# PROLIS™
RESULTS

Version 4.0

PROLIS RESULTS

The resulting routines in Prolis, are used to apply the analysis values to the tests performed on the specimens and those of the controls run with the analysis. There are 2 routines for resulting context. The manual Result Entry & Review and the Apply Results for the testing performed on the automatic instruments and the results downloaded to Prolis using the interface.

Result Entry & Review

The routine is used to result controls and specimens for the manual tests, review the results for correctness, commenting the results and finally release the results. This routine is also aimed to be used to result the manual descriptive analysis like cytology and or microbiology.
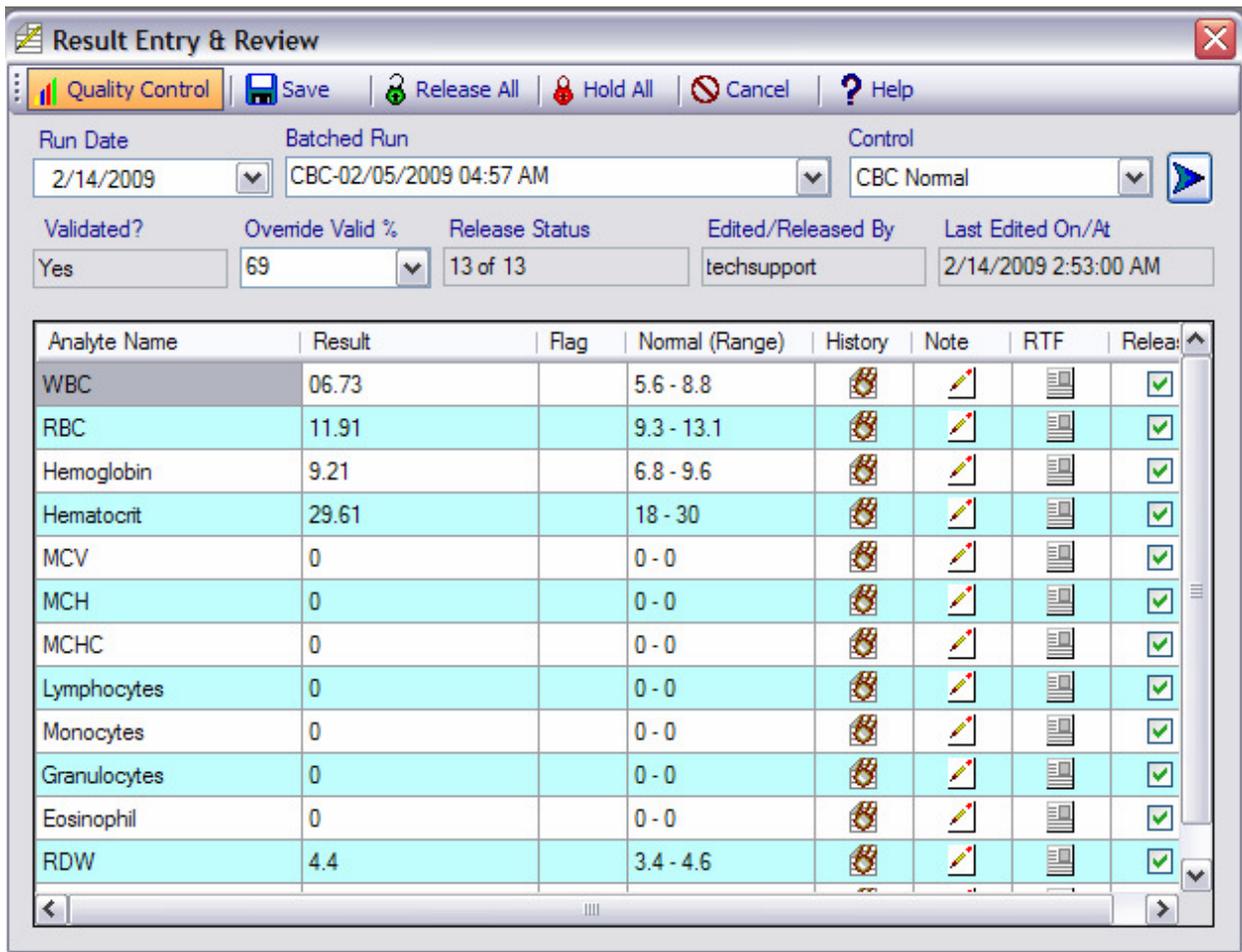
Functional Bar: The buttons on the top functional bar, are used as explained below;

| Control/Accession Switch | Save Button | Result Release | Result Hold | Cancel button | Help Button |

Control Accession Switch: This button is clicked to switch the routine to enter the results for the controls and those of the accessions. The display status of this switch, controls the functions of the other parts of the routine. For example if this switch is displaying 'Quality Control', the Release All button will release the results of controls, the Hold All button will hold the results of control, the 'Save' button will function in the control context and so on.
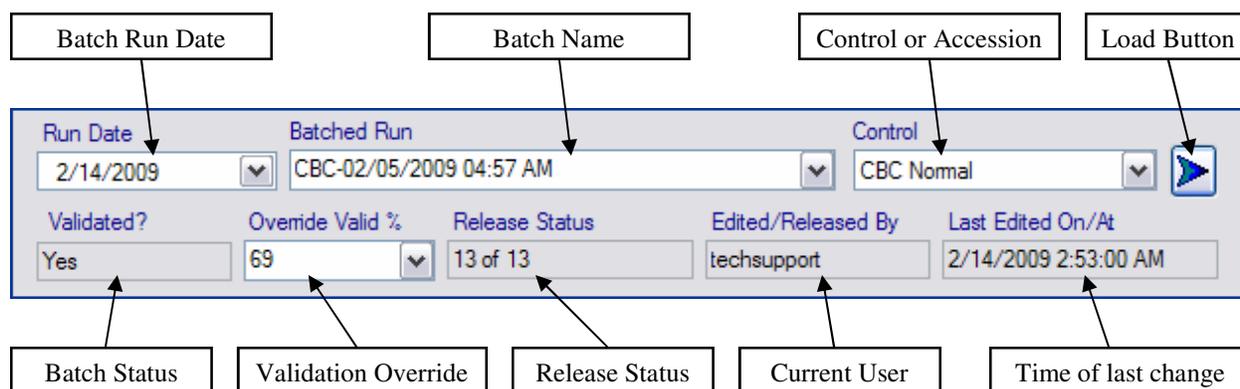
Save Button: This button is clicked to save the changes made by the user both for the accessions as well as the controls.

Release All Button: This button is clicked to mark the displayed results of accession or control, to be released. The accession results can not be released until the applicable batch is not validated. The batch is validated by entering the results of the controls first and released. If the control values are within range, the batch is validated upon saving the last control results. See the procedural note for detail, later in this chapter.

Hold All Button: This button is clicked to mark the displayed results of accession or control, to be held for any reason. Held results can not be reported in reports, Client Service or in Outreach.

Cancel Button: This button is clicked to exit the routine.

Help Button: This button is used to access the online help.

Batch Run Date	Batch Name	Control or Accession	Load Button

Run Date	Batched Run	Control	
2/14/2009	CBC-02/05/2009 04:57 AM	CBC Normal	▶

Validated?	Override Valid %	Release Status	Edited/Released By	Last Edited On/At
Yes	69	13 of 13	techsupport	2/14/2009 2:53:00 AM

Batch Status	Validation Override	Release Status	Current User	Time of last change

Batch Run Date: This date field is used to filter and access the batches in the system. This field is effective only if the Control or Accession drop down box is empty.

Batch Name: This drop down box holds all the batches run dated the value of previous field. This field is populated according to the date selected in the previous field or is populated on the priority bases , making the base to the value of Control or Accession field on its right.

Accession or Control drop down: This drop down is populated if any batch is selected in the Batch Name drop down (previous field). If the Batch Name drop down field has no batches populated or with batches present but none selected, this field behaves like a free text box. The user can type any accession in it to fetch the results form. But if the batch is selected in the previous field, this drop down is populated with either the set of controls ran with the selected batch or with all the accessions contained in the selected batch. The user can select any accession or control from within this drop down to fetch the result from.

Load Button: This button is clicked to fetch the results or results form of the control selected in the previous field or the accession either selected or freely typed according to the situation.

Batch Status: This field displays 'Yes' if the selected batch has been validated. That means the control results have been entered and are in to get the batch validated. The field will say 'No' if the selected batch is not validated which means the user can not release the results of any accession ran under the selected batch. The has no access to this field.

Validation Override: This drop down field is applicable to the batches ran for the multi-test analysis. For example CBC and the general chemistry. The percentage values within this drop down are calculated based upon the total number of analytes ran for the batch, not available on the instrument. For example, on a chemistry instrument capable of running 28 chemistry, if only five tests have been run on all the accessions, the percentage values within this drop down will represent only five tests, not 28. If Prolis is controlling the instrument via bi-directional interface, only five tests will be ordered to the instrument for all control levels thus supporting the reagent conservation.
Through this field, Prolis provides you the flexibility to validate the batch by offering you the option of lowering the percentage value of controls being in the range, to accommodate any malfunctioning channel. PROLIS strongly suggests to document the cause of lowing the percentage. The percentage should not be lowered to override the situation of controls being out of range. The intended cause to use this field covers only a malfunctioning channel or the reagent outage.
This field is available only while entering the results of controls, not when processing the accession.

Release Status: This field displays the number of released results.

Current User: This field displays the logged in user.

Last Edit Time: This field displays the date and time of the last change made to the control or the accession.

1	2	3	4	5	6	7	8

Analyte Name	Result	Flag	Normal (Range)	History	Note	RTF	Release
WBC	8.85	N	3.5 - 11.5	🔩	✏	📄	☑
RBC	4.9	N	4.2 - 5.5	🔩	✏	📄	☑
Hemoglobin	16.8	N	12 - 17.1	🔩	✏	📄	☑
Hematocrit	27	L	35 - 50	🔩	✏	📄	☑
MCV	97	N	80 - 100	🔩	✏	📄	☑
MCH	29	N	27 - 33	🔩	✏	📄	☑
MCHC	34	N	32 - 36	🔩	✏	📄	☑
Lymphocytes	48	N	10 - 50	🔩	✏	📄	☑
Monocytes	6.78	N	2 - 8	🔩	✏	📄	☑
Granulocytes	56	N	37 - 80	🔩	✏	📄	☑
Eosinophil	6.90	N	1 - 8	🔩	✏	📄	☑
RDW	14.5	N	11 - 15.5	🔩	✏	📄	☑

Result Grid: This multi-column grid displays all the tests for the selected control or the selected accession along with the result column, the flag, the history column, the Note column, the RTF column and the Release column.

1 - Analyte Name: As is obvious from the name, this column displays each analyte in the Control or the Accession.

2 - Result: This column is built on the fly as each cell has different characteristics. Analytes with numeric results have this corresponding free text box where you can enter a free text. For a non numeric text, system will warn you but will accept the entry. Analytes with the Choice type results have the corresponding cell with the drop down box populated with the all possible selectable results thus no room for errors. The snapshot on the right side is showing all possible values configured for the analyte 'Urine Culture' where the user can select any value.

Analyte Name	Result	
THINPREP PAP	Negative	▾
Urine Culture		▾
	No Growth	
	10,000	
	50,000	
	>=100,000	

3 - Flag: This column contains the value indicating status of the Control or the accession. For controls, the options are 'IN' or 'OUT'.
For the accession, options are 'N = Normal', 'A = Abnormal', 'L = Low', 'H = High', 'P = Panic', 'LP = Low Panic', 'HP = High Panic'

4 - Normal Range: This column lists the normal range.

5 - History: The button in this column is clicked to calculate the history of the corresponding analyte.

6 - Note: The buttons in this column are used to enter any comment about the corresponding test. After the user enters the comment for the test result, the color of the button is changed.

Has Comment
No Comment
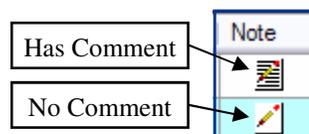
7 - RTF: The RTF column is used to enter the descriptive result for the corresponding analyte. Like the previous field, if underlying field has the descriptive result, the color of the button will be changed.

Has Result
No Result
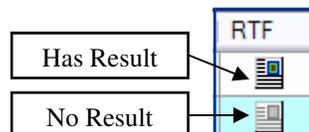
8 - Release: Each check box in this column, is used to release or hold the result of the corresponding analyte for the applicable control or the accession.

Procedural Note
The routine makes accessions accessible only upon batching the accessions governed by various analyses set up in the system. This routine is intended to be used to enter the results for the analyses run manually. Though results produced by automatic instruments, can be entered using this routine.

1. Click the Accession/Control Switch to select the Quality Control.
2. Enter the appropriate date in the Batch Run Date field that will populate the available batches in the Batched Run drop down.
3. Select the desired batch that will populate the controls ran for the batch. For example CBC.
4. Select the first control the results of which you need to enter. For example Low Control.

5. Click the 'Load' button that will display the result form to enter the result.
6. Enter all the results. Type in the numeric results and select in the Choice type results. A check is placed in the corresponding 'Release' field of the analyte automatically. This check does not release the result but simply marks the result to be released upon saving.
7. Adjust the Validation Override percentage according to your situation.
8. Save your entries by clicking the 'Save' button. The system will ask you to digitally sign the results. Sign it.
9. Repeat this process for all the controls in the batch. When the last control (of the required no. of validating controls) is saved, the system validates the batch provided a required number of results are in range for each control.

Note: The number of controls required to validate a batch, could be equal to or less than the total number of controls assigned to the analysis. Following is a matrix indicating the regulatory requirement.

Total No. of Controls assigned	Required minimum no. of Validating Controls
0	0
1	1
2	2
3	2 or 3
4	2 or more
5	3 or more
6	3 or more

10. Though system requires the results of validating number of controls only but it is recommended to enter the results of all assigned controls for the analysis.
11. Click the Accession/Control Switch to change its mode to the accession which will populate the accessions ran for the batch.
12. Select the first accession and click the 'Load button.
13. Enter the results of all the displayed analytes.
14. To enter a comment for a specific analyte result, click the corresponding 'Note' button that will open the following displayed comment entering dialog.

- **Type in the comment as a free text or click the 'Phrase Lookup' button to select any existing saved phrase in the system. The selected phrase can be**
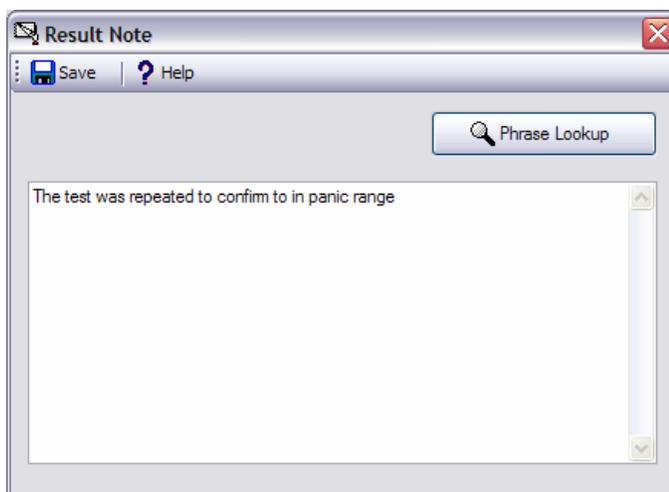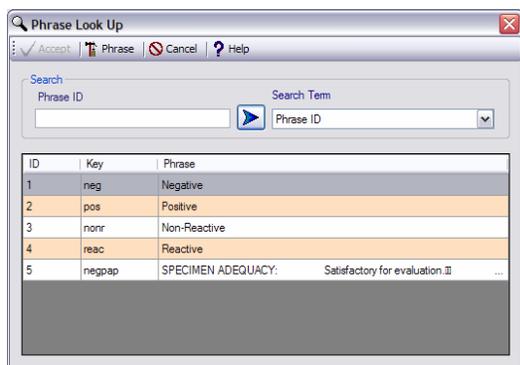
edited without affecting the saved one. The comment is 250 characters or less.

- **Save the comment you just entered by clicking the 'Save' button that will close the comment dialog but after saving your entry.**
- **If you need to remove the previously entered comment, simply access it by clicking the 'Note' button in the main routine. Select the comment text and erase it followed by clicking the 'Save' button.**

15. If you need to enter a descriptive result with possibly any image or a picture. Click the 'RTF' button which will open a sub routine as shown below.

- The Extended Result Routine has some characteristics of a word processing application. You may enter the descriptive result as a free form text by typing directly in the space provided or pull and paste any of the saved phrases by clicking the phrase lookup button.

- You may rearrange the present text in the field with the help of various buttons in the top function bar.
- You may insert an image in to the descriptive result by using the appropriate button.
- Click the 'Save' button to save the result and close the sub routine.
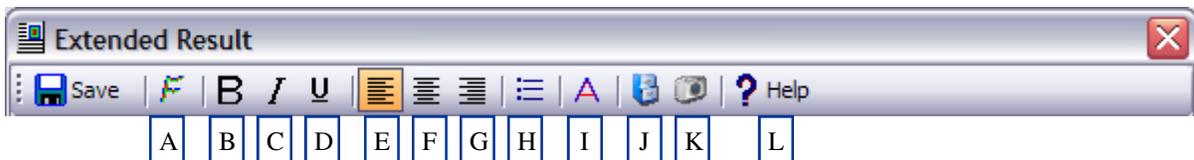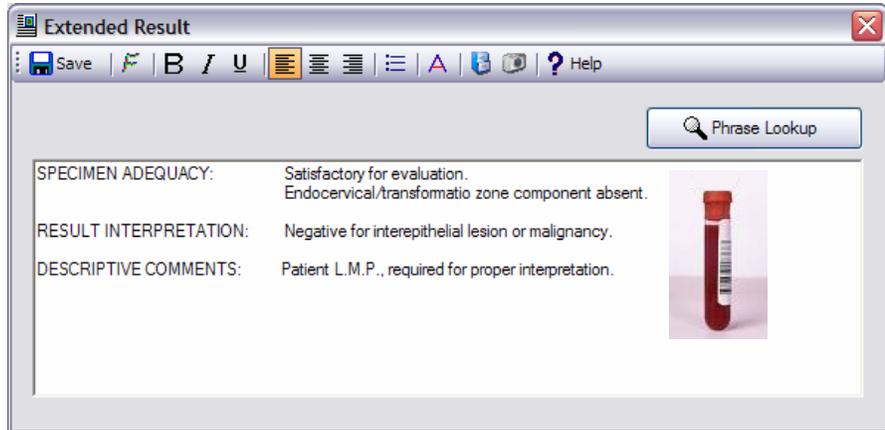
A. Font Selection button.
B. To make the selected text "Bold' or 'Regular'.
C. To make the selected text "Italic' or 'Non Italic'.
D. To underline the selected text or change back.
E. To left align the text.
F. To center align the text.
G. To right align the text.
H. To create a bulleted list.
I. To change the color of the text.
J. To insert an image from a file.
K. To capture an image from a twain compatible device.
L. Help button.

16. After you are done entering the results, click the save button. If the results are marked to be released and the accession controlling batch is validated, you will be asked to sign the results. Sign it. The results will be saved and available to be reported.

17. Please note that results will be saved for the batches not validated but not released even if marked to be released.

Apply Result

This is an optional routine and is provided as a part of the Equipment Interface, to achieve the automation. The routine is used to apply the results downloaded from the equipment, to the controls and accessions ran in the batch. The routine provides a very high level of automation but a very limited control of the result manipulation to the user.
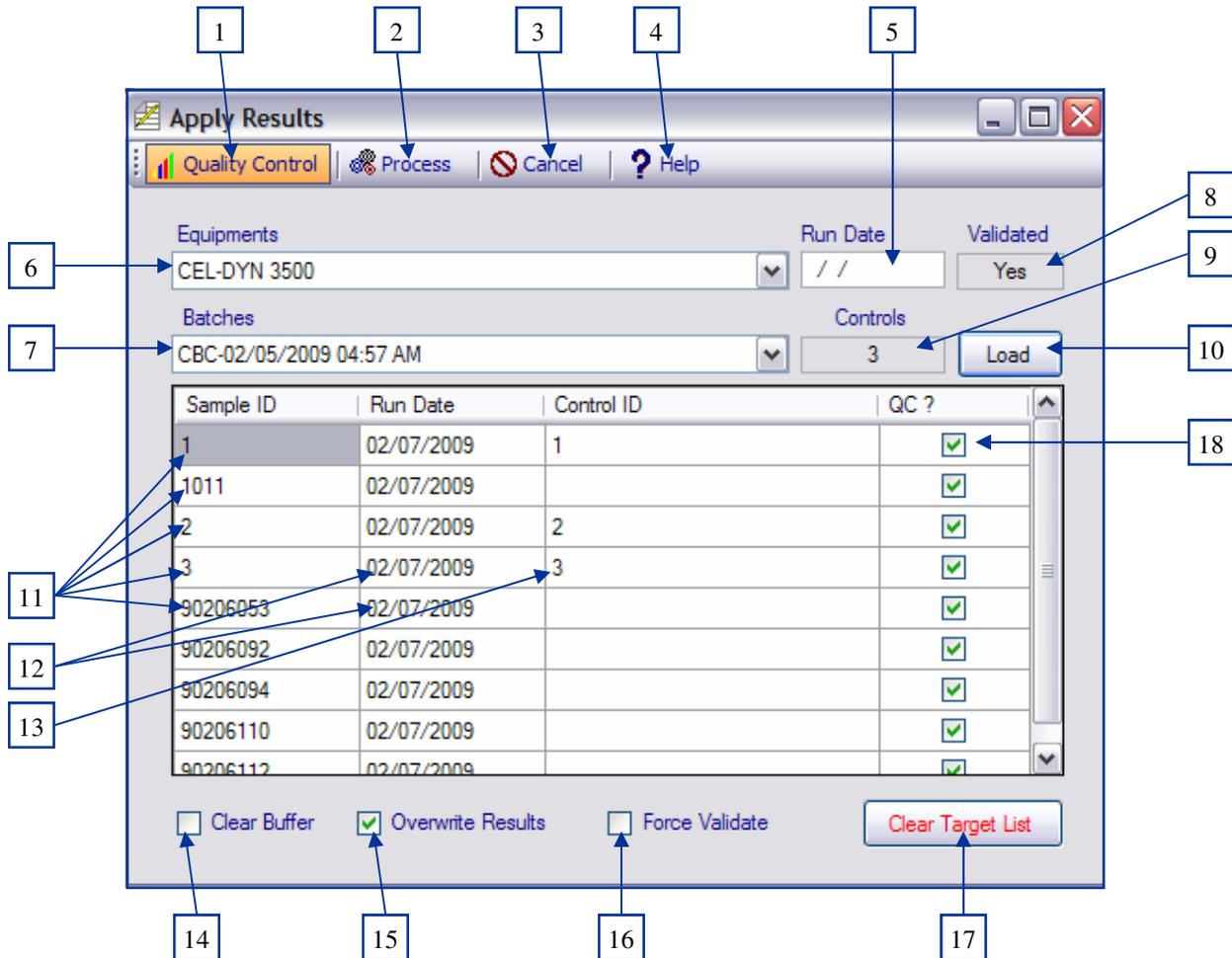
1. **Accession/Control Switch:** This button is clicked to change the routine mode between Control and the Accession. The display status of this switch controls other functions of the routine.
2. **Process Button:** This button is clicked to execute the apply process, after selecting and specifying all the parameters.
3. **Cancel Button:** The button is clicked to exit the routine.
4. **Help Button:** The button is clicked to access the help.
5. **Run Date Field:** This field is if provided the date value with, used to filter the downloaded results by the date in this field.
6. **Equipment:** The drop down box is populated with the names all equipments with the downloaded results in to the buffer, from.

7. **Batches:** This drop down box is populated with all available batches upon selecting the equipment in the 'Equipments' drop down. The routine can display the buffer contents of the downloaded results for the equipment selected in the previous field but results can not be applied if no batch is selected in this drop down.

8. **Validated:** This field displays the validation status of the batch selected in the previous field.

9. **Controls:** The field displays the total number of controls assigned to the analysis, not the validating number of controls.

10. **Load Button:** Click this button to display the buffer contents of the downloaded results.

11. **Sample ID Column:** The column displays the equipment assigned Control ID or the equipment operator assigned Control ID or the equipment operator assigned accession ID or the accession ID read by the equipment's barcode reader or the equipment assigned sample ID. The later is retrieved by the Interface if the accession ID was not entered by the operator or not available for any reason.

12. **Run Date Column:** The column displays the equipment run date.

13. **Control ID / Accession ID Column:** This column is accessible by the user and is to enter the Control ID if the routine is in the Control mode and is for entering the accession ID if the routine is in the accession mode. The column heading display the appropriate required ID (Control or accession) according to the current mode.

> **Note:** For an analysis with one control, the ID is always 1. For the analysis with the 2 controls, the IDs are always 1 and 2. For an analysis with the 3 controls, the IDs are 1, 2 and 3 and so on.

14. **Clear Buffer:** If a check is placed in this field prior to executing the apply process, the downloaded result buffer is emptied.

15. **Overwrite Results:** If checked, makes the routine overwrite the existing results regardless of their release status.

16. **Force Validate / Release Non Panic:** This mode dependant field is used to instruct the routine to validate the batch if the control results are in range and the routine is in the Control mode. If the routine is in the Accession mode, this field instructs the routine to release the accession results if the result is not in the panic range and the applicable batch is validated.

17. **Clear Target List Button:** The target list is the Control ID / Accession ID column which is populated automatically if the equipment in question is supplied with the accession numbers manually by the operator or read by the barcode reader and the Control ID are the same as adopted by Prolis. Otherwise this list has to be filled by the user. For any reason, if this list needs to be cleared, clicking this button will clear the list.

18. **QC Column:** For the Control mode, the whole column is checked automatically but for an accession mode, a checked entry indicates that the results set of the corresponding Sample ID was recognized as a control and was run accordingly.

Procedural Note

The routine can only be used if you have one or more Equipment Interfaces installed and operational.

1. Click the Accession/Control Switch to select the Control mode.
2. Select the Equipment you want to apply the result for. This will populate the available batches.
3. Optionally you may type in the date of the equipment run.
4. Click the 'Load' button to display the available results.
5. Fill the target list if the Control IDs are not there already. Your entry in the target list should be equal to the number of controls indicated in the # 9 field 'Controls'.

6. Place a check in the field 'Force Validate'. **Do not check the 'Clear Buffer'** as it will clear the buffer after applying the control results if checked.
7. Click the Process button.

Enjoy the Prolis automation.

8. Check if the batch in question has been validated. If 'Yes', skip the following manual validation but if 'No', follow the 'Manual Validation Procedure'.

Manual Validation Procedure
- Access the Result Entry & Review Routine
- Select the Control mode
- Specify the date in question and select the Batch in question.
- Select the first control and display the contents by clicking the 'Load' button.
- Browse the cursor through all the results to check for the control result falling out of the range.
- Determine the cause, fix the problem if possible. It is assumed that the operator might have run the accessions after making sure that all the controls are in range. After this assumption, there could be only a minor problem that is out of the scope of re-running the batch.
- Adjust the Override Validation percentage and click the Save button.
- Repeat this step for all the controls. At least for the validating number of controls until your batch is validated.

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9. Switch the routine to the accession mode.
10. Select the Equipment, you process the controls for.
11. Select the same batch already processed the controls for.
12. Click the Load button to display the buffer with the downloaded results.
13. Fill the target list with the accession IDs if not already there.
14. Place a check in the field 'Release Non Panic'. **Do not place the check in the 'Clear Buffer' field**.
15. Click the process button.
16. If no error, repeat above steps to display the buffer.
17. Click the button 'Clear Target List'.
18. Place a check in the 'Clear Buffer' field.
19. Click the Process button.

Done!