Canadian Blood Services
Société canadienne du sang

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INFORMATION ONLY

Changes to Red Blood Cell Extended Antigen Printing on the End Label

Customer Letter # 2017-39

2017-09-25

Dear Customer:

We are making a change that will allow us to automate a manual and time consuming process, that will in the large majority of cases, remove the need to manually apply a tag for tested once RBC extended antigens. The change will also improve the number of red blood cell (RBC) extended antigen results that will be part of the eye readable portion of the RBC end label. This change also aligns with the recent clarification from the CSA Standards Committee. The CSA Standards committee provided clarification regarding the need for hospitals to retest if the antigen test has been performed once by the blood supplier. Posted April 21, 2017; http://www.csagroup.org/documents/Formal_Interpretations.pdf"

In February 2018, pending Health Canada approval, Canadian Blood Services will print all RBC extended antigens that have been tested once and are negative, in the eye readable section of our RBC blood component end label. Currently, only antigens tested twice on two separate donations print in the eye readable section of the RBC end label.

This change will affect all RBC extended antigens that we test, including the 11 commonly tested RBC extended antigens (C, E, c, e, K, Fya, Fyb, Jka, Jkb, S, s). Hospitals customers are reminded that Canadian Blood Services employs a testing algorithm for the 11 common RBC extended antigens, and not all 11 common RBC extended antigens are tested on every donation.

The tested once RBC extended antigen results will also be encoded in the bar code. Hospital customers are reminded that the bar code currently includes antigens that test negative (tested twice), as well as antigens that test positive.

This change is expected to increase the number of RBC antigens that could appear on future RBC component end labels by more than 55,000.

Eye Readable Font Format

Below is the format that will be used for the eye readable portion of the end label. This format is concordant with that currently used by Héma-Québec, and approved by Health Canada for their use.

Tested once: regular font
Tested twice: **bold font**
Tested on the current donation: <u>underlined</u>

The above font format does not imply any difference in the accuracy of the antigen test result.

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Phenotype Tags
The planned February 2018 change will reduce the frequency of circumstances where a tag with antigen information may need to be applied to an RBC unit. The Phenotype Tag – Tested Using Unlicensed Reagents, label #100016874 2015-03-15 will be rescinded and no longer used. Only one tag (Phenotype Tag, label #L040995) may on occasion be attached to a RBC unit. This tag will only be required if antigen testing was completed after the RBC unit was end labeled. The Phenotype Information Red Blood Cell Label and Tags visual aid has been updated to reflect these changes (attachment).

Unlicensed Reagent Testing
Licensed testing reagents are always used by Canadian Blood Services whenever they are available, but in some circumstances, they may not be available. Currently, a tag (Phenotype Tag – Tested Using Unlicensed Reagents, label #100016874 2015-03-15) is attached to any RBC units issued that have been tested for an RBC antigen using unlicensed reagent. As part of the February 2018 change and submission to Health Canada, a tag will no longer be attached to the RBC unit when an unlicensed reagent was used. A disclaimer on the RBC end label indicating unlicensed reagent was used for testing will no longer be required. Any antigens tested using unlicensed reagent will print on the RBC end label.

A follow up customer letter will be provided with the planned implementation date for this change after Health Canada approval is received.

This customer letter can also be viewed at www.blood.ca in the "Hospitals" section. If you have questions about this letter, or if you require it in an accessible format, please contact your local hospital liaison specialist.

Sincerely,

Dana V. Devine

Dana Devine, Ph.D.
Chief Medical & Scientific Officer

Attachments; Phenotype Information Red Blood Cell Label and Tags.