ANTIGEN PLUS V8.5	Validation Plan
Rowny Systems Inc.	1 OF 38

TITLE: ANTIGEN PLUS - VALIDATION	FILE: SOP-VALIDATION 8.5.docx
Revised for Version 8.5	EFFECTIVE DATE: September 14, 20018

#### 1.0 PRINCIPLE

Antigen Plus is a software program designed to store and select red cells for antibody identification testing, by phenotype. Antigen Plus Version 8.5 is a medical device under the provisions of the FDA, 510(k) clearance number BK11045.

In order to be used as a tool by an immunohematology reference laboratory or transfusion service, the program must be validated to function as stated in the users' manual after it is installed. All validation testing scenarios will be performed by any medical technician experienced in antibody identification.

Testing will be done in a database created for that purpose. This database will be maintained as long as the program is in use, but will not be used once validation is completed. All patient data saved in the database will not use actual patient names or identifiers. For instructions on creating a database for validation, consult «Antigen Plus 8.5 Installation and Configuration » or contact <a href="mailto:customerservice@antigenplus.com">customerservice@antigenplus.com</a> for a Cloud installation.

### 2.0 SCOPE/RELATED POLICIES

The scope of this validation plan is to assure that the program performs to specification in the laboratory setting. SOPs will be developed to guide the use of the program and the required maintenance plan. The program will be available to all blood bank or reference laboratory technologists, including staff rotating through the special testing areas.

### 3.0 SPECIMEN

N/A

### 4.0 MATERIALS

A minimum of 50 different RBC samples from commercial suppliers. The mix should consist of:

5 commercial red cell panels and 3 screening cell panels from any supplier used by the lab is to be downloaded electronically from a website and stored on the end user's system. One panel should be out of date.

Validation Lots supplied electronically by Antigen Plus.

### 5.0 SAFETY

Compliance with Laboratory Quality Practices: Bloodborne Pathogens Employee Exposure Control Plan.

#### 6.0 RECORDS/FORMS/DOCUMENTS

User testing documentation of program activities will consist of select cell panels and panels printed by lot number to be compared with the corresponding antigram provided by the panel supplier. The results of all validation testing will be printed directly from Antigen Plus.

Screen capture pictures will be printed to demonstrate warning flags and necessary screen information.

### 7.0 QUALITY CONTROL

N/A

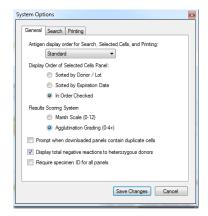
### 8.0 PROCEDURE

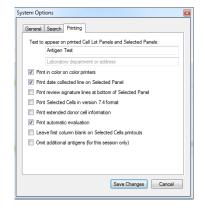
The following is a list of functions that must be validated before being used by the laboratory staff to create select cell panels and evaluate test results. Test case scenarios will be developed to cover the following:

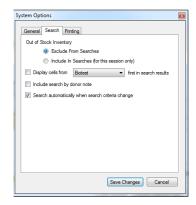
- 1. Verification of user log-in and permission status
- 2. Entry of all electronic information of all RBCs as they are received by the lab must be shown to contain the correct donor#, lot #, supplier and expiration date after entering the program database.
- 3. Out of stock designation assigned when a cell has been used to exhaustion or as they are discarded must be shown to not be presented on a selected cell panel with the out-of-stock cell or appearing in the lot # printout.
- 4. Deletion of individual cell information that has not been saved with any patient identifier to correct an incorrect entry or if a sample will never again be available to the lab must be shown to remove the cell's phenotype information.
- 5. Deletion of a panel not used in a saved work-up by lot # must be shown to delete every cell listed in the lot #.
- 6. Cell selection by phenotype must be shown to be consistent.
- 7. Print functions must be shown to provide the correct information.
- 8. Out-of-date function must apply itself automatically when required.
- 9. For those labs entering their own cells, program must be shown to maintain correlation between Wiener phenotypes and Rh antigen typing as described in the user manual.
- 10. Test the save function by reloading the panel and compare printouts.
- 11. Show that the program can differentiate between frozen inventory and liquid inventory by selected searches.
- 12. Using test panels provided, verify that result columns accurately rule out the appropriate antigens.

### 9.0 Initial Settings in Options

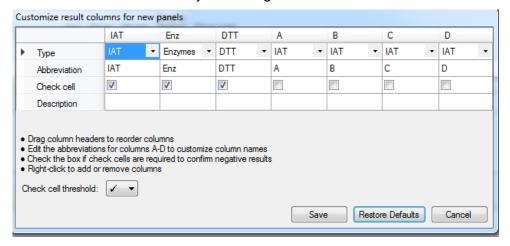
From the Options Menu, check to see that these are your settings in System Options



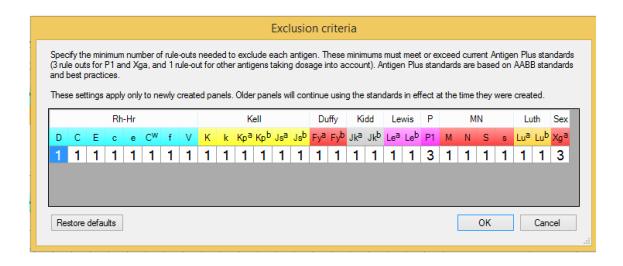




### Check to see that these are your settings in Customize result columns



Check to see that these are your settings in Exclusion criteria



- Following directions in the User's Guide create user accounts with passwords to cover all permission levels.
- ◆ Log in and out changing users from the Switch User command in the User menu. Return to original user log-in with administrator level

#### Scenario 2

- Download a 10+ cell commercial lot from each of the commercial suppliers that you use\* until you have 5 panels including one panel that is out of date. Do the same for 3 screen cell lots.
  - \* If you use or plan to use Immucor panels, check the SUT box when downloading and select some additional antigens from the list to include on your download. When doing the line-by-line comparison of the data, check against the SUT sheet from Immucor to make sure your selections have been added in the proper places. You may delete one of these lots and download it again with different criteria to double check.
- ◆ In the Add/Edit screen, select a lot in the Lot Number box and use the print lot profile function on the lot drop menu to print a copy of each lot added to the database.
- ◆ Do a line-by-line comparison of the data on the printout compared to the data in the antigram from the supplier.
- Document any variations. Sign and date the Antigen Plus copy once it contains exactly the same information as the antigram. Keep both copies as user testing documentation.

- ◆ From the Add screen select a cell and mark it out of stock. Note the donor and lot number of the marked cell. Click on the Save button.
- ◆ Select the Search screen and enter the donor number—verify that it is not found. Clear the donor number and enter the lot number—verify that the out-of-stock cell is not among the cells found in the lot.
- Select the Add screen. Locate the out-of-stock cell and verify that it is marked out-ofstock in red.
- In Systems Options, change the settings to include out-of-stock in searches.
- ◆ Tab to the Search screen and enter the donor number—verify that it is found

ANTIGEN PLUS V8.5	Validation Plan
Rowny Systems Inc.	5 OF 38

- On the Add/Edit screen select a donor number from the donor drop box that appears only once in the list.
- Bring up the cell information and do a print screen for the record.
- ◆ Delete the cell from inventory.
- ◆ Drop the donor drop box and type in the deleted donor number and open the list box. The list should show that the number is not there and no information will populate the Add/Edit screen.
- ◆ Do a print screen to confirm this for documentation.

#### Scenario 5

- ◆ On the Search screen select a lot number from the lot # drop box. Click Select all and choose View Selected Cells from the Panel menu. Print the Selected panel. Then click Clear All Selected Cells.
- ◆ Select that lot on the Add Screen. Delete the lot using the Delete Lot button on the bottom of the screen.
- ◆ Drop the lot # drop box and type in the deleted lot number and open the list box. The list should show that the number is not there and no information will populate the Add/Edit screen.
- Do a print screen to confirm this for documentation.
- Using the select cell panel printed in the first step, try to select at least 2 of the cells on the panel by donor number and confirm that they are no longer in the inventory attached to that lot number.

### Scenario 6

- ◆ Use the following: a)C+, K-, Js(a-), 2 examples; b) D-,K+, Js(a-), 2 examples; c) C-, K-, Js(a-), 2 examples; to construct a select cell panel. Select the first 2 cells presented with each request. Save the panel with the name Sc6-1. Print the selected panel. Clear all selected cells. Go through the process again and name the panel Sc6-2.
- ◆ When both panels are printed, do a line-by-line examination to ensure that the program presented the same 6 cells in the same order and that they match the requirements set.
- Clear all selected cells and search criteria

- ◆ From the Systems Options menu, select Antigen Display Order for Search, select Biotest, and using one of the previous select cells panels from Scenario 6, go to the Results panel through the File drop box. Add 0 for a negative result in all the IAT column boxes for the 9 cells selected and then select Print at the top of the screen.
- ◆ Repeat this printout 6 times by returning to the Options menu and selecting Antigen Display Order numbers for the other commercial suppliers, and returning to the Results Worksheet and selecting Print at the top of the screen.
- Compare the printed copy to the information on the screen. Note any discrepancies.
- ◆ From the Add/Edit screen, drop the lot # drop box and select one of the lot numbers on the Results Worksheet. Use the print lot # panel on the File drop box list to print this panel.

ANTIGEN PLUS V8.5	Validation Plan
Rowny Systems Inc.	6 OF 38

- ◆ Compare the cell data between the Results Worksheet printout and the lot # printout.
- Document any inconsistencies.
- Clear all selected cells and search criteria

- In the search screen, select an out of date panel from the list of lot #s.
- ◆ Verify that upon selection of an out of date cell or cells, the Review Selected Cells screen appears and click Review on one cell
- ◆ From the Cell testing History screen, drop down the list of antigens to retest, check one or more and save changes, verify that these antigens now appear in the Antigens Retested list
- ◆ Print the selected cells and note the OOD designation in the far left column. Go back to **the search screen** and **clear selected cells** when this step is complete.
- ◆ Select the same panel again and verify that the retesting changes you made have been maintained with today's date.
- ◆ From the **Add/edit screen**, change the expiration date on the panel to one that is now in date. From the **search screen**, print the selected cells either from the Preview Selected Cells button or by opening the Selected Cells Worksheet in the Panel menu. Compare the first printout to the second one and look to see if the OOD designation no longer appears on every cell of the "date-altered" panel.
- Save all printouts and document any inconsistency.
- ◆ Clear all selected cells and search criteria

# Scenario 9—NECESSARY ONLY FOR LABS THAT WILL MANUALLY ENTER THEIR OWN CELLS

- ◆ Using the Add/edit screen, clear the page as if to enter a new cell. Go to the Rh-Hr drop box and select a Weiner phenotype. Check to see if the antigen typing results that appear are correct for the phenotype selected.
- ◆ Create cell entries starting with RH1 through RH36 with a common lot number to prove that all the Weiner phenotypes produce the correct cell typings in the Rh-Hr section of the common typings.
- ◆ Change one of the RhHr antigens from positive to negative and click on save. Verify that a pop up stating that the phenotype has been cleared appears.
- Print the panel by lot number and review for any discrepancies including checking for the absence of a Phenotype designation in the cell you changed. Document findings.

- ◆ On the search screen choose Select/Add Patient and enter name, dob, and identification number for a patient, then select Add.
- Verify that patient name and number appear on the search screen.
- ◆ Create a selected panel (e.g. to exclude Anti-E) that includes one expired cell
- When the expired cell is selected, choose Review and select and save one of the relevant antigens.
- ◆ Click on Panel and open the Selected Cells worksheet and save the panel using the save selected panel. Type "Panel 1" in the Full Panel Description box, and save with

ANTIGEN PLUS V8.5	Validation Plan
Rowny Systems Inc.	7 OF 38

the panel number 1. Close the window and open the Results Worksheet from the Panel Menu and print it.

- Verify that the Results Worksheet contains the patient name and number and the attributed panel description.
- ◆ On the search screen, select **clear selected cells**. The number of cells selected at the bottom of the Search screen should now read 0. Do print screen to document.
- Go to the panel menu, drop the box and select load saved panel. Choose the panel saved and double click on the highlighted panel. The number of cells selected at the bottom of the Search screen should now read the same as contained in the panel printout from the first step.
- Print out the screen and document any unexpected findings.
- ◆ On the search screen, select clear selected cells and search criteria, then repeat the steps above using a new patient name, dob, and identification number and saving the panel with the number 2.
- Clear all selected cells and search criteria
- ◆ Select any of the cells used in the saved panel on the Add Screen and attempt to delete it. Verify that the delete is blocked with information about where that cell has been used.

### Scenario 11

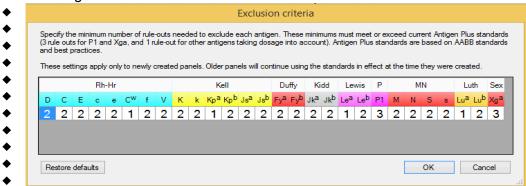
- ◆ Change the status of one of the 3-cell panels in stock from liquid to frozen by using the frozen button on the Add/edit screen (find the lot on the search screen, click on a cell phenotype on the screen and switch to Add/Edit screen—check to see if the lot number matches and if not drop the donor number list and select the instance of that donor with the correct lot number). Each cell must be changed individually. Save the change.
- ◆ Go to the Search screen and do a search for frozen cells only. The entire lot # of cells frozen should be presented for selection.
- ◆ Select them all and print the select cell panel resulting from the search. All cells should be marked FZN. No other cells should be presented in the search.
- ◆ Switch to the Results panel and print a copy. All cells in the Results Worksheet should still carry the FZN designation in the far left column.
- Document any inconsistencies
- Clear all selected cells and search criteria

- ◆ Search for a red cell lot and select it by clicking on "Select All Matches." Clear the search criteria.
- ◆ Search for a cell that is negative for E and C and select the oldest one (at the bottom of the Search grid).
- ◆ Open the Results worksheet from the Panel Menu. Assume you are testing a patient positive for E and C and enter the appropriate results
- ◆ Select File/Save Panel from the top menu
- ◆ Select a patient (enter a new patient as in Scenario 10)

ANTIGEN PLUS V8.5 Validation Plan Rowny Systems Inc.

- Enter 11 for a panel number and Save
- Print and then Exit the Results Worksheet and click "Clear Selected Cells"
- Select Exclusion Criteria from the Options menus. Change the default criteria to the following:

8 OF 38



- Select Load Saved Panel from the Panel menu and load Panel 11.
- Click on the red text "old exclusion criteria"
- ◆ Click on "update' in the Exclusion Criteria box that appears
- Print the resulting worksheet and compare the exclusions to the print out from the earlier print out. Verify that the rule-outs are the same, but the exclusions are now based on more rule-outs.
- Select more cells to allow an exclusion to occur on an antigen that had only been ruled out once. Save the panel. Print the resulting panel and verify.
- Clear all selected cells and search criteria

#### Scenario 13

- From Load Saved Panel, highlight panel number 11
- Click duplicate
- Exit the Selected Panel screen and open the Results worksheet
- Print the Results worksheet and verify that the printed panel is identical to the earlier print out for Panel number 11 except that there are no results in the new panel.
- Clear all selected cells and search criteria
- From Load Saved Panel, highlight panel number 11
- Click duplicate with fresh cells
- Print the Results worksheet and verify that the printed panel contains some new cells with phenotypes substantially identical to older ones the earlier print out for Panel number 11
- ◆ Clear all selected cells and search criteria

- Select a panel of cells, keeping track of which cells you select in order. Be sure to select some cells from the same lot (but not selected in sequence) and cells with different expiration dates including some that are out of date.
- Print the Selected Cell worksheet.
- Open the Results worksheet and select the View Menu
- Choose By Expiration Date
- Observe the changed order of the cells that are now in date then lot then vial order
- Print the Selected cells worksheet to confirm.

- ◆ Select a lot number that appears on the print out for saved panel 11 and find it on the Maintain Lots screen.
- ◆ Attempt to delete that lot
- Verify that you may not delete a lot that has been used in saved work.

#### Scenario 16

- ◆ Log out and back in as a full user.
- ◆ From the Panel menu load saved panel 11 and review it
- Confirm that after review, no results can be entered then uncheck review
- ◆ Enter results in column A and check technologist change in the View menu
- Review the panel
- ◆ Save the panel and print the results worksheet
- Verify that the review appears in Panel History and that prior iterations can be called up from there
- Clear selected cells

### Scenario 17

- ◆ Log out and back in as an administrator.
- ◆ From the Panel menu load saved panel 11 and add second review.
- ♦ Save the panel
- Verify that both reviews appears in Panel History
- ◆ Confirm that after review, no results can be entered then uncheck review
- Clear selected cells
- ◆ From the Panel menu load saved panel 11 and uncheck both reviews
- Right click on each of the columns labeled A. B. C. or D and remove them
- ◆ Right Click on the ENZ column and edit the column by adding a description (e.g. Ficin)
- ◆ Right click on the DTT column and add an IAT column with not check cell labeled LIS
- ◆ Add a few results in the LIS column and save the panel.
- Print the worksheet to confirm that all the new entries appear on the print out
- Verify that the old reviewed panel appears in Panel History and that it can be called up from there
- ◆ Clear selected cells
- ◆ From the Options menu, select Customize result columns and set up columns for the way your lab generally tests (unevaluated columns with no check cells for Spin etc., columns without check cells for gel and so on).
- ◆ Select a lot with a search and open the Results worksheet to verify that the columns you set up have been established
- ◆ Select Panel 11 from Load Panel menu—follow the prompt to discard current work
- ♦ Verify that the columns for Panel 11 are the way they were before
- Clear all selected cells and search criteria

### Scenario 18

Log out and back in as a read-only user

ANTIGEN PLUS V8.5 Validation Plan Rowny Systems Inc. 10 OF 38

- ◆ Confirm that you have read only ability by attempting save selected cells
- ◆ Log out and back in as a save panels user
- ◆ Confirm that you cannot review a saved panel, but can save one—check Panel History to verify.

#### Scenario 19

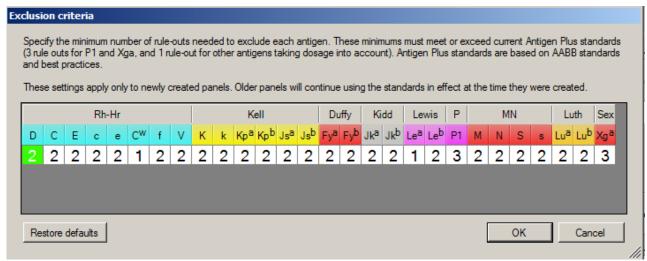
- While logged in as a save panels user
- Verify from system Options that you can view but are unable to change Exclusion Criteria
- ◆ Verify that you are unable to open "Customize result columns"
- ◆ Select a lot from the lot number drop down and select all cells
- Open the Results worksheet
- ◆ Confirm that the result columns conform to the specifications that you entered in Scenario 17
- ◆ Enter some random results
- ◆ Confirm that you are unable to review the panel
- Enter a new patient and save the panel with the number that appears in the panel number box
- ◆ Clear all selected cells and search criteria
- Log out and log back in as a full user

#### Scenario 20

- ◆ From Load Saved Panel, select panel number 11
- Open the Results worksheet and confirm from the View menu that all the histories conform to the work you have done on this panel up to now. Record any inconsistencies.
- From the Save Panel menu enter the conclusion of Anti-E and Anti-C and save the panel
- Confirm that the Conclusion now appears on the screen with the patient
- Right click on the patient name and select view patient details
- Click on edit and enter phenotype details in the array
- ◆ Type Phenotype in the reason box and Save
- ◆ Confirm that the phenotype criteria now appear n the Auto control row
- ◆ Close the Results worksheet and confirm that the patient phenotype appears under the patients name on the screen
- Clear all selected cells and search criteria

- This installation disk (or Validation database in the Cloud version) contains sample lots for validation testing. These are the same lots used for our internal unit testing, and are carefully selected to exercise all parts of the evaluation code. Every release of the software has these steps performed automatically.
- ◆ In the Options Menu change the Exclusion criteria to the default settings
- ◆ In the Options Menu Customize Result columns by deleting all columns except the IAT and removing the check cell requirement from that remaining column.

- To use these files:
- Use the File > Import Data command in Antigen Plus to import the .PNL files in this folder
- Search for one of the lots by name, select all cells, and open the Results Worksheet from the Panel menu.
- ◆ Enter the same test results in Antigen Plus that you see in corresponding Test Panel image reproduced below (pp 12-31).
- Verify that the rule-out counts and evaluation text are the same as in the image.
- ◆ Close the Results Worksheet and clear the selected cells.
- ◆ Repeat steps 2-6 for the other lots up to #27.
- ◆ Change your exclusion criteria to 4 for P1 and Xga and 2 for all the others and then enter the pictured results for #28.
- ♦ Change your exclusion criteria to



Repeat steps 2-6.

### Scenario 22

◆ The except for the final one, checks performed in Scenario 21 are based on the minimum exclusion criteria available to Antigen Plus. Keeping the current Options/Exclusion Criteria select the test panel Panel 10—Anti\_E\_K\_Fya\_IAT and enter the same results. Note that the S is no longer excluded and has changed to orange on the single dose exclusion row. Go back to then search screen and select a cell that is negative for E, Cw, K, Fya, Jka, and positive for S and negative for s (if you don't have such a cell it is currently available in Immucor lots 04113 and 39327, BioTest lot 805011 or Ortho lot 8RA24349 all of which are currently downloadable—or you can create such a test cell on the Add screen). Select that cell, go back to the worksheet and enter a negative result. Big S should no longer be orange and will be excluded. You may repeat this kind of scenario with as many panel and results as you like, but one is sufficient to show that the program functions are working.

### INTERPRETATION

Acceptable result criteria:

- 1. There will be no difference between the supplier antigram and the program printout by lot # once the panel has been transferred electronically into the Antigen Plus database.
- 2. Once marked out-of-stock, the cell(s) should not appear in a Search or on the panel printed by lot number.
- 3. Once deleted, there should be no record of the donor # in the program.
- 4. Once deleted, there should be no record of the panel lot # in the program.
- 5. Donors or lots saved with a patient may not be deleted but may be marked out-of-stock
- 6. All identical data should be reproduced in exactly the same manner and contain identical information if selected in exactly the same manner.
- 7. Cell information must be identical whether the cell appears on a lot # panel or on a Result panel. All print functions should print the information required in the correct format and there must be no altering of data between formats.
- 8. The out-of-date designation will appear when appropriate and be noted on the results panel and on the Search screen.
- 9. All Weiner phenotypes will produce the correct antigen types when selected (for manual data entry only).
- 10. The data in the original printout and the data in the printout produced from the same panel being saved and reloaded will be identical.
- 11. Only frozen cells will appear in the search results and the printout will carry the FZN designation for each frozen cell. The results panel used to test these cells will also show the FZN designation.
- 12. The Evaluations must be correct according to the Exclusion Policy located under Help. Specifically, there may be no exclusions of -K under DTT testing, and no exclusion of -Fy<sup>a</sup> under ENZ testing.
- 13. The Evaluations must show that for Scenario 13, in the first printout K, Kp<sup>a</sup> and Js<sup>a</sup> were properly ruled out and accurately counted, and that in the second printout none of these were ruled out.
- 14. All patient data will be maintained with saved panels
- 15. Only an administrator can remove someone else's review or edit patient data.
- 16. Testing history is be maintained by user and date accessible in the Results Worksheet View Menu under Technologists and Panel History
- 17. All test panel results should agree with the images provided.

### 11.0 RESULT REPORTING

All documentation produced by the validation scenarios will be saved as part of the program's validation record.

### 12.0 LIMITATIONS

As with any software program, it is only as good as the staff that maintains it. Maintenance is critical to the function of the program.

A hazard analysis will be developed based on all information gained while performing the program validation in the laboratory setting.

### 12.0 REFERENCES

AABB Technical Manual, 17<sup>th</sup> Edition, (ch 16: pg 470-1)

Standards for Immunohematology Reference Laboratories, 6 <sup>th</sup> edition. Bethesda, MD: data in the original printout and the data in the printout produced from the same panel being saved and reloaded will be identical.  Standards for Blood Banks and Transfusion Services, 26 <sup>th</sup> edition. Bethesda, MD: American Association of Blood Banks, 2009.  User's Manual, Version 8, Antigen Plus. Rowny Systems Inc. Gaithersburg, MD: 2013	NTIGEN PLUS V8.5 owny Systems Inc.	Validation Pla 13 OF 3
American Association of Blood Banks, 2009.	data in the original printout and the data in the printout produ	
User's Manual, Version 8, Antigen Plus. Rowny Systems Inc. Gaithersburg, MD: 2013	· · · · · · · · · · · · · · · · · · ·	dition. Bethesda, MD:
	User's Manual, Version 8, Antigen Plus. Rowny Systems Inc	. Gaithersburg, MD: 2013.

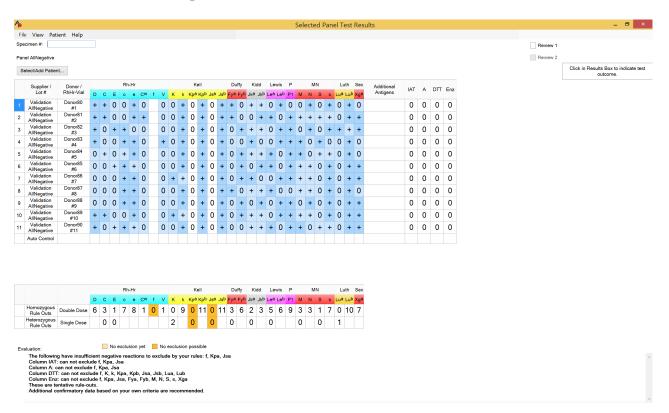
DATE

DATE

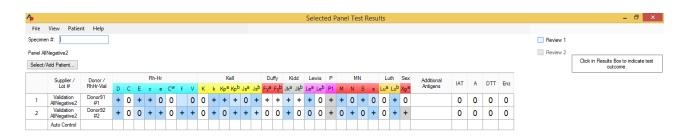
ANTIGEN PLUS V8.5 Rowny Systems Inc.			Validation Plan 14 OF 38
		DATE	
		DATE	
Signatures on file			
	WORK RECORD		
PERFORMED BY		DAT	E
REVIEWED		DAT	

Validation Plan 15 OF 38
DATE

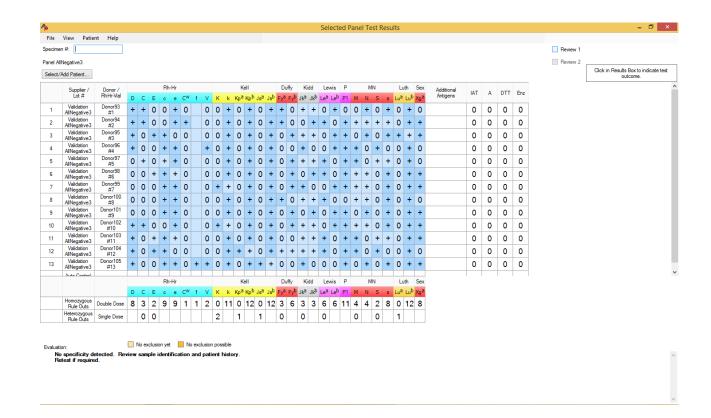
# Test Panel 1-- All Negative



# Test Panel 2-- All Negative 2



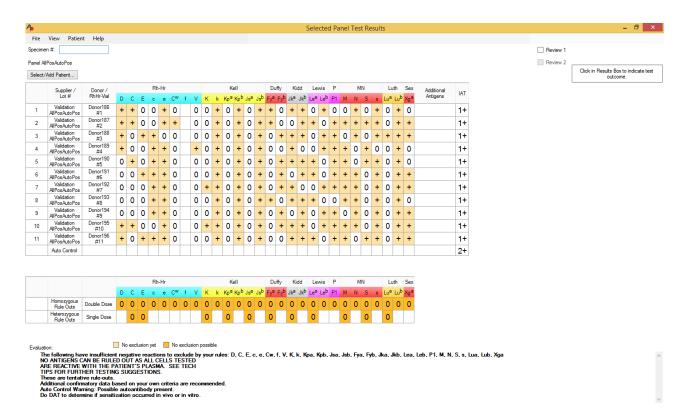
# Test Panel 3-- All Negative 3



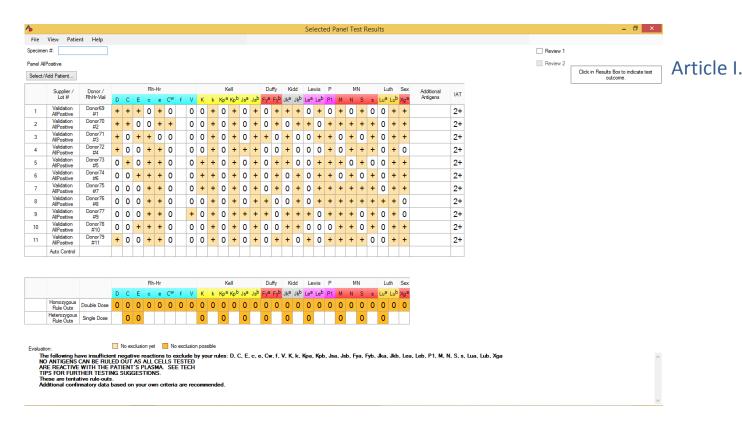
**Validation Plan** 

18 OF 38

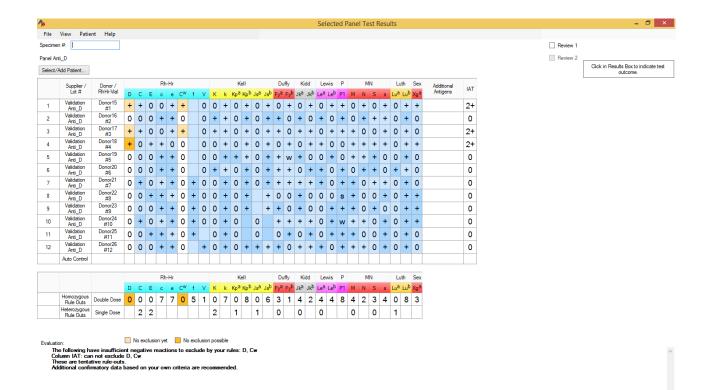
## Test Panel 4—AllPosAutoPos



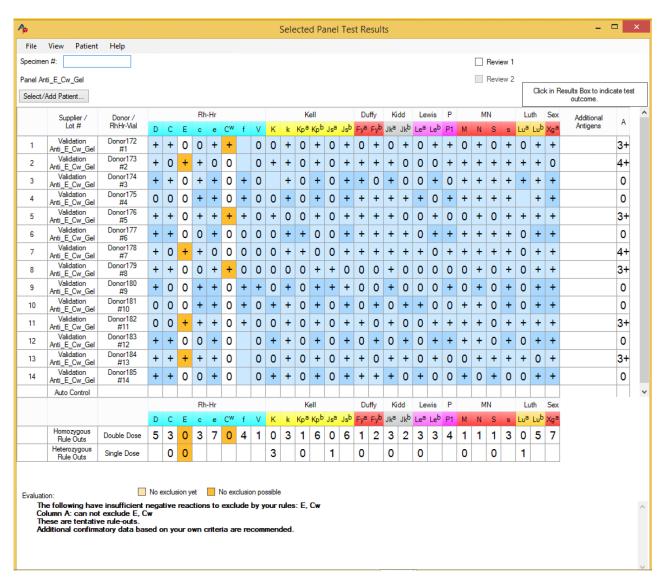
### Test Panel 5—AllPositive



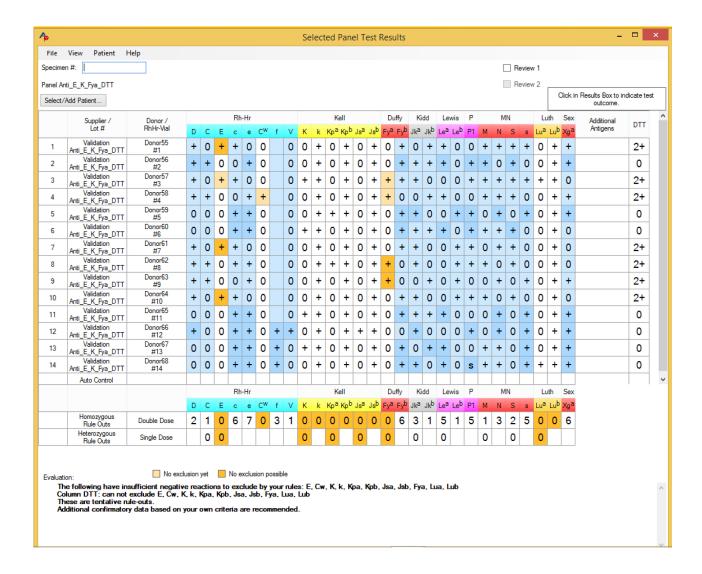
# Test Panel 6—Anti\_D



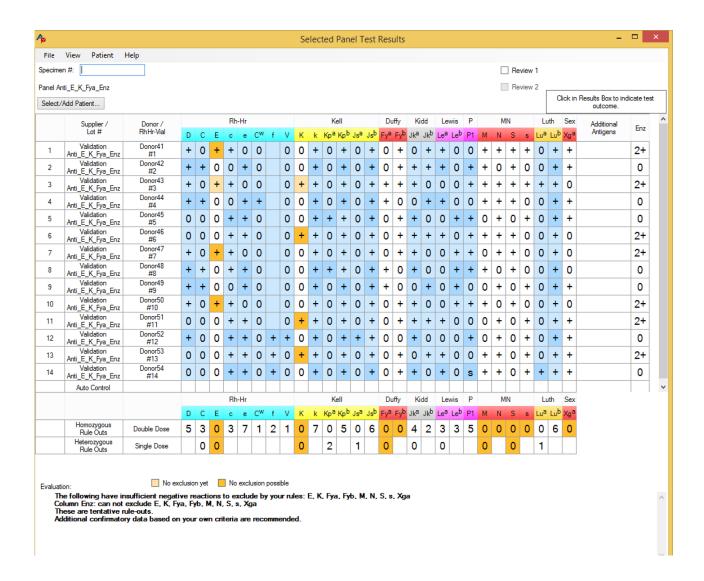
# Test Panel 7—Anti\_E\_Cw\_gel



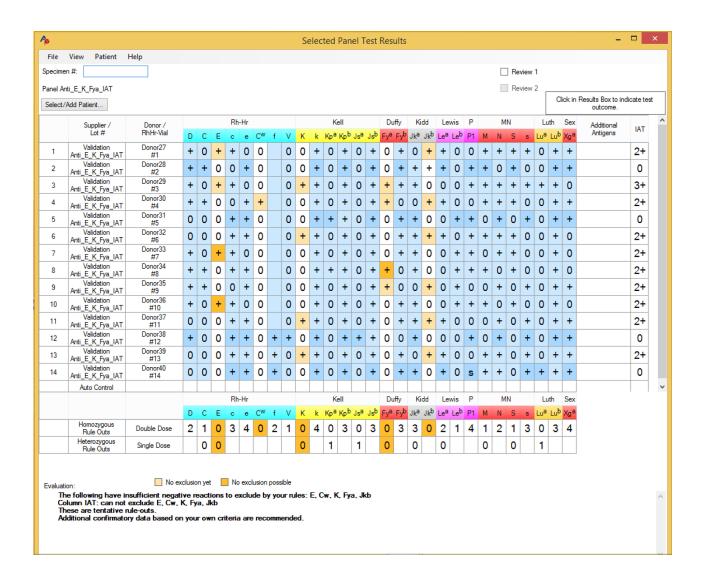
# Test Panel 8—Anti\_E\_K\_Fya DTT



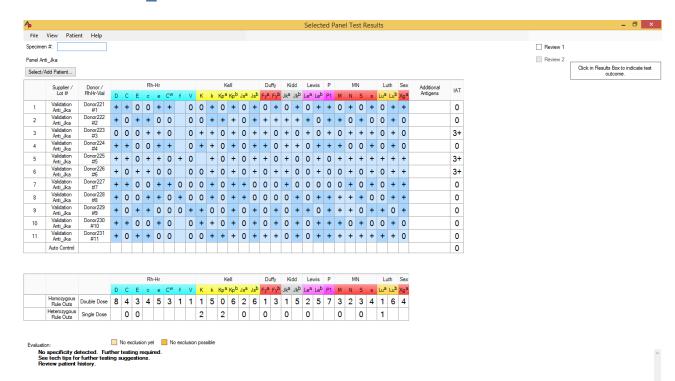
# Test Panel 9—Anti E K Fya Enz



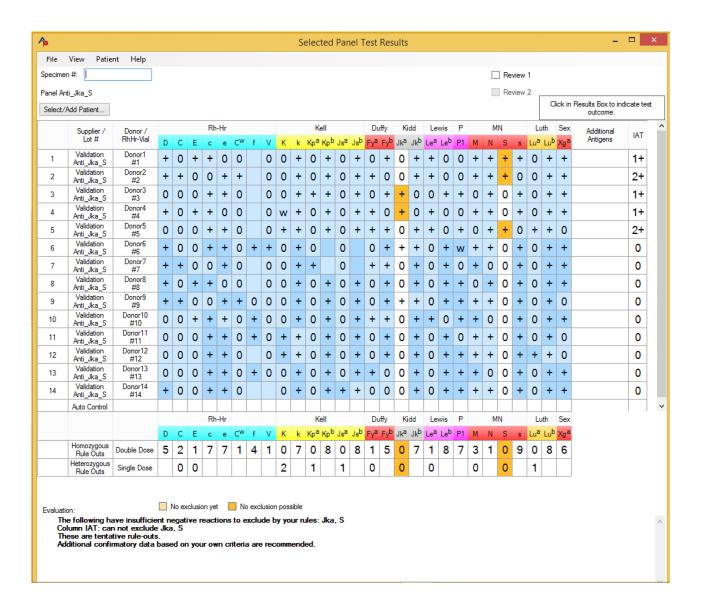
# Test Panel 10—Anti E K Fya IAT



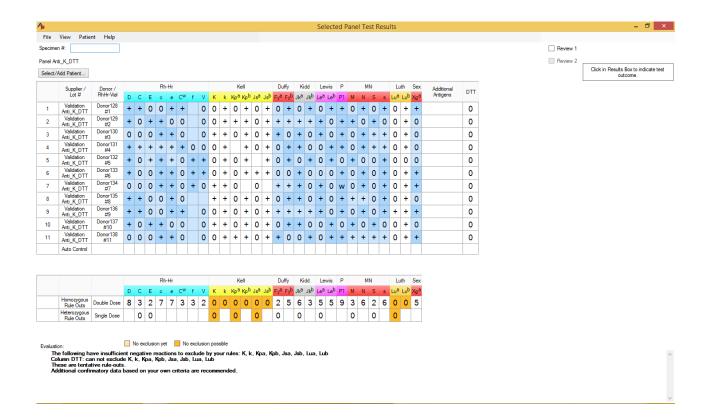
# Test Panel 11—Anti\_Jka



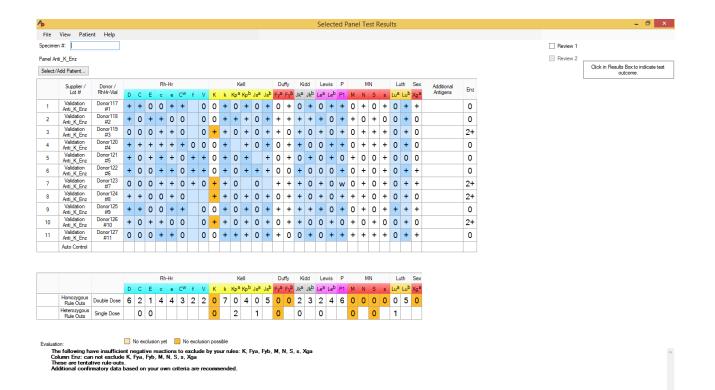
# Test Panel 12—Anti Jka S



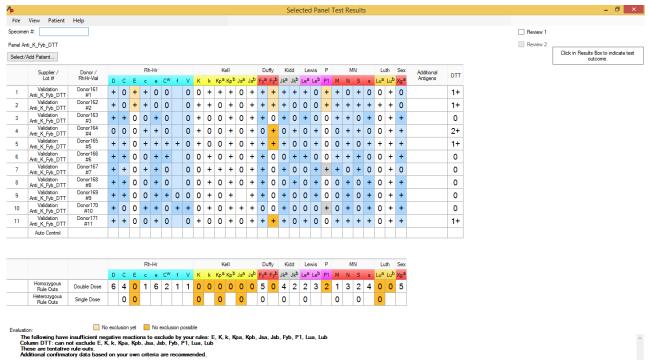
# Test Panel 13—Anti K DTT



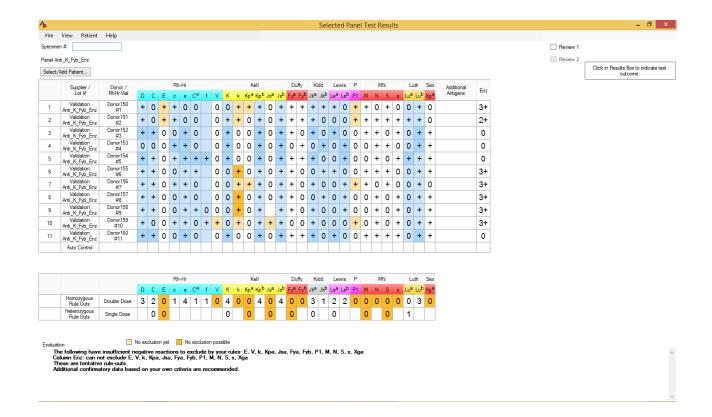
# Test Panel 14—Anti\_ K\_Enz



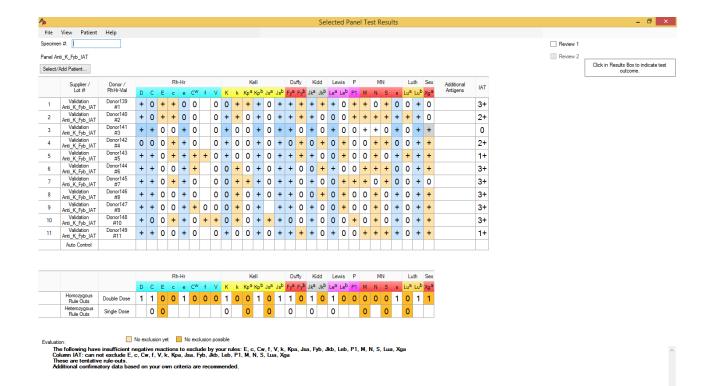
# Test Panel 15—Anti K Fyb DTT



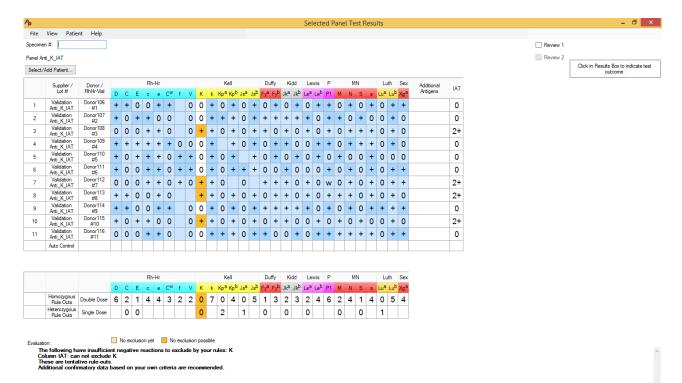
# Test Panel 16—Anti\_ K\_Fyb\_Enz



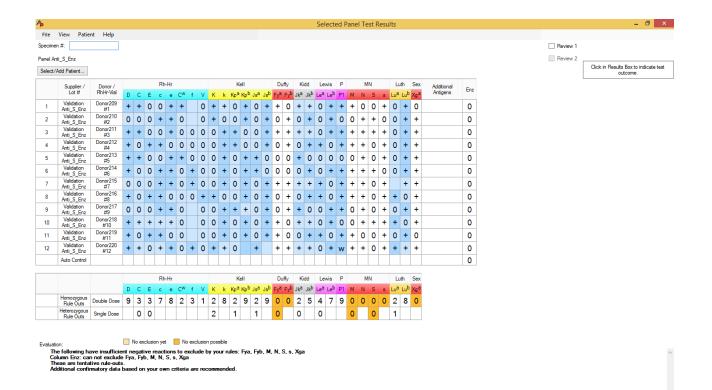
# Test Panel 17—Anti\_ K\_Fyb\_IAT



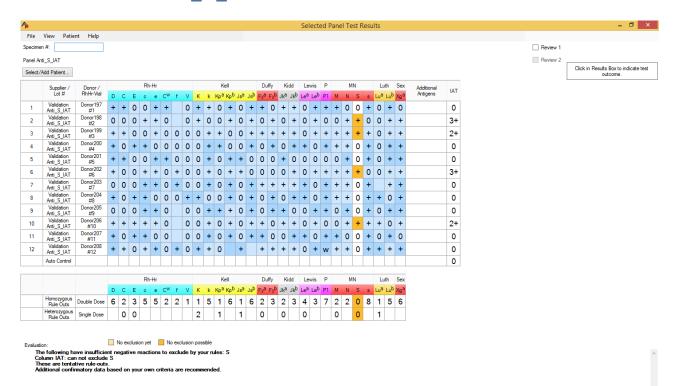
# Test Panel 18—Anti K IAT



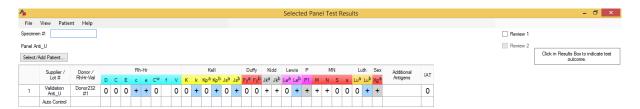
# Test Panel 19—Anti\_S\_Enz

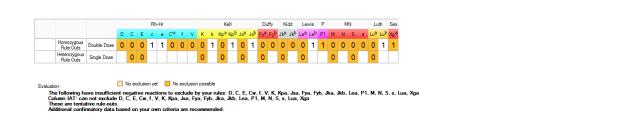


# Test Panel 20—Anti S IAT

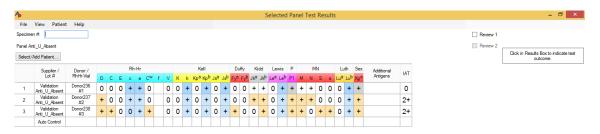


# Test Panel 21—Anti\_ U





# Test Panel 22—Anti\_U\_Absent

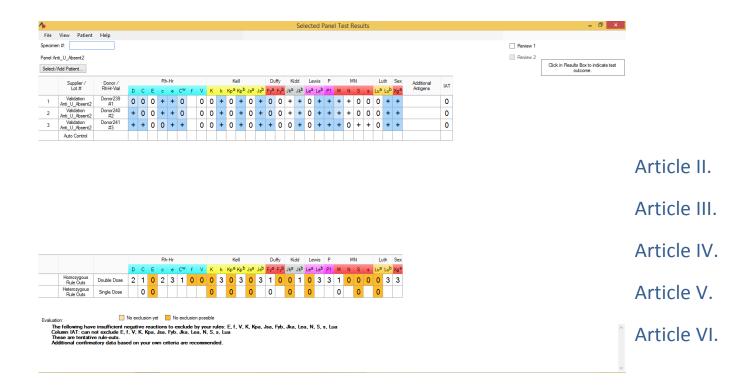




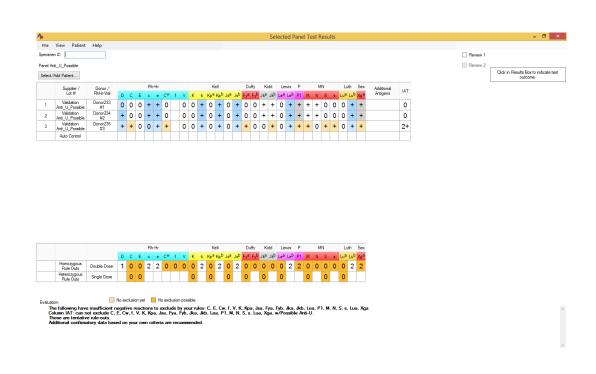
lustion: No exclusion yet No exclusion possible

The following have insufficient negative reactions to exclude by your rules: D, C, E, Cw, f, V, K, Kpa, Jsa, Fya, Fyb, Jka, Jkb, Lea, P1, M, N, S, s, Lua, Xga
Colamn IAT: can not exclude D, C, E, Cw, Y, V, K, Kpa, Jsa, Fya, Fya, Fya, Fya, Fya, Jsa, Jsb, Lea, P1, M, N, S, s, Lua, Xga
These are institute rule outs.

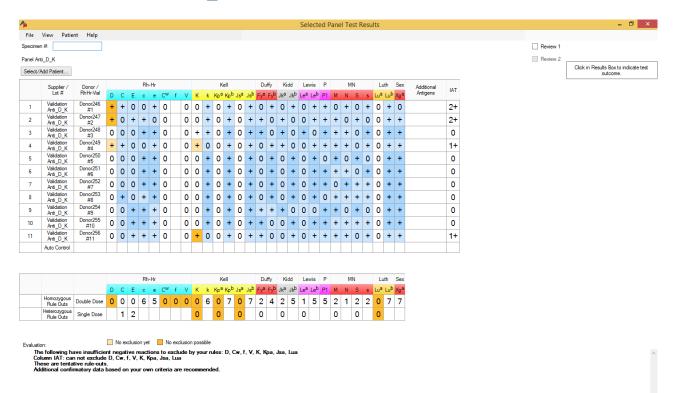
# Test Panel 23—Anti\_U\_Absent2



# Test Panel 24—Anti U Possible

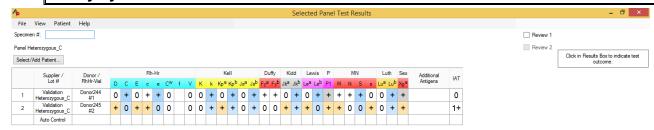


# Test Panel 25—Anti D\_K



### **ANTIGEN PLUS V8.5** Rowny Systems Inc.

### **Validation Plan** 37 OF 38



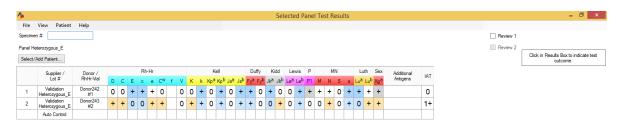
				Rh	-Hr						К	ell			Du	iffy	Кі	dd	Le	wis	Р		N	N		Lu	th	Sex
	D	С	Е	С	е	CW	f	٧	К	k	Кра	Κρ <sup>b</sup>	Jsa	Jsb	Fya	Fyb	Jka	$Jk^b$	Lea	Leb	P1	М	N	S	s	Lua	Lub	Xga
Homozygous Rule Outs Double Dos	C	0	0	0	1	0	0	0	0	1	0	1	0	1	0	0	0	1	0	1	1	0	0	1	0	0	1	1
Heterozygous Rule Outs Single Dose		1	0						0		0		0		0		0		0			0		0		0		

No exclusion vet No exclusion possible

JUSTION: The following have insufficient negative reactions to exclude by your rules: D, E, c, Cw, f, V, K, Kpa, Jsa, Fya, Fyb, Jka, Lea, P1, M, N, s, Lua, Xga Column IAT: can not exclude D, E, c, Cw, f, V, K, Kpa, Jsa, Fya, Fyb, Jka, Lea, P1, M, N, s, Lua, Xga These are tentative rule-outs.

Additional confirmatory data based on your own criteria are recommended.

# Test Panel 27 Heterozygous E





Audition Continue of the Conti

No exclusion yet No exclusion possible

# Test Panel 28 K\_Kpa\_Jsa\_Anti\_S

