

FACILITY:	RED BLOOD CELL REFERENCE LABORATORY

TITLE: ANTIGEN PLUS AbID - VALIDATION	FILE: apval.doc
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Version 7.0	

1.0 PRINCIPLE

Antigen Plus is a software program designed to store and select red cells for antibody identification testing, by phenotype. The program was designed and validated by Peter Rowny of Rowny Systems Inc. The FDA has reviewed Antigen Plus, and provided documentation that this is a software tool and not a medical device.

In order to be used as a tool by the laboratory, the program must be validated to function as stated in the users' manual after it is installed on the laboratory workstation or network. All validation testing scenarios will be performed by an experienced user.

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 technologists, including rotating staff.

3.0 SPECIMEN

N/A

4.0 MATERIALS

A minimum of 100 different RBC samples from commercial suppliers.

The mix should consist of:

5 commercial panels from Immucor/Gamma to be uploaded electronically.

5 commercial panels from Ortho-Clinical Diagnostics to be uploaded electronically.

5.0 SAFETY

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

6.0 RECORDS/FORMS/DOCUMENTS

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

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. Test case scenarios will be developed to cover the following:

1. Entry of all electronic information of all RBCs as they are received by the laboratory must be shown to contain the correct donor#, lot #, supplier and expiration date after entering the program database.
2. Entry of all manual information must be shown to maintain 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 maintain information while not populating a select cell panel with the out-of-stock cell.
4. Deletion of individual cell information to correct an incorrect entry or if a sample will never again be available to the laboratory must be shown to remove the cell's phenotype information.
5. Deletion of a panel 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. All print functions must be shown to provide the correct information.
8. Out of date function must apply itself automatically when required.
9. Program must 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. Test inventory function by printing rare cell inventory.

Scenario 1

- Enter 10 commercial panels supplied electronically.
- Use the print lot# panel function on the file 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.

Scenario 2

- To test the out of stock functions of the program, mark all the Kp (a+) cells as out of stock. Run a search for Kp(a+) cells and do a print screen of the message that no cells are available. Restore 2 Kp(a+) to inventory by removing the out of stock flag and repeat search. Print select cell panel for documentation.

Scenario 3

- 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 press enter. 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 4

- On the Add/Edit screen select a lot number from the lot # drop box. Bring up the cell information on a select cell panel and print it for the record. 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 press enter. 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 3 of the cells on the panel by donor number and confirm that they are no longer in the inventory attached to that lot number. Print the screen for each alternate version of the cells located.

Scenario 5

- Use the following : a)D+, K-, Js(a-), 2 examples; b) D-,K+, Js(a-), 2 examples; c) D-,K-, Js(a+), 2 examples; to construct a select cell panel. Select the first 2 cells presented with each request. Go through the process 5 times. Each time, print the select cell panel. When all 5 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.

Scenario 6

- 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 6 cells selected and then select Print at the top of the screen. Compare the printed copy to the information on the screen. Note any discrepancies.
- From the File drop box, select selected cell panel for the same 6 cells last selected and click on Print at the top of the screen. Compare the cell data

to that on the screen and do a line-by-line comparison with the cell data on the results panel printout.

- From the main screen, drop the lot# drop box and select one of the lot numbers on the select cell panel. Use the print lot # panel on the File drop box list to print this panel. Compare the cell data between the select cell panel printout and the lot# printout. Document any inconsistencies.

Scenario 7

- Using the Add/edit screen, select an in date panel from the list of lot #s. Use print lot # panel. When the print is completed, change the expiration date on the panel to yesterday's date and save the data.
- Repeat the first step, by selecting the same lot# and print the panel using the selected panel. Compare the first printout to the second one and look for the OOD designation on every cell of the "date-altered" panel. Check the screen for the red OOD flag underneath the expiration date box. Save all printouts and document any inconsistency.

Scenario 8

- 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 results that appear are correct for the phenotype selected. Check all the Weiner phenotypes and document any discrepancies.

Scenario 9

- Create a panel to exclude anti-E and save the panel using the save selected panel function found on the utilities drop box list. Print the Results panel before saving the panel.
- Go to utilities, drop the box and select clear selected cells. The number of cells selected at the bottom of the Search screen should now read 0.
- Go to utilities, drop the box and select load selected panel. Choose the panel saved and click on reload. 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.

Scenario 10

- Change the status of one of the panels in stock from liquid to frozen by using the frozen button on the Add/edit screen. 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. Take 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. Document any inconsistencies.

Scenario 11

- Go to utilities and select rare cell inventory and print the complete rare cell inventory. Do a line-by-line comparison with the commercial

information supplied on the 10 panels entered into the database.

- Document any discrepancies.

9.0 INTERPRETATION

Acceptable result criteria:

1. There will be no difference between the supplier antigram and the program printout by lot #.
2. There will be no difference between the supplier antigram and the program printout by lot #.
3. Once marked out-of-stock, none of the Kp(a+) cells should appear in a search.
4. Once deleted, there should be no record of the donor # in the program.
5. Once deleted, there should be no record of the lot # in the program.
6. All identical data should be reproduced in exactly the same manner and contain identical information.
7. 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.
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.
12. There will be no differences between the rare cells recorded on the suppliers' panel sheets and the rare cell inventory printed by the program.

10.0 RESULT REPORTING

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

11.0 LIMITATIONS

As with any software program, it is only as good as the staff that maintain 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

Technical manual, 14th edition. Bethesda, MD: American Association of Blood Banks, 2002.

Standards for Immunohematology Reference Laboratories, 2nd edition. Bethesda, MD: American Association of Blood Banks, 2001.

Standards for Blood Banks and Transfusion Services, 21st edition. Bethesda, MD: American Association of Blood Banks, 2002.

Accreditation Requirements Manual, 6th edition. Bethesda, MD: American Association of Blood Banks, 1995.

Users Manual, Version 7, Antigen Plus. Rowny Systems Inc. 2009.