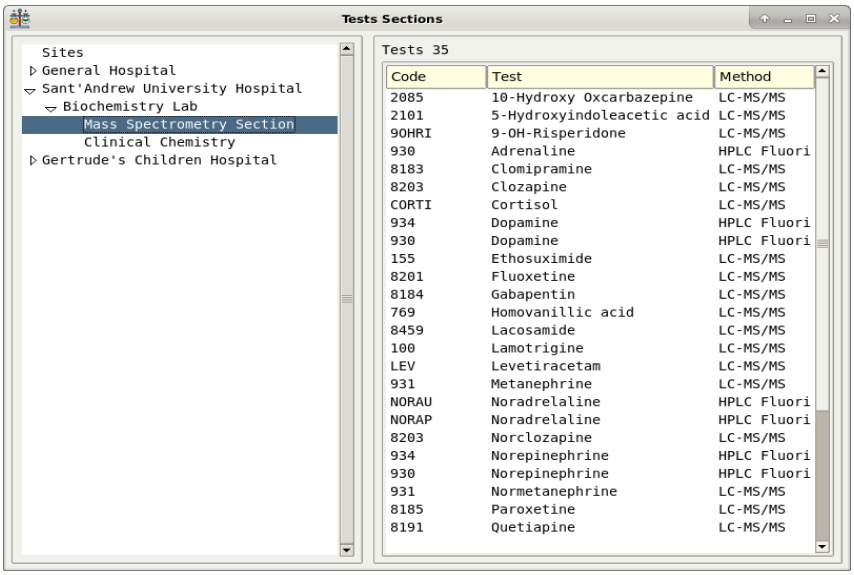
Remember that the code field must be unique.

The *Mandatory* field is used to highlight the test when exporting the IQC data to report that there are no results for this test.

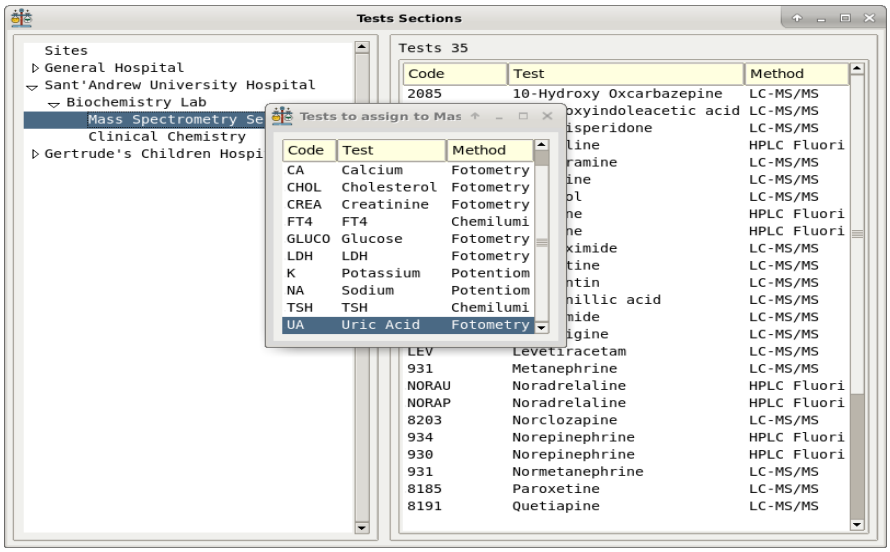


Assign a test to a section

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

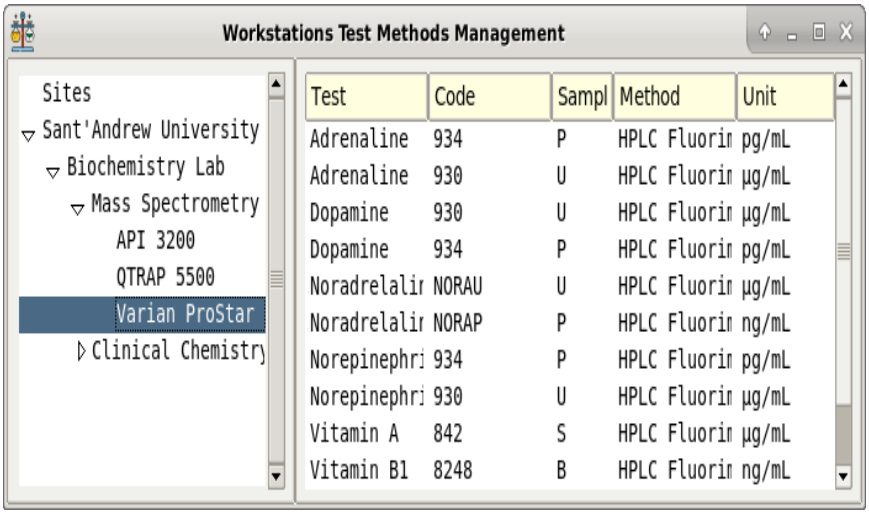


Double-click on it, locate on the list that opens the test you want to assign and double-click on it to assign it to the section, the assignment can be seen because the test appears in the list on the right that represents the executed tests of the section.



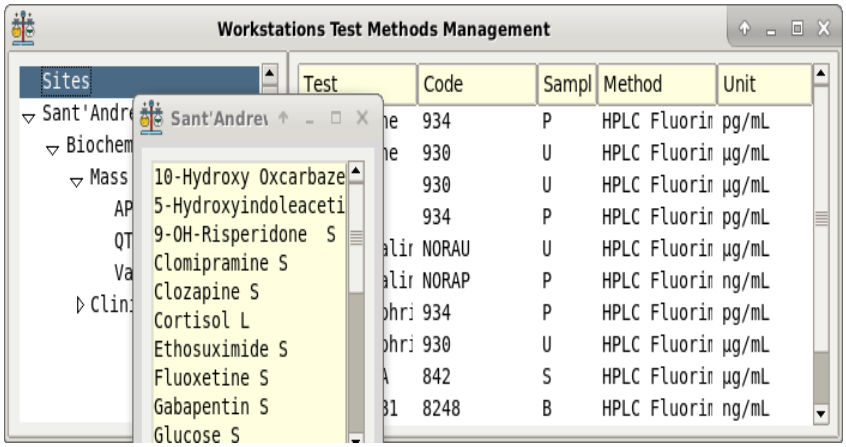
Assign a test to a workstation

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.



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.

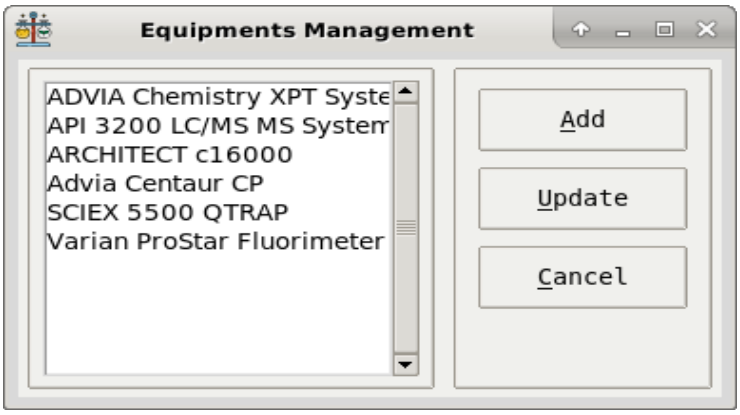
Creating an equipment

Only a user with administration rights can create or modify a test.

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

Uses left buttons to add or update an equipment.

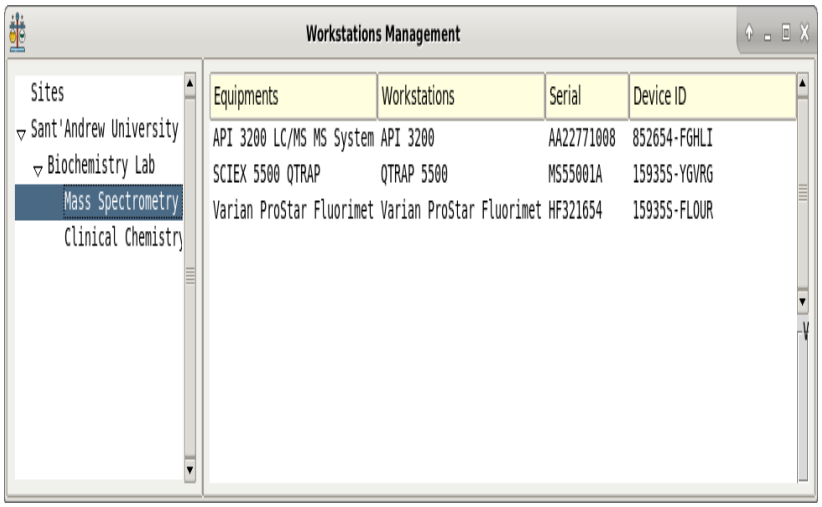
Remember that an equipment is a general model of a workstation.



Creating a workstation

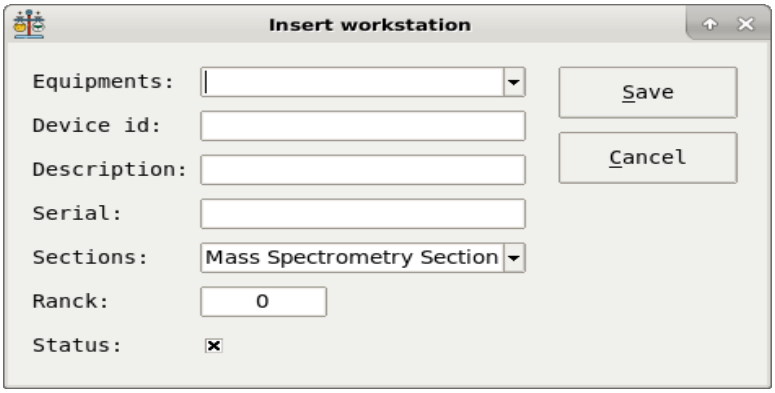
Opening the *Workstations* window from the *Edit* item on the menu bar.

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



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.



Manage Controls

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

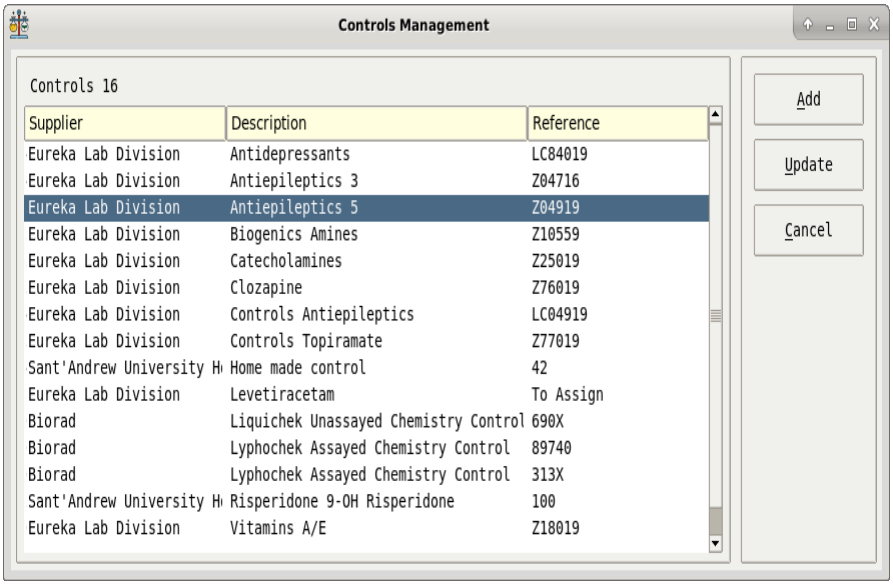
Creating a controls

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.

You can update a control but no delete it.

You can only enable it using *Status* field.



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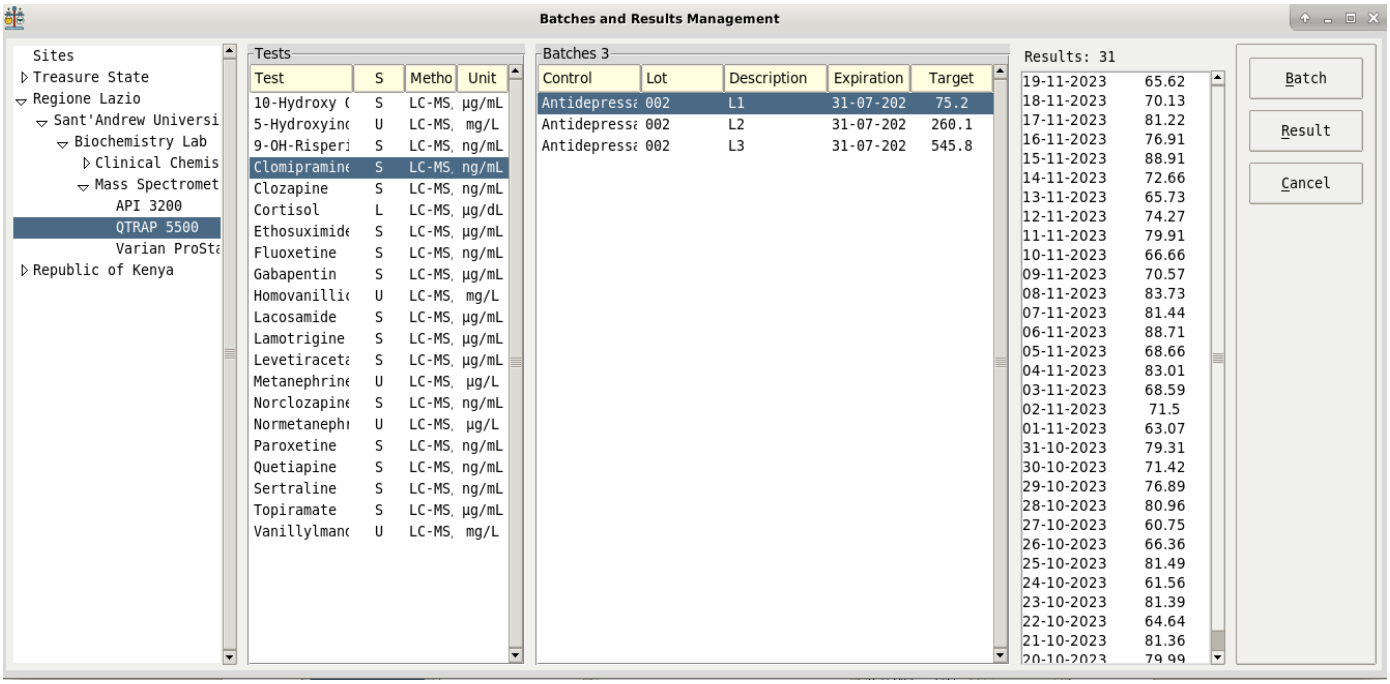
Creating a batch

This functionality is reserved to user with at least level 1 set.

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.

To enter the batches of the controls from the menu bar locate the *File* item and then *Data*.

Click on *Data* to open the corresponding window.



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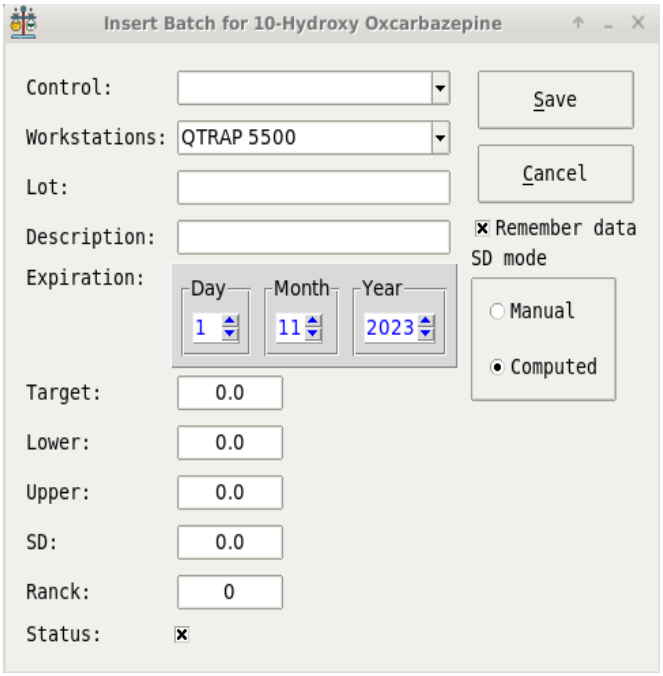
In the window that opens fill in all the fields assigning a control, the batch, a description, usually it is Level 1 or Level 2, the expiration date, and the target.

If you enter the minimum and maximum value t, *Lower* and *Upper* fields,he 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.

If set, *Remember data*, once a batch has been entered the next time the window is reopened, the previous data will be proposed again



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Manage results

Adding a result

Control results can be entered in two ways.

If the user has rights other than 2 from the *Data* window otherwise from the main program window.

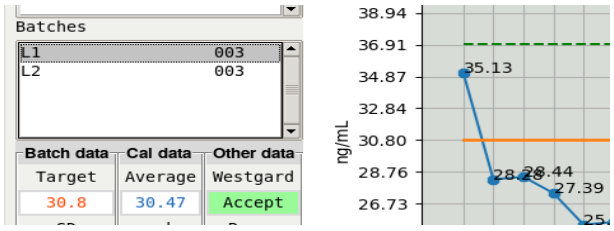
To enter a result in the main window you must first select the *Test Type* from the combo at the top left, then select the *Tests* in the combo just below.

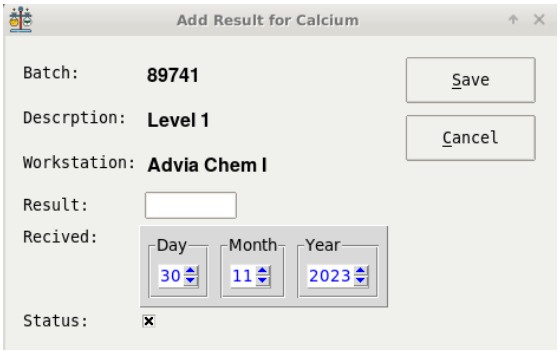
By selecting the test, you will see in the list under *Workstation data source* appear the list of workstations associated with the selected test.

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 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, rights, equal to 2 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, rights, greater than 2 he will also be able to delete the result, the *Delete* button will appear.

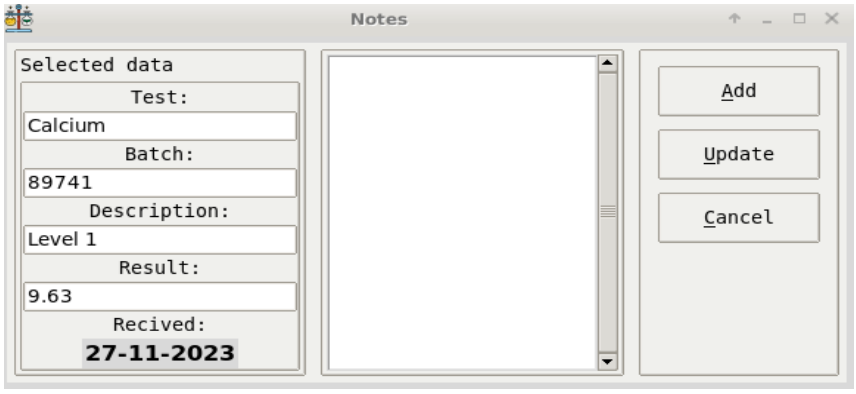
Adding a note to a result

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

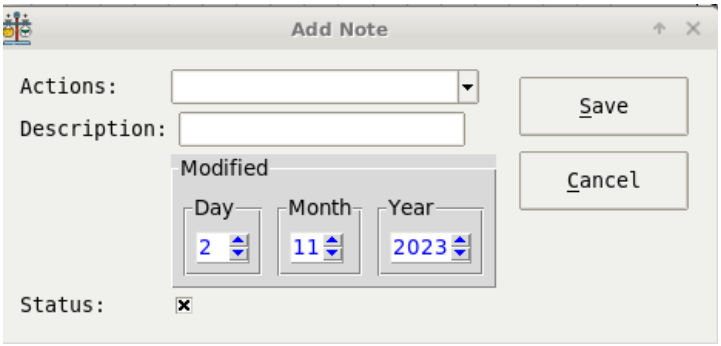
You can do this by putting a check mark on the *Notes* command on the *status bar* and then double-click on the result to which you want to add a note.

The following window will open.

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



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 *Exports* by clicking on the *Notes* item.

Comments can be exported, in excel format starting from a given date.

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

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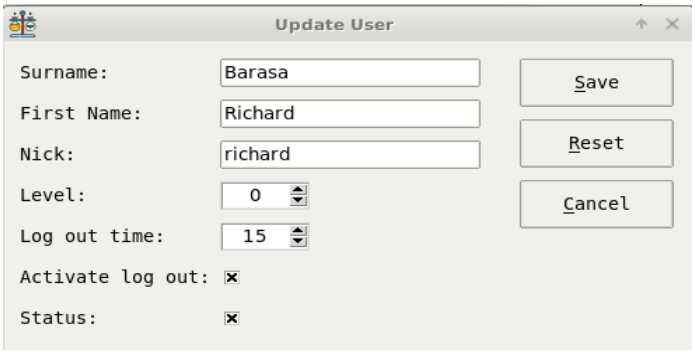
Manage Users

Users are managed from the *Users* window found from the menu bar by clicking on the *Admin* 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 window is open, users can be added or modified.



Nick field is the user identify request on login

The *Level* field is used to assign rights to the user, read below.

Log time out is used to determine the automatic closing time, it is the program idle time that must elapse to automatically close the program.

Activate log out enables the automatic log out function.

When creating a user, the default password is "pass".

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 to edit all menu voices except for the administrator voices.

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

Manage Sites

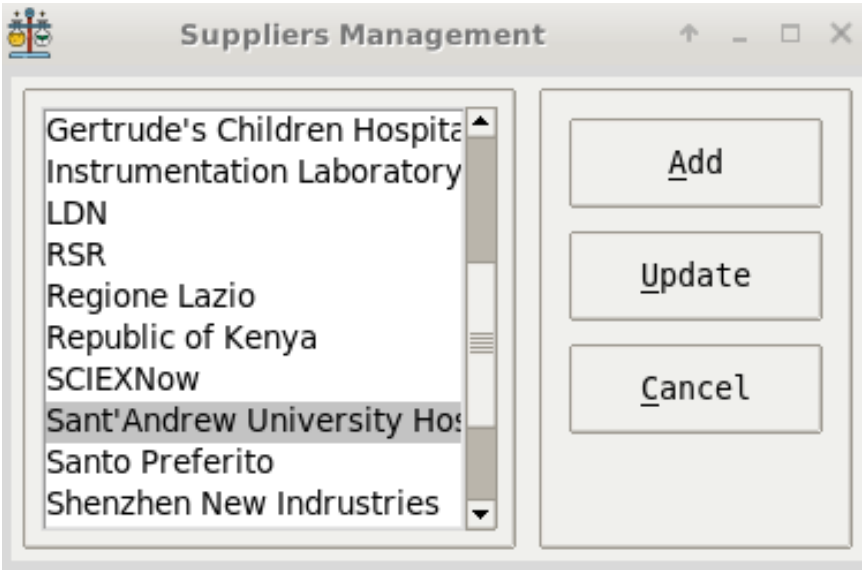
The management of the sites is reserved to the users with preset level to 0 that is that of administrator.

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

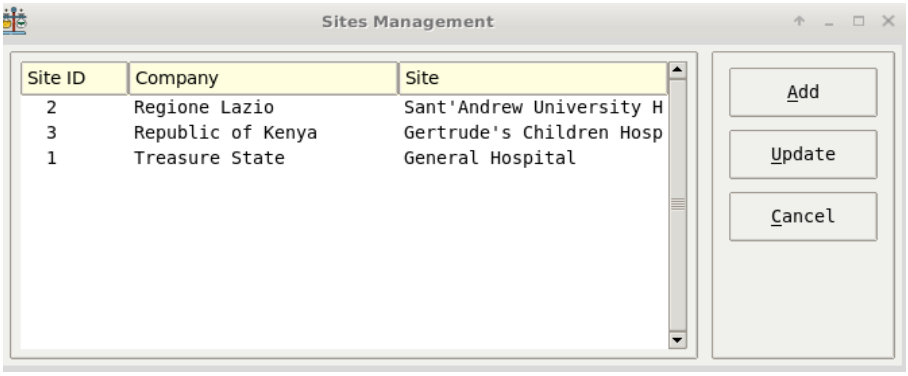
For example, it is able to manage the results associated with a particular batch for the cholesterol test coming from different laboratories located in different places and involving different hospitals

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 locate 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

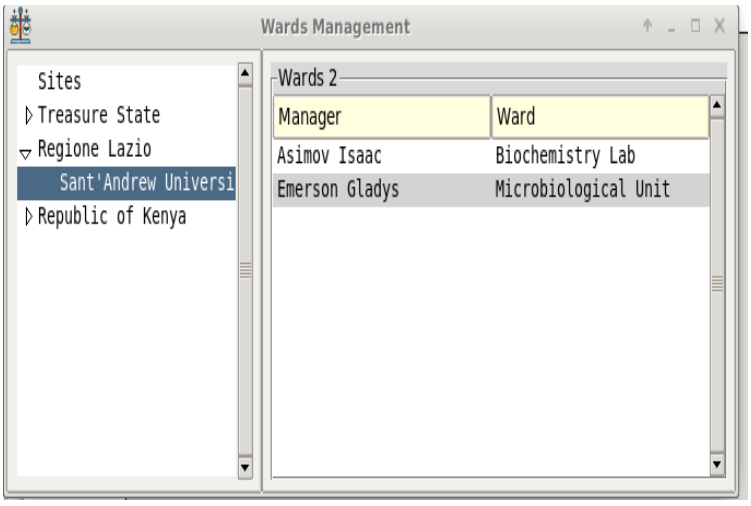
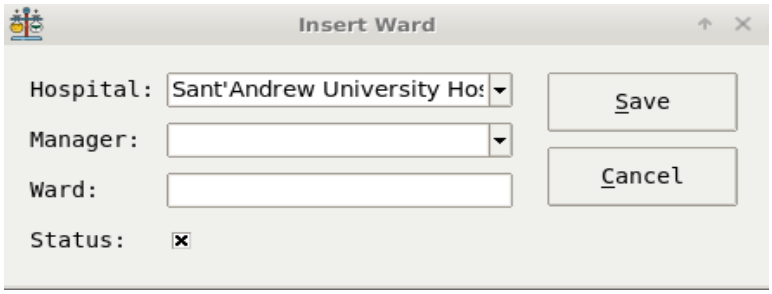


Creating sites

Open the window *Sites* under Admin	
Pressing the *Add* key will open the following window. 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	

Creating wards

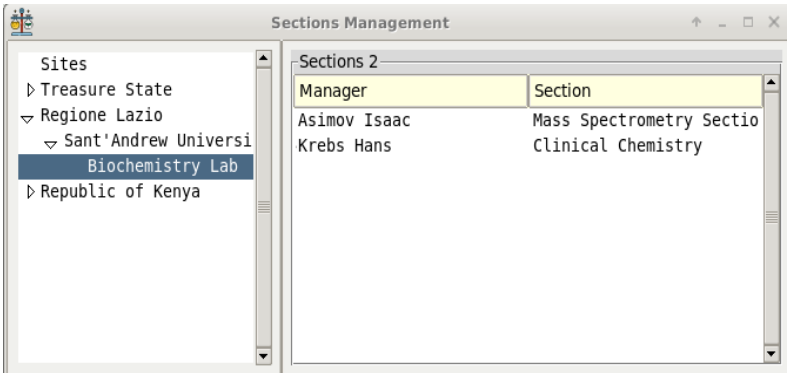
Once we have created the site we have to create the wards, that is, the laboratories of the site.

To do this we open from *Admin* the window *Wards* From the list on the left we want to add a ward to selected site, hospital,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*.	

Creating sections

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

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



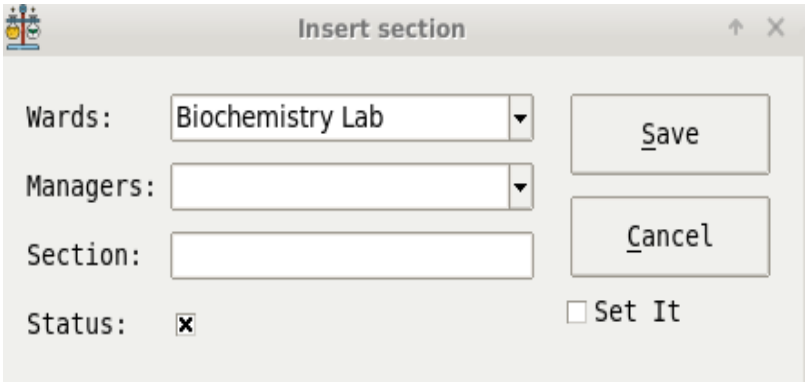
Locate on the left list the ward previously created and where you want to create a section and click on it twice to open the data entry window

Fill in all fields and save.

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

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*.



Plots

Biovarase can generate the following graphs

Levey-Jenning

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 *Plots* 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 same workstation provided that the two batches have the same number of results.

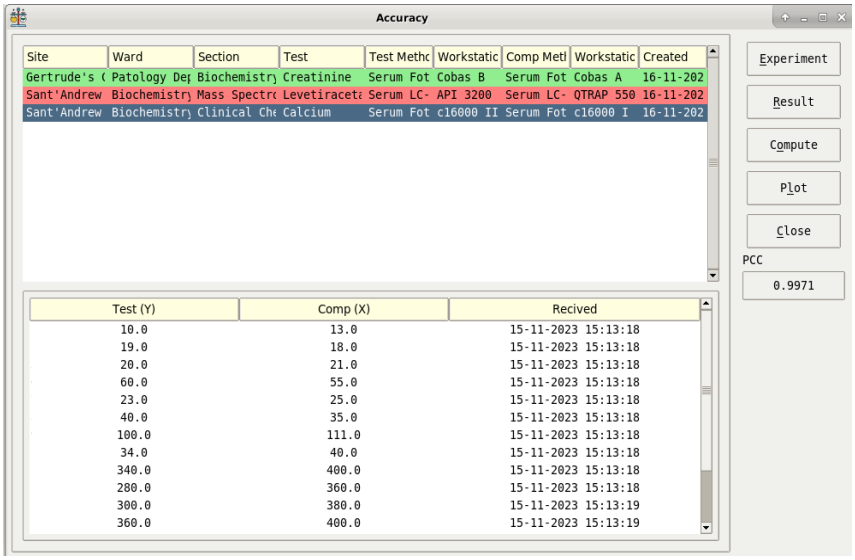
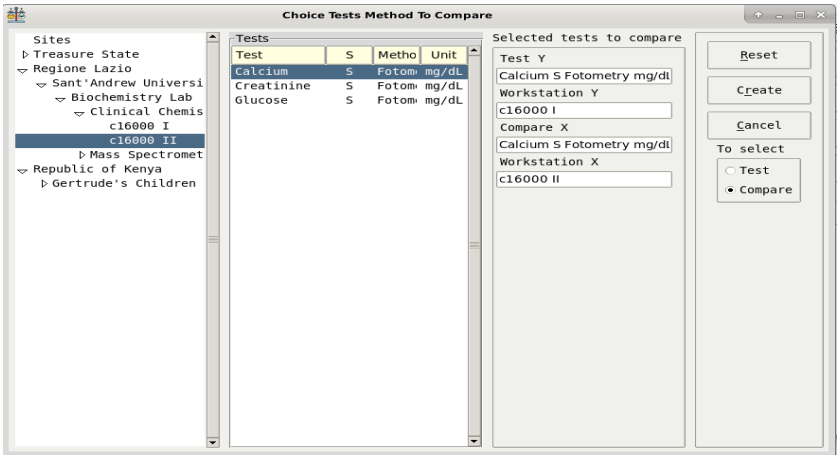
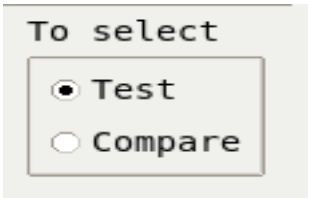
After selecting a workstation on the main window and then two batches clicking on the item in the menu bar under *Plots* and then *Youden* is generated this type of chart.

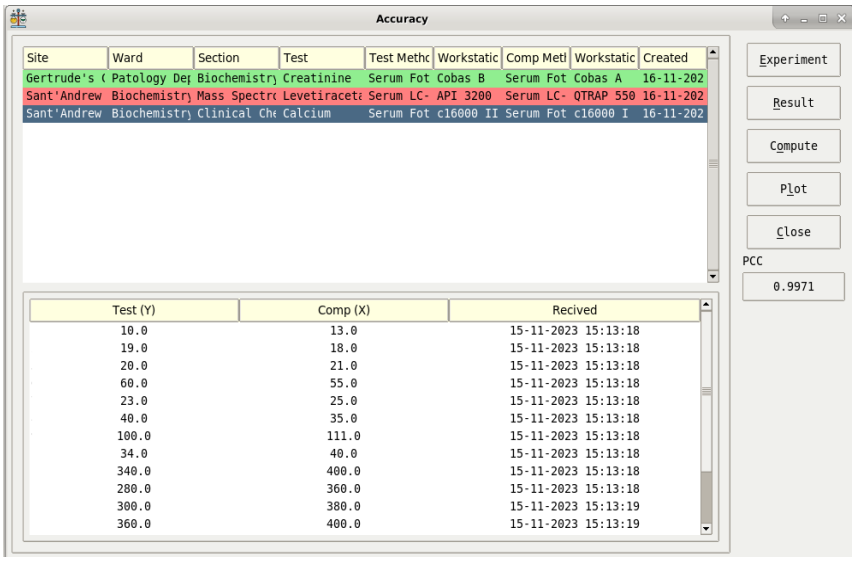
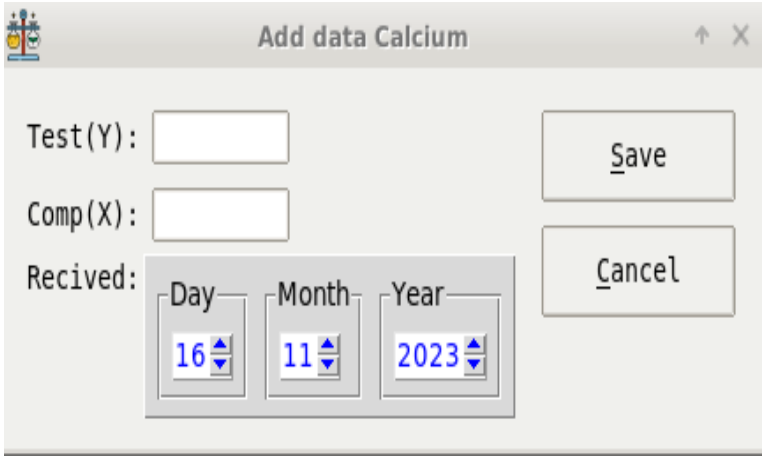
Tea

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

Accuracy

Biovarase allows calculation of the accuracy of two sets of results from different workstations.

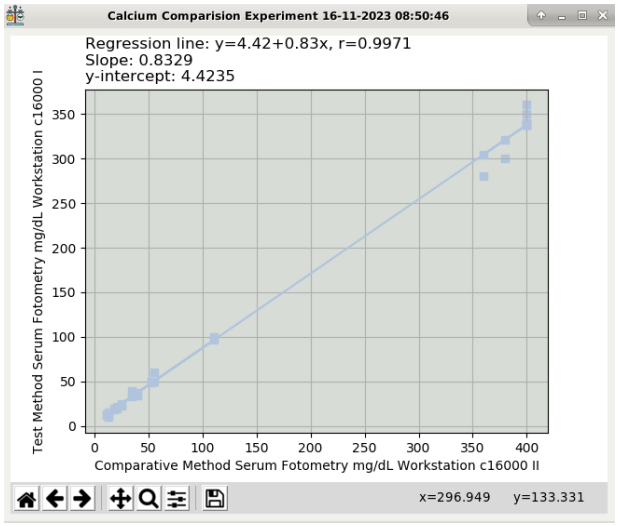
Locate on menu bar under *Plots* group the voice Accuracy *and click on it*	
Click on *Experiment* button to open window where we will choose the two test methods to compare We have to choose the test ad its relative workstation. After press *Create* button a new experiment will be create	
Remember to select the right choice.	

Select the right experiment to add the results pressing the *Result* button	
Fill all field and press *Save* do add the coupled data to the selected experiment.	

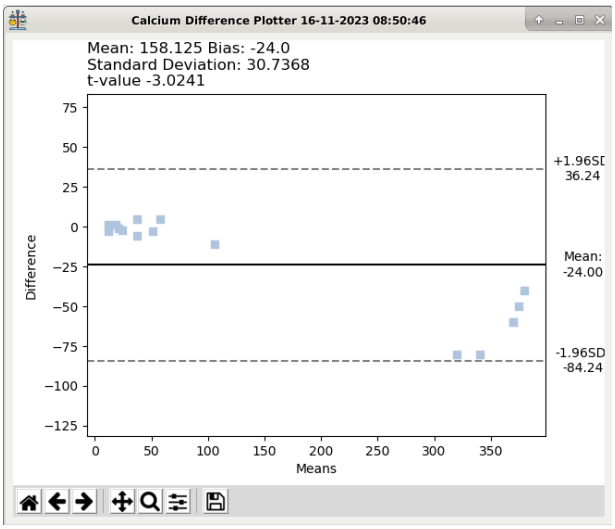
When you have finished adding data press Compute to calculate the PCC (Pearson Correlation Coefficient) and eventually save it.

If you save the PCC the experiment line if the value is greater than 0.970 will be green if less will be red.

Press *Comparisions* or *Differences* button to see related graphs.



ComparisionPlot



Differences plot

Exporting data

Biovarase can export the results data in excel format.

From the menu bar select the *Exports* item on the *File* items.

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 window for assigning methods to tests.

To do this, once a method has been assigned to the test from the *Test Methods Management* window, 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.*

Quick data analysys

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.

Control list

Shows the list of controls used with expiration dates and supplier.

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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 yyyymmddhhmmss.sql, something like 20231101133155.sql

Audit trails

Each batch or result entry or change operation is automatically written to the audit tables to keep track of both the changes made to a particular record and who and from where, from which computer, this changes result from .

It is possible to view audit trail data by opening the *Audit Trails* window found on the menu bar under *Admin*.

This functionality is reserved for Biovarase administrators then for users with level set to 0.