



CANADIAN BLOOD SERVICES
SOCIÉTÉ CANADIENNE DU SANG

Customer Letter #2003-17

Information to Health Care Professionals on the Red Cell, Platelet and Frozen Plasma Products that will be distributed by Canadian Blood Services During the Summer and Fall of 2003 and the Risk of Transfusion-Transmitted West Nile Virus (WNV) of These Blood Components - Summary

2003-07-07

As of July 2, 2003 all blood donations (both allogeneic and autologous) collected by Canadian Blood Services will be tested for WNV using an investigational nucleic-acid based test (NAT) recently developed by Roche Diagnostics Inc. In addition, during the last two weeks of June, in Ontario, approximately one-third of the blood donations were tested for WNV. Over the next four weeks Canadian hospitals will have a dual inventory consisting of blood components tested for WNV (those collected once testing began) and blood components not tested for WNV (those collected prior to the onset of testing).

Name of Test	Region used	Date of Implementation
CBS In-house testing	Southern and Eastern Ontario (tagged units)	June 17, 2003
Roche Early Testing (SAP)	Ontario (tagged units)	June 23, 2003
Roche Testing (ITA)	All of Canada	July 1, 2003

The risk of transmitting WNV through transfusion of platelets, red cells (RBCs) or frozen plasma products depends on the number of donors infected with WNV and, in the presence of infectious donors, the sensitivity of the WNV screening test. The presence or absence of WNV in the donor population is seasonal and regional, i.e., exists only when infected mosquitoes are present to propagate an avian epidemic, and only after the epidemic has "spilled over" from birds to humans. Blood products collected before human cases of WNV infection appear in any particular year carry only a most remote risk of transmission of WNV through transfusion whether or not they are tested for WNV. As of June 30 this year, dead birds with confirmed-positive WNV infection had been reported in Ontario, Quebec, Saskatchewan and Manitoba; there was no confirmed human case anywhere in Canada and no blood donors (over 10,000 tested) had a positive WNV-NAT.

It has been estimated that at the peak of the 2002 epidemic in areas of maximal disease activity (e.g., Detroit in August 2002) that the risk of collecting and transfusing blood from a viremic donor was as high as 1 in 1,000 donations. Overall in Ontario in the summer and fall of 2002 the risk was estimated to be 1 in 15,000 donations although in late summer in certain areas of Ontario the risk may have approached the risk in Detroit. The risk this year, even in the presence of a comparable epidemic, will be greatly reduced due to the introduction of screening of all donations by WNV-NAT. However, as this test is new, there is not yet sufficient data to quantify the residual risk of transfusion-transmitted-WNV in tested donations. It is unlikely that the test will identify all infectious donations. **For more comprehensive details, please refer to Customer Letter 2003-16, issued to Canadian Blood Bank Physicians dated 2003-06-30 at www.bloodservices.ca.**

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Based on the foregoing understanding of the risk of transmission of WNV through transfusion in 2003, as of July 2, red cells, platelets and frozen plasma products distributed by Canadian Blood Services to hospitals will be prepared from donations:

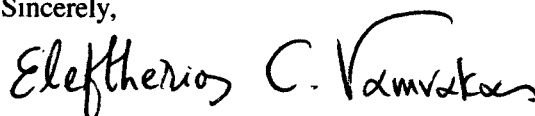
- collected after July 1, 2003 and tested for WNV RNA (*untagged*: tested status can be identified by the collection date of each unit), *or*
- collected between June 16, 2003 and June 30, 2003 in Ontario, and tested for WNV RNA (*tagged*), *or*
- collected prior to June 1, 2003 (in the case of frozen plasma products), *or*
- collected during June 2003 and *not* tested for WNV RNA provided **at least two weeks have elapsed since the collection date and provided that: 1) there has been no report of a confirmed human case of WNV infection in the area where the units were collected, and 2) there has been no positive result for WNV RNA among blood donors in the area where the units were collected.**

Canadian Blood Services considers all aforementioned blood components to be equivalent, in terms of the risk of transmission of WNV infection through transfusion. In the event that the preceding blood components are not available, WNV untested blood components, particularly red cells that are in short supply, collected within the previous two weeks will be released for transfusion at the discretion of a CBS Medical Director.

Canadian Blood Services recommends that information on the risk of transfusion-transmitted WNV be included when obtaining informed consent for transfusion and that the possibility of transfusion-transmitted WNV be considered in patients presenting signs and symptoms of WNV within 4 weeks of blood transfusion.

Physicians who wish to discuss the relative safety of the various blood components listed in this letter, or wish to order WNV-tested products for a particular patient, should contact the Medical Director of their local Blood Centre. (list attached)

Sincerely,



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Executive Vice President,
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