



CANADIAN BLOOD SERVICES
SOCIÉTÉ CANADIENNE DU SANG

Customer Letter #2003-21

Precautionary Voluntary Withdrawal of Red Blood Cells and Frozen Plasma Components Collected in Saskatchewan Between August 4, 2003 and August 31, 2003 inclusive

September 3, 2003

Dear Customer:

Starting with the collections made on Tuesday, September 2, 2003, Canadian Blood Services (CBS) moved to single-unit (as opposed to mini-pool) testing for West Nile Virus (WNV) RNA of all donations made in Saskatchewan. At the same time, CBS is undertaking a voluntary withdrawal of red blood cells (RBCs) and frozen plasma components collected in Saskatchewan between August 4, 2003 and August 31, 2003. All these collections have been tested for WNV RNA by a mini-pool nucleic acid technology (NAT) test, and CBS is undertaking these measures on a purely *precautionary* basis, to add an extra layer of safety for the Canadian blood supply until the sensitivity of the screening test for WNV RNA is determined.

Frozen plasma components (fresh frozen plasma, frozen plasma, cryoprecipitate and cryosupernatant plasma) will be replaced by stockpiled frozen plasma components collected between January 1 and June 1, 2003; replacement of hospital stocks will begin within the next 24 hours. RBCs will be replaced by units prepared from donations made in other provinces; replacement of hospital stocks will begin within the next 48 hours. We anticipate that hospital stocks of RBCs and frozen plasma components will be complete by September 12, 2003 with the probable exception of group AB cryoprecipitate which we may not be able to completely replace. (Units collected in Saskatchewan can be identified as described in Appendix I.)

Until replacement of targeted units is complete and to assist CBS in carrying out this withdrawal and replacement you are asked to:

1. quarantine all units of red blood cells, fresh frozen plasma, frozen plasma, cryoprecipitate, and cryosupernatant plasma collected in Saskatchewan between August 4, 2003 and August 31, 2003 inclusive;
2. provide information to CBS on the number of quarantined units broken down by product and by ABO group;
3. release these units for transfusion *only if* no replacement components are

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- available for release;
4. destroy quarantined components *after* receiving replacement components from CBS; and
 5. confirm in writing to CBS the unit numbers of destroyed components and the date of destruction.

In prioritizing the use of quarantined components, please consider the clinical diagnosis of the transfusion recipient. Where possible, for patients at high-risk for WNV encephalitis preference should be given to issuing replacement components received from CBS over components collected in Saskatchewan between August 4, 2003 and August 31, 2003. These patients include (in the following order):

1. immunocompromised persons;
2. patients with hematologic malignancies;
3. pregnant women, women immediately post-partum, and neonates; and
4. the elderly. The elderly can be defined as patients over 65, or over 70 years of age, depending on availability of replacement components.

The rationale for these *precautionary* measures is discussed below.

Single-unit (as opposed to mini-pool) testing for WNV RNA in units collected in Saskatchewan as of September 2, 2003

On July 2, 2003, CBS (along with other North American blood centers) started screening all blood donations for WNV RNA. Two systems for WNV RNA detection are used presently in North America, one developed by Roche Molecular Systems and one developed by Chiron/Gen-Probe. CBS uses the Roche system. In both the U.S. and Canada the test systems are being used as part of investigational (research) protocols. The Roche assay has been configured in mini-pools of 6, that is, 6 donor samples are pooled and tested for WNV RNA after pooling.

In theory, the WNV RNA test would be expected to perform better (i.e., to be more likely to detect low-level WNV RNA in the circulation of a blood donor) if single-unit testing (as opposed to mini-pool testing) were used. However, the sensitivity of the test system is unknown at present, and data collected during the 2003, and perhaps also the 2004, WNV epidemic will be used to determine the sensitivity of the test. As of now, there are no empirical data: 1) on the clinical sensitivity of the Roche test (used either singly, or in mini-pools of six), or 2) to support the theoretical prediction that single-unit testing is superior to mini-pool testing. Whether this is so will depend on the lower limit of viral load that can transmit WNV infection through transfusion. However, although it remains uncertain that single-unit testing by the Roche test is *superior* to mini-pool testing, it can be assumed that single-unit testing is at least as safe as mini-pool testing.

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Most North American blood centers cannot implement single-unit testing of all blood donations for WNV RNA during the 2003 mosquito season, because of various considerations relating to logistics, technology, and workload. Because CBS is a national blood system, however, it is able to implement very limited single-unit testing for WNV RNA on all blood donations made in a *restricted* geographic area. The size of the geographic area in which single-unit testing can be implemented must be carefully considered against the capacity of the entire system to absorb an increase in the testing needs of that area by six-fold.

Thus, CBS will move to single-unit testing in a *restricted* geographic area (Saskatchewan) during the *peak* of the 2003 WNV epidemic. If the sensitivity of mini-pool testing were lower than that of single-unit testing, this intervention would contribute the *most* to the safety of the Canadian blood supply if it targeted the area with the highest level of WNV disease activity. Thus, CBS is moving to single-unit testing for Saskatchewan, because 8 of 12 WNV-positive donations made as of August 31, 2003 in provinces supplied by CBS have been made in Saskatchewan. After the 2003 epidemic in Saskatchewan subsides, CBS will move back to mini-pool testing. CBS may also switch back to mini-pool testing if data collected in the interim, in both the U.S. and Canada, show no superiority of single-unit testing over mini-pool testing.

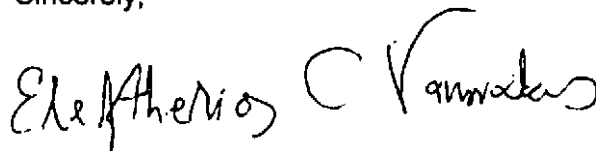
Withdrawal of red blood cell and frozen plasma components collected in Saskatchewan

If the clinical sensitivity of the Roche screening test were suboptimal, the test would be most likely to miss an infectious donation in the area where the highest level of WNV disease activity exists (and most WNV-positive infectious donations are made). One WNV-positive donation was made in Saskatchewan on July 22, 2003, but no other WNV-positive donation was made there until the week of August 4, 2003. Because 7 WNV-positive donations were made in Saskatchewan between August 4, 2003 and August 31, 2003, it is conceivable that some infectious donations made during August might have been missed by the Roche test if the clinical sensitivity of the test were suboptimal. For this reason, CBS opted to undertake a *voluntary* withdrawal of red blood cell and frozen plasma components collected in Saskatchewan between August 4, 2003 and August 31, 2003. **This withdrawal is undertaken on a purely *precautionary* basis. To date, there have been no confirmed cases of transfusion-transmitted WNV infection, which might have been transmitted by a WNV-screened unit that was missed by the Roche test.**

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

Appendix I: Instructions for Identifying Blood Components Collected in Saskatchewan

Appendix II: Regional CBS Medical Directors

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Appendix 1

Instructions for Identifying Blood Components Collected in Saskatchewan

Each Canadian Blood Services Centre has a unique three digit identifying code. The following list identifies the unique three digit numbers that are applicable to our sites in Saskatchewan:

- 530
- 531

This three digit Centre identifier is located to the left of the Blood Unit Identification Number. The following illustration is a graphic depiction of where the three digit identifier is found.



The date of collection is located under the Blood Unit Identification Number. The following illustration is a graphic depiction of where the date of collection is found.



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

Centre	Contact	Phone	Email
BC & Yukon	Medical Consultant Dr. Jerry Growe	604-707-3449	Gershon.growe@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
Halifax	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