



Version 4.0

## Analysis Setup

The purpose of 'Analysis Setup' routine is to configure the testing process in the laboratory. Properly configured tests within this routine, insure the proper work flow, PROLIS has been built around. The routine provides the functionality to set up various required elements of the testing process. Obviously, the routine is applicable to components, the testing practice is carried out in the laboratory, not to the services outsourced.

An analysis set up under this routine, could be an analysis with a single analyte like shown below in the snapshot or the one with multiple analytes, for example CBC with WBC, RBC, HGB etc. The analysis being set up in the routine, is configured to be performed on an automatic Analyzer like CEL-DYN 3500 or is configured to be performed manually. For example Pregnancy Serum, shown below.

The routine is equipped to define control levels, Lot numbers, the expiration of the control material and the predetermined value ranges of each control level.

**Note:** Assays performed on Analyzers not communicating with PROLIS, are considered to be manual.

The screenshot shows the 'Analysis Setup' window with the following details:

- Analysis ID:** 1
- Analysis Name:** Pregnancy Serum
- Department:** Serology
- Instrument:** No Communicating Instrument
- Tab:** Analytes
- Table:**

Prolis	Inst	Analyte Name
301	301	Pregnancy Serum
- Fields below table:** Analyte ID, Analyte Name, Inst Test
- Buttons below table:** +, X, XX

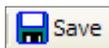
Above snapshot represents this routine in which the 'Pregnancy Serum' analysis has been displayed. We will discuss each and every part of this routine in detail.

## Mode Selector



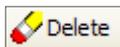
or

The first button on the toolbar is a mode selector button which is used to select either 'Edit' mode or 'Add' mode by clicking the button it self.



### Save command

The command is available both in 'Edit' (default) mode and the 'New' mode but is activated only when the required fields (Labeled with red color) and conditionally required fields (labeled with lavender Color) have the data. Otherwise the command is disabled.



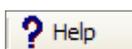
### Delete command

The command is only available in 'Edit' mode and is activated only when a record is being displayed.



### Cancel command

The command is always available and is used to exit from the routine. It does not prompt you to save the data.



### Help command

The command is always available and is used to access the help files.

## Analysis core fields

Analysis ID	Analysis Name
<input type="text" value="1"/>	<input type="text" value="Pregnancy Serum"/>
Department	Instrument
<input type="text" value="Serology"/>	<input type="text" value="No Communicating Instrument"/>

Analysis ID
<input type="text" value="1"/>

**Analysis ID** is a numerical required field, a unique value of which is automatically assigned by PROLIS. The user can change the PROLIS assigned value to any other value of her choice but the new value must be unique.

**Analysis Lookup button**,  is used to view and browse the list of Analyses in the system.

Analysis Name
<input type="text" value="Pregnancy Serum"/>

**Analysis Name**,  is a 60 characters long required field and could have any value. Following are some recommendations. CBC, Chemistry I, CX7, Axsym, Chemistry General, Sickle Screening etc.

Department
<input type="text" value="Serology"/>

**Department**,  is the drop down field from within a desired department can be selected to associate with the analysis being configured.



**Supportive Routine access button** is used to access the building routine. The routine this button accesses, depends where this button is located. The button located next to the department drop-down field, will access the Departments routine and the one next to Instrument drop down, will access

the laboratory Instruments building routine.

### Analysis building Tabs

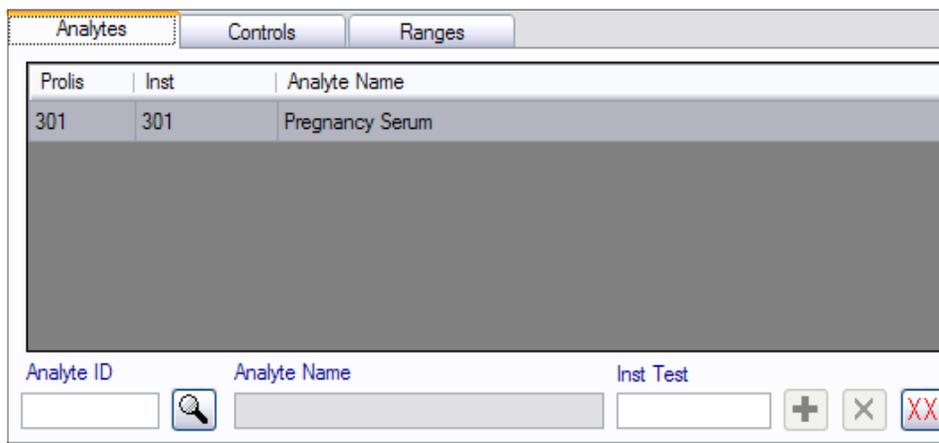
The system provides 3 tabs to build an analysis.

#### Analytes Tab

The tab provides the functionality to specify individual analytes to be analyzed under this analysis being configured.

The major constituent of this tab is the **grid**, to hold the association between the analyte and its identification for the lab Instrument. In the given snapshot, the analyte ID labeled

'Prolis' is 301 the assay ID of the Instrument is also 301 which is default and must be changed to the actual assay ID of the Instrument. In this case since it is a manual single analyte analysis, it can be left unchanged.



**Analyte ID** is the field where the analyte ID can be either typed directly or fetched from the displayed list of analytes using the next **Lookup button**. The next field **Analyte Name** does not accept any user input and is there for a proper identification of the desired analyte,

**Inst Test** is the field to type in directly the actual assay ID of the Instrument. Its default value is the same as that of **Analyte ID** field.

The **+** labeled button is available only upon having all required values (the value of **Analyte ID**, that of **Analyte Name** and that of **Inst Test**) and is used to enter this association in to the **grid**.

The **X** labeled button is available only upon selecting an analyte association from within the grid and is used to remove the selected analyte association from the grid (analysis).

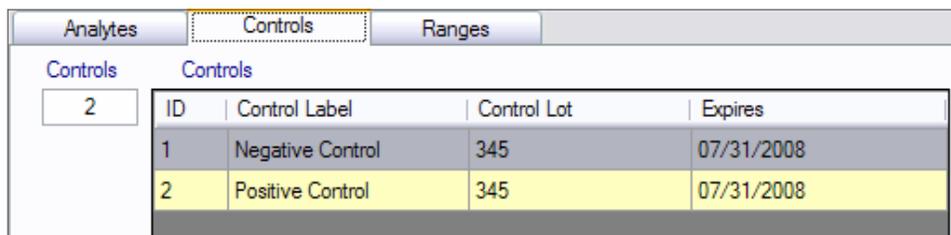
The **XX** labeled button is available only if there is one or more analyte associations in the grid. The button is used to clear the whole grid with one click.

#### Controls Tab

The tab provides the functionality to enter the number of control levels, the name, Lot number and the expiration date of each level. Prolis supports a

maximum number of 24 levels of controls. So, upon entering a number between 1 and 24, Prolis will populate the same number (as typed in the **Controls** field) of control entry lines in the **Grid**.

**Control Label** (Name), **Control Lot** and the **Expires** (expiration) can be entered/typed in to the grid.



## Ranges Tab

The tab provides the functionality to enter or select the predetermined control value ranges for controls entered under the Controls Tab.

PROLIS calculates the number of place holders to hold the value range of each Control Level corresponding to each analyte entered in the Analyte Tab.

The formula used in this calculation is as follows;

$$\text{Place Holders (Ranges Tab)} = \text{Analytes (Analytes Tab)} \times \text{Control Levels (Controls Tab)}$$

The first column in a place holder, is the name of the control. For example 'Negative Control' and 'Positive Control'.

The second column is the name of the analyte. For example 'Pregnancy Serum'.

The third column labeled 'Mean Normal' is to enter the mean value of the control if the analyte is quantitative and is presented to accept numerical values. But if the analyte is of Choice type (qualitative) like shown above, the column turns in to a drop down box populated with result choices of the analyte. The user is expected to select the predetermined choice result of the control. For example in the snapshot, the Negative Control should have the value 'Negative' selected in this column.

The 4th column labeled '(+-) Abnormal' is the column serving a dual purpose. If the analyte is numerical (quantitative), the corresponding field will be presented like a text box and accept the numerical values. This is the factorial value to calculate the low and high limits. Upon entering this value, PROLIS will calculate the low and high limits and display in appropriate columns. But if the analyte is of the result choice type (qualitative), the corresponding field will turn in to a drop down box with the analytes result choices populated. The user is expected to select the unexpected result thus making the assay invalid.

The 5th column is to either enter the low limit of the control or let PROLIS calculate the low limit automatically if the analyte is numerical (quantitative). In case the corresponding analyte is qualitative, this field is not accessible and PROLIS will display zero (0) in it.

The 6th column is to either enter the high limit of the control or let PROLIS calculate the high limit automatically if the analyte is numerical (quantitative). In case the corresponding analyte is qualitative, this field is not accessible and PROLIS will display zero (0) in it.

Control	Test Name	Mean Normal	(+ -) Abnormal	Low	High
Negative Control	Pregnancy Serum	Negative	Undetermined	0	0
Positive Control	Pregnancy Serum	Positive	Undetermined	0	0