



CANADIAN BLOOD SERVICES
SOCIÉTÉ CANADIENNE DU SANG

Customer Letter #2003-16

Commencement of Testing of All Donations for West Nile Virus (WNV) as of July 2, 2003, and WNV-status of Blood Components Distributed by Canadian Blood Services after July 2, 2003

2003-06-30

Dear Doctor:

Canadian Blood Services (CBS) is in the process of introducing West Nile Virus (WNV) testing of all donations, by an investigational test. All allogeneic and autologous products with a collection date of July 1, 2003 or later will have been tested. These products will have **no additional labeling** and can be **identified by the collection date**. In the event that a product collected on or after July 1, 2003 has to be released for use prior to the completion of testing, the untested status of that product will be identified by an emergency issue label attached to the product.

The test for WNV RNA is investigational, and follows a Clinical Protocol prepared in association with the distributor, Roche Diagnostics (Canada). The test has been approved under a Health Canada Investigational Testing Authorization (ITA), and the protocol has Research Ethics Board approval. As was the case with the introduction of tests for HCV and HIV RNA, the test for WNV RNA is not licensed for use in blood screening, therefore no claim can be made for the performance of the test. The data collected during testing under the ITA will be used by the manufacturer to support a licensing application to Health Canada.

This letter provides updated information to health professionals on the platelet, red cell, and frozen plasma products that will be distributed by CBS during the summer and fall of 2003, that is, during the period of the anticipated 2003 *human* epidemic of WNV in Canada.

Risk of transmission of WNV infection through transfusion

The risk of transmission of WNV through transfusion is *regional* and *seasonal*. It exists *only* when mosquitoes are present to propagate an avian epidemic, and *only after* the epidemic has "spilled over" from birds to animals and 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.

According to data compiled by the U.S. Centers for Disease Control and Prevention (CDC), the risk of transmission of WNV through transfusion in 2002 was low in June and October, started increasing by mid-July, peaked by mid- to late August, and had declined by mid- to late September. A risk of transmission of WNV through transfusion during the month of June, 2002 existed only in those states where human cases of WNV infection had occurred. Thus, in June 2002, the risk of transmission of WNV through transfusion in North America was confined largely to the southern U.S.

For the peak of the 2002 epidemic, and in areas of *maximal* disease activity (e.g., Cleveland, Ohio or Detroit, Michigan), the CDC estimated that the risk of transmission of WNV through transfusion last year was greater than 1 viremic donation per 1,000 donations. This risk should be greatly reduced this year, thanks to the introduction of screening of all donations for WNV. The risk of transmission at the peak of the 2003 epidemic cannot be predicted, as it will depend on the magnitude of the 2003 human epidemic and on the (still unknown) sensitivity of the investigational test used to screen blood donations. Also, the risk of transmission will vary over time, depending on the timing of the 2003 human epidemic. If the 2002 events were to be reproduced, the risk of transmission in mid- to late August and in areas of maximal disease activity would be in the range of 1 viremic donation per 1,000 donations *in the absence of blood screening*. As screening of all donations will be performed, the 2003 risk of transmission at the peak of the epidemic might be 1 viremic donation per 1,000,000 donations (if the screening test turned out to have 99.9% sensitivity, that is, sensitivity similar to that of other tests used to screen the blood supply for infectious disease markers). Conversely, the risk might be 1 viremic donation per 10,000 donations (if the screening test had 90% sensitivity). It is impossible to predict the actual risk, however, because the clinical sensitivity (and overall performance) of the investigational test for WNV RNA will not be known for several months.

Blood products collected *before* human cases of WNV infection appear in any particular region of Canada carry only a most remote risk of transmission of WNV, regardless of whether they have been tested for WNV RNA (or not). Eighty percent of human WNV infections are asymptomatic, however, and—when a symptomatic case arises—two weeks (or more) may have elapsed before a diagnosis of WNV infection can be confirmed by laboratory testing. Thus, in the presence of only *passive* human disease surveillance, the safety of *untested* blood products collected in any particular period cannot be ascertained before two (of more) weeks have elapsed and no case of human WNV infection has been reported. In 2003, however, blood donor screening will serve as an approach to *active* disease surveillance. Blood donors are asymptomatic, and they will be tested for WNV RNA; if no case of WNV infection is detected among blood donors, and a sufficiently large number of donors has been tested, it can be inferred that there is a most remote risk that a human case may have occurred in a population of asymptomatic adults likely to make a blood donation.

On June 16, 2003, both CBS and Héma-Québec introduced "early testing" for WNV. Between June 16, 2003 and June 28, 2003, CBS tested over 10,000 donor samples from Ontario for WNV RNA; and Héma-Québec tested a similar number of samples from Québec. **All were found to be negative for WNV RNA, indicating that—in June 2003—WNV disease activity had, most likely, not yet occurred among asymptomatic adults likely to present as blood donors in Canada.**

As of 2003-06-27, 2,717 dead birds had been tested for WNV, including 524 from Ontario, 327 from Québec, 312 from Manitoba, and 246 from Saskatchewan. Twenty-five birds had produced confirmed-positive results for WNV: 17 from Ontario, 4 from Manitoba, 2 from Saskatchewan, and 2 from Québec. Only one human case of WNV infection had been reported in North America—in a patient from South Carolina—but this case has not yet been confirmed by the CDC. Thus, the 2003 human epidemic of WNV appears to lag behind the 2002 epidemic (when the first human case was reported on June 10 in Louisiana). Based on the foregoing understanding of the risk of transmission of WNV through transfusion in 2003, CBS will be distributing to hospitals the following blood components after July 2, 2002.

Red cells

Red cells shipped to hospitals after July 2, 2003 will be:

- collected on or 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 by either the investigational "in-house" test or the Roche test (*tagged*: see DCL 2003-13), *or*
- collected before July 1, 2003 and *not* tested for WNV RNA. Such units will be shipped to hospitals if **at least two weeks have elapsed since their 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.**

Frozen plasma products

Fresh frozen plasma (FFP), fresh frozen plasma collected through apheresis, frozen plasma (FP), cryoprecipitate, and cryosupernatant plasma (CSP) shipped to hospitals after July 2, 2003 will be:

- collected on or after July 1, 2003 and tested for WNV RNA, *or*
- collected **before May 20, 2003** (i.e., during a period when human WNV disease activity would be most unlikely) and stockpiled by CBS for use (after the onset of the 2003 human WNV epidemic. As a period of more than one month has elapsed since these products were collected, and no human WNV disease activity has yet been reported in Canada, CBS considers that these products carry a *most remote* risk of transmission of WNV.

Platelets

Platelets shipped to hospitals after July 2, 2003 will be:

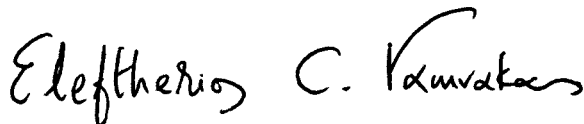
- collected on or after July 1, 2003 and tested for WNV RNA (*untagged*: tested status can be identified by the collection date of each unit), *or*
- collected in the last week of June, 2003 in Ontario, and tested for WNV RNA by the Roche test (*tagged*: see DCL 2003-13), *or*
- collected before July 1, 2003 *outside Ontario* and *not* tested for WNV RNA. Because only minimal avian WNV disease activity has been reported outside Ontario, CBS considers that these products carry a low risk of transmission of WNV infection. Such products will be distributed only during the first week of July, 2003. **After the first week of July, 2003, all platelet components distributed by CBS will have been tested (and found negative) for WNV RNA.**

In conclusion, for the reasons given in the first section of this letter ("Risk of transmission of WNV infection through transfusion"), CBS considers all aforementioned blood components (that will be distributed by CBS in the summer and fall of 2003) to be *equivalent*, in terms of the risk of transmission of WNV infection through 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 Center.

Further Information

To contact Canadian Blood Services, please refer to the attached listing of Regional Medical Directors.

Sincerely,



Eleftherios C. Vamvakas, M.D., Ph.D., MPH
Executive Vice President,
Medical, Scientific and Research Affairs

**CANADIAN BLOOD SERVICES
MEDICAL DIRECTORS
LISTED BY PROVINCE WEST TO EAST**

Centre	Contact	Phone	Email
BC & Yukon	Medical Consultant Dr. Mark Bigham	604-707-3505	mark.bigham@bloodservices.ca
Edmonton	Medical Director Dr. Judy Hannon	780-431-8714	Judy.hannon@bloodservices.ca
Calgary	Medical Director Dr. Dale Towns	403-410-2676	Dale.towns@bloodservices.ca
Saskatchewan	Medical Director Dr. Edward C. Alport	306-347-1652	Ted.alport@bloodservices.ca
Winnipeg	Medical Director Dr. Debra Lane	204-789-1079	Debra.lane@bloodservices.ca
Sudbury	Associate Medical Director Dr. Teofil Ciszewski	705-688-7336	Teofil.ciszewski@bloodservices.ca
London	Medical Director Dr. Robert Barr	519-690-3944	Bob.barr@bloodservices.ca
Hamilton	Medical Director Dr. Morris Blajchman	905-521-2100 Ext 76274	Blajchma@mcmaster.ca
Toronto	A/Medical Director Dr. Barbara Hannach	416-313-4431	Barbara.hannach@bloodservices.ca
Ottawa	Medical Director Dr. Peter Lesley	613-560-7209	Peter.lesley@bloodservices.ca
New Brunswick	Medical Director Dr. John Mackay	506-648-5059	John.mackay@bloodservices.ca
Nova Scotia and Prince Edward Island	Medical Consultant Dr. Irene Sadek	902-474-8286 902-474-8211	Irene.sadek@bloodservices.ca
Newfoundland & Labrador	Medical Director Dr. Karl Misik	709-758-8037 709-758-8086	Karl.misik@bloodservices.ca