

TITLE: ANTIGEN PLUS – VALIDATION	FILE: SOP-VALIDATION7.docx
Revised for Version 7.4.10	EFFECTIVE DATE: January 23, 2013

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 7.4 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, the program must be validated to function as stated in the users' manual after it is installed on the user 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 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 panels from any supplier used by the reference lab is to be downloaded electronically from either a website or an e-mail file and stored on the end user's system.

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 RCRL 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 reference lab must be shown to contain the correct donor#, lot #, supplier and expiration date after entering the program database.
2. 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.
3. Deletion of individual cell information to correct an incorrect entry or if a sample will never again be available to the reference lab must be shown to remove the cell's phenotype information.
4. Deletion of a panel by lot # must be shown to delete every cell listed in the lot#.
5. Cell selection by phenotype must be shown to be consistent.
6. All print functions must be shown to provide the correct information.
7. Out-of-date function must apply itself automatically when required.
8. Program must maintain correlation between Wiener phenotypes and Rh antigen typing as described in the user manual.
9. Test the save function by reloading the panel and compare printouts.
10. Show that the program can differentiate between frozen inventory and liquid inventory by selected searches.
11. Using 3 specificities where 1 is destroyed by enzyme treatment, 1 by DTT and 1 not affected, put the probable reactions in the IAT, DTT and ENZ columns of the results panel. Print the results to include all the evaluations and how many examples of antigens had been nonreactive when tested.

Scenario 1

- ◆ Enter 5 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 antigenogram from the supplier.
- ◆ Document any variations. Sign and date the Antigen Plus copy once it contains exactly the same information as the antigenogram. Keep both copies as user testing documentation.

Scenario 2

- ◆ Capture Options settings to show "out of stock" not included in Search
- ◆ Capture screen to show cell marked out of stock
- ◆ Add a panel by Lot# to the selected cells and print a copy of the selected panel that contains at least 1 low incidence antigen.

- ◆ Mark the cell with the low incidence antigen as “out of stock” and capture screen to print.
- ◆ repeat printout of select cell panel with the altered lot# added to demonstrate the out of stock cell has been removed.
- ◆ To test the out of stock functions of the search program, use the cell already marked as out of stock. Run a search for the low incidence antigen on the “out of stock” cell and do a print screen of the message that no cells are available.

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.

Scenario 5

- ◆ 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. 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

- ☐ Select Antigen Display Order #1 from the Options menu, and using one of the previous select cells panels from Scenario 5, 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 2 through 7, and returning to the Results panel and selecting Print at the top of the screen.
- Compare the printed copy to the information on the screen. Note any discrepancies.

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

Scenario 7

- ◆ Using the Add/edit screen, select an out of date panel from the list of lot #s. In **Utilities** select **add lot to selected cells**. Print the selected cells and note the OOD designation in the far left column. Go back to **Utilities** and **clear selected cells** when this step is complete.
- ◆ In the Add/edit function, change the expiration date on the panel to one that is now in date.
- ◆ 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 to see if the OOD designation no longer appears on every cell of the "date-altered" panel.
- ◆ 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 typing results that appear are correct for the phenotype selected.
- ◆ Create a cell entry starting with RH1 through RH37 to prove that all the Weiner phenotypes produce the correct cell typings in the Rh-Hr section of the common typings.
- ◆ When a typing does not appear and there is a flag stating no typing results are associated with the phenotype, print screen to confirm.
- ◆ Assign a common lot number to the group of 37 cells.
- ◆ Print the panel by lot number and review for any discrepancies. Document findings.

Scenario 9

- ◆ Create a panel to exclude anti-E and under **Utilities**, save the panel using the **save selected panel**. Print the Results panel before closing it.
- ◆ 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. Do print screen to document.
- ◆ 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.
- ◆ Print out the screen and document any unexpected findings.

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. 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 panel should still carry the FZN designation in the far left column.
- ◆ Document any inconsistencies.

Scenario 11

- ◆ Using the selected panel from Scenario10, above, Fill in results in the IAT column for 3 specificities (i.e. -K, -Le^a, -Fy^a : 1 that is destroyed by enzymes, 1 by DTT & 1 not affected).
- ◆ Fill in the appropriately altered results in the ENZ column and the DTT column.
- ◆ Print the results panel to include all the Evaluations.
- ◆ Manually assess the Evaluations for correctness according to the Exclusion Policy located under Help. Document any discrepancies.
- ◆ Manually count the total number of examples of each time an antigen has been found non-reactive. Document any discrepancy.

Scenario 12

- ◆ Create a panel with heterozygous positive specificities for K+/k+, Kp^a+/Kp^b+, and Js^a+/Js^b+, one example of each.
- ◆ Add three more cells with homozygous specificities for K+/k-, Kp^a+/Kp^b-, and Js^a+/Js^b-, one example of each.
- ◆ In the IAT and ENZ columns, enter a negative result for each of the heterozygous entries.
- ◆ Print the results panel to include all the Evaluations
- ◆ In the IAT and ENZ columns, enter a positive result for each of the homozygous entries.
- ◆ Print the results panel again to include all the Evaluations.
- ◆ Manually count the total number of examples of each time an antigen has been found non-reactive in both printouts. Document any discrepancy.

9.0 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) with the low incidence antigen 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. All identical data should be reproduced in exactly the same manner and contain identical information if selected in exactly the same manner.
6. 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.
7. The out-of-date designation will appear when appropriate and be noted on the results panel and on the Search screen.
8. All Weiner phenotypes will produce the correct antigen types when selected.

9. The data in the original printout and the data in the printout produced from the same panel being saved and reloaded will be identical.
10. 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.
11. 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^a under ENZ testing.
12. The Evaluations must show that in the first printout K, Kp^a and Js^a were properly ruled out and accurately counted, and that in the second printout none of these were ruled out.

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 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

Technical manual, 16th edition. Bethesda, MD: American Association of Blood Banks, 2009.

Standards for Immunohematology Reference Laboratories, 6th edition. Bethesda, MD: The data in the original printout and the data in the printout produced from the same panel being saved and reloaded will be identical.

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Users Manual, Version 7.0, Antigen Plus . Rowny Systems Inc. Bethesda, MD: 2010.

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Signatures on file

WORK RECORD

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SIGNATURES ON FILE.