# Surveillance Report

# 2013

Canadian Blood Services
*it's in you to give*

# Executive summary

We are pleased to present the second report for our stakeholders describing infectious disease surveillance. High quality and timely surveillance is key to the safety of the blood supply. This includes monitoring of transmissible disease markers that the blood is tested for (including bacterial infections), investigation of any reports of possible transfusion transmission, as well as a horizon scan for any new pathogens that may pose a risk now or in the future.

The most up-to-date tests for pathogens are used to identify infectious donations and prevent their release for patient use. In 2013, transmissible disease rates per 100,000 donations continued to be very low: HIV 0.2, Hepatitis C 5.3, Hepatitis B 6.3, HTLV 1.1 and Syphilis 3.9. Selective testing of donors at risk of Chagas' disease identified 2 positive donations, and there were 6 donations positive for West Nile Virus. The residual risk of a potentially infectious donation from a unit of blood also remains very low at 1 in 8 million donations for HIV, 1 in 6.7 million donations for HCV and 1 in 1.7 million donations for HBV. Lookback and traceback investigations did not identify any transfusion transmitted infections. Bacterial growth was identified in 8 platelet products.

Horizon scanning for emerging pathogens has identified no immediate threats to safety, but a seroprevalence study to assess the risk from Babesiosis, a tick borne disease currently seen in the USA, was completed in 2013. It showed no donations were positive for antibody to babesia of over 10,000 tested. Studies in the USA and some European countries suggest that some blood donors may have hepatitis E infections and although transfusion transmitted cases have not been reported, samples stored from this study will also be tested for hepatitis E.

In summary, transmissible disease continues to be very rare in Canadian Blood Services' donors. Ongoing surveillance will continue to play a prominent role in the safety of the blood supply.

# Introduction

Safety of the blood supply from pathogens involves a multifaceted approach. Donor education materials on the internet and required reading just before donating explain risk factors for transmissible diseases and who should not donate. Before donating blood everyone must complete a health history questionnaire which includes questions about specific risk factors for transmissible diseases and answers are used to decide if people are safe to donate. All donations are tested for markers of transfusion transmissible agents including HIV (the AIDS virus), Hepatitis B (HBV) and Hepatitis C (HCV), Human T-Cell Lymphotropic Virus (HTLV) (a rare leukemia virus), Syphilis and West Nile Virus (WNV). In addition, donors at risk of Chagas' disease (which is acquired from the bite of an insect in Latin America) are tested, and all platelet products are tested for bacteria.

Canadian Blood Services carries out comprehensive surveillance of blood borne pathogens to monitor changing trends in known infections and to identify new infectious diseases. This information will allow us to put additional safeguards in place to reduce any risk to recipients of blood products. Surveillance includes monitoring of transmissible disease testing in blood donors, investigation of possible transfusion transmitted infections in blood recipients and horizon scanning for new, emerging pathogens. Although surveillance is conducted in "real time" over each year, final verification steps generally impose a short delay in producing a final report. This report describes Canadian Blood Services' approach to transmissible disease surveillance, as well as data for 2013.

# 1. Blood Donor Surveillance

The number of blood donations (whole blood and platelet and plasma apheresis) in donations from first time and repeat donors are shown in Figure 1. The majority of donations are from repeat donors (90.4%) with 9.6% of donations from new donors.

***The "Classical" Pathogens***

All blood donations are tested for transmissible diseases and are monitored in order to detect changes in trends. Details of screening tests used and dates of implementation are shown in Appendix 1. In Table 1 the number of positive donations and the rate is shown for 2013 by demographic groups. All transmissible disease positive donations occurred in whole blood donations (none in apheresis donations). As shown in Figure 2, the rate per 100,000 donations has decreased for most markers and the rate for repeat donations is extremely low. When a transmissible disease is detected, it is most often in a first time donation as these donors have not been tested previously and may have acquired the infection at any time in their life.

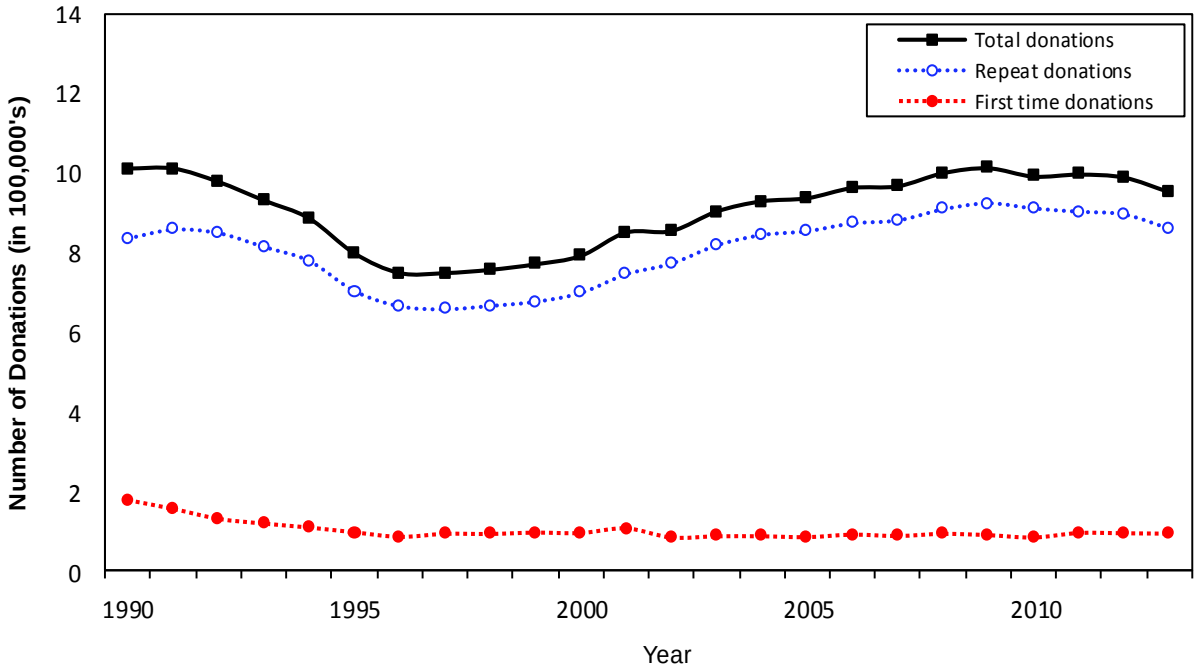
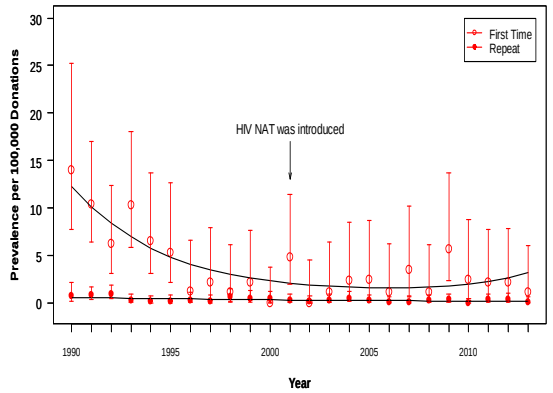


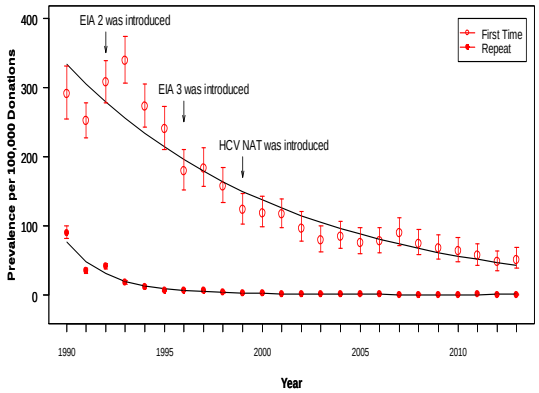

**Figure 1** Donations in all Canadian Blood Services Regions, 1990-2013

**Table 1** Confirmed positive donations and prevalence rates per 100,000 donations in 2013

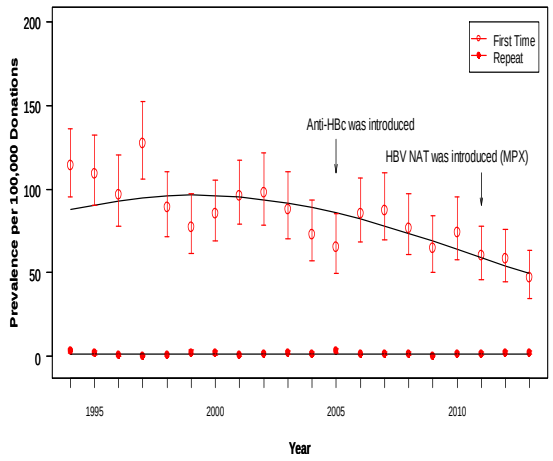
| Characteristic | Number of Donations | Percent of Donations | HIV | | HCV | | HBV | | HTLV | | Syphilis | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | Pos | Rate | Pos | Rate | Pos | Rate | Pos | Rate | Pos | Rate |
| **Donor status** | | | | | | | | | | | | |
| **First time** | 91,578 | 9.6 | 1 | 1.1 | 47 | 51.3 | 43 | 47.0 | 9 | 9.8 | 28 | 30.6 |
| **Repeat** | 859,108 | 90.4 | 1 | 0.1 | 3 | 0.4 | 17 | 2.0 | 1 | 0.1 | 9 | 1.1 |
| **Sex** | | | | | | | | | | | | |
| **Female** | 408,132 | 42.9 | 1 | 0.3 | 21 | 5.24 | 17 | 4.2 | 7 | 1.7 | 10 | 2.5 |
| **Male** | 542,554 | 57.1 | 1 | 0.2 | 29 | 5.4 | 43 | 7.9 | 3 | 0.6 | 27 | 5.0 |
| **Age** | | | | | | | | | | | | |
| **17-29** | 210,576 | 22.2 | 0 | - | 9 | 4.3 | 19 | 9.0 | 3 | 1.4 | 7 | 3.3 |
| **30-39** | 130,591 | 13.7 | 1 | 0.8 | 7 | 5.4 | 9 | 6.9 | 0 | - | 6 | 4.6 |
| **40-49** | 181,520 | 19.1 | 0 | - | 6 | 3.3 | 17 | 9.4 | 3 | 1.7 | 15 | 8.3 |
| **50+** | 427,999 | 45.0 | 1 | 0.2 | 28 | 6.5 | 15 | 3.5 | 4 | 0.9 | 9 | 2.1 |
| **Total** | **950,686** | **100** | **2** | **0.2** | **50** | **5.3** | **60** | **6.3** | **10** | **1.1** | **37** | **3.9** |



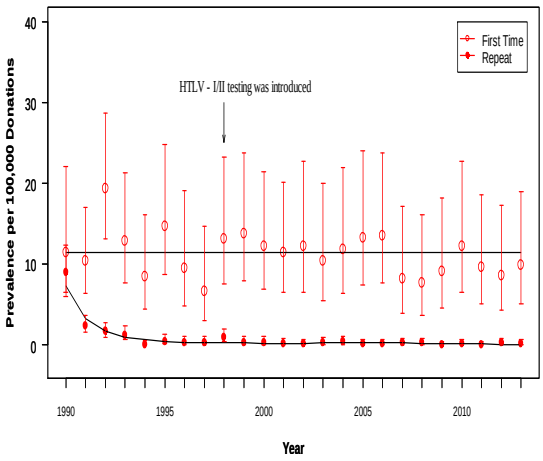

HIV prevalence per 100,000 donations
by donation status, 1990-2013



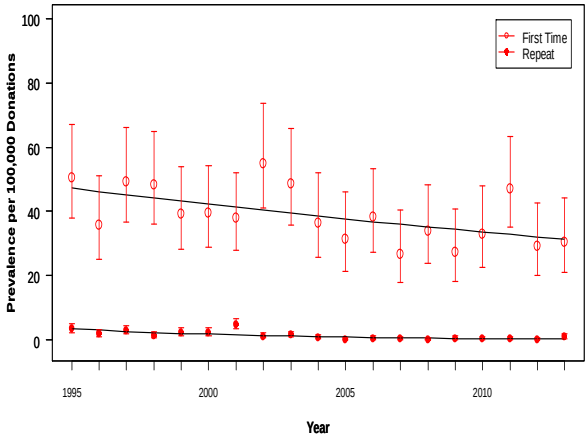

HCV prevalence per 100,000 donations
by donation status, 1990-2013




HBV prevalence per 100,000 donations
by donation status, 1994-2013




HTLV prevalence per 100,000 donations
by donation status, 1990-2013




Syphilis prevalence per 100,000 donations
by donation status, 1995 - 2013

**Figure 2** Rate of HIV, HCV, HBV, HTLV and Syphilis in first-time and repeat donations (Note that these graphs have different scales on the y-axis)

All transmissible disease positive donations are destroyed and never released into inventory. The main source of risk is from blood donors with a very recently acquired transmissible disease that is too recent to be detected by testing, but may be transmitted by transfusion. This is called the "window period" of infection. With current state-of-the-art testing the window period is very short. For HIV and HCV an infection would be detected within about 1 to 2 weeks of a donor being infected, and for HBV within one month. The residual risk of infection as shown in Table 2 is the estimated risk of a potentially infectious donation being made during the "window period", and is currently extremely low, but of course it can never be zero.

**Table 2** Estimated residual risk of HIV, HCV and HBV

| HIV | HCV | HBV |
|---|---|---|
| 1 in 8 million donations | 1 in 6.7 million donations | 1 in 1.7 million donations |

***Risk Factors***

Risk factor interviews are carried out with donors who test positive for transmissible diseases. For HIV the main risk factors are multiple sex partners. For HCV the main risk factors are a history of intravenous drug use or a sexual partner with a history of intravenous drug use, a history of blood transfusion (prior to testing the blood for HCV), having been in prison and being born in Africa or Asia where HCV is more common. For HBV the main risk factor was being born in Africa or Asia where HBV is more common. For HTLV the main risk factors were being born overseas (especially the Caribbean), as well as a history of other sexually transmitted diseases, and a history of blood transfusion. For Syphilis the main risk factor was a history of Syphilis. It should be noted that participation is voluntary and therefore there is only data for some donors, and that for many donors no risk factors were identified.

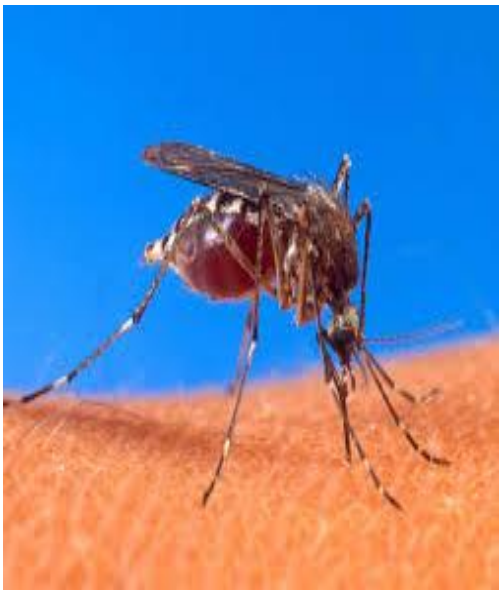
***Chagas Disease*** *(Trypanosoma cruzi)*

Riduviid bug which carries *T. cruzi* (the parasite that causes Chagas' disease)

Chagas disease is caused by infection from a parasite called *Trypanosoma cruzi* (*T. cruzi*). People can become infected with it after being bitten by an insect that is found mainly in parts of Mexico, Central and South America but the *T. cruzi* parasite can also be passed on from an infected mother to her child during pregnancy and from an infected blood donor by blood transfusion. The insect is not able to live in Canada. Since May, 2009, Canadian Blood Services has been asking questions about risk of Chagas' disease on the donor health history questionnaire originally to not make platelets from at-risk donors. In May, 2010 testing at-risk blood donors for antibodies to *T. cruzi* started. In 2013, there were 15,090 donations from donors with risk factors, and 2 had positive tests for *T. cruzi* antibody.


Regions of the world endemic for T. cruzi

***West Nile Virus***



West Nile Virus is a mosquito borne virus that has been present in North America since 1999 (in Canada since 2002). Although symptoms can be severe, they are usually mild and most people are not aware of their infection. All donations are tested in a minipool of 6 donations. However, to further reduce the risk, a risk assessment algorithm is applied to identify all donations from areas where West Nile Virus is active and these are tested as single units rather than in a minipool. In 2013, 6 donations tested positive for West Nile Virus. They were identified over the summer and fall months (August – November) in Saskatchewan and Ontario. There were also community cases in these areas.

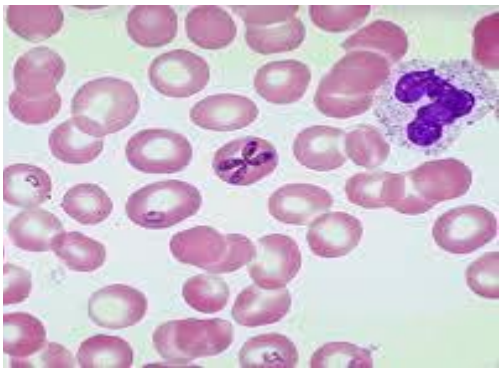
## 2. Surveillance for emerging pathogens

A central feature of surveillance is a horizon scan of potentially blood transmissible infectious diseases in the general community. It is important to be aware of emerging infectious diseases in other parts of the world as well as in Canada since international travel is commonplace and infections can circulate from other countries quite rapidly. To ensure that potential risks are identified in a timely fashion, Canadian Blood Services needs to be connected with the latest infectious disease information at all times. Integral to this is active participation of Canadian Blood Services medical and scientific staff in public health and infectious disease professional organizations as well as monitoring of web sites and journals where new information is posted. In order to ensure readiness to act in the event of a new infectious disease threat, Canadian Blood Services maintains a plan to address pandemic influenza, which can be adapted to deal with other large outbreaks affecting staff and donors.

***Babesiosis***

Babesiosis is usually acquired from the bite of a tick (*Ixodes scapularis*), more commonly called the black legged tick. Usually it causes mild flu-like symptoms, and many people are not even aware that they have had it. However, it can also be transmitted by blood transfusion from an infected donor, and infection in blood recipients can result in severe illness or death. To date babesiosis cases have been documented in the United States, mainly in the North Eastern States, but the number of reported cases has been increasing following the designation of this infection as a reportable disease, and over 100 infections in the USA are believed to have been acquired from a transfusion. Ticks capable of carrying this parasite are found in Canada, but there is little active surveillance in Canada. In 2013 10,062 blood donations were tested for antibody to *Babesia microti* in a study (donors were from areas in Canada bordering risk areas in the USA - southern Ontario, southern Manitoba, Nova Scotia and New Brunswick). None of the donations were positive, thus at this time *Babesia microti* does not appear to be a threat to the blood supply. However, as this may change ongoing vigilance is required.

Black-legged tick



*Babesia microti*

***Hepatitis E***

Hepatitis E is relatively common in developing countries where it is spread through contaminated food and water. Healthy people often do not get very sick, generally clear the infection and often never know that they had it. However, blood recipients could become very ill. We do not know how often Hepatitis E occurs in Canada, and are testing donors for Hepatitis E on stored samples from the study for babesiosis (see section above).

### *Middle East Respiratory Syndrome*

The Middle East respiratory syndrome (or MERS) was first reported in Saudi Arabia in 2012. It is caused by MERS-CoV, a coronavirus from the same family of viruses that caused the SARS outbreak in Toronto in 2003. So far over 180 cases of MERS-CoV have been reported, but they have all been linked to the Middle East (mostly Saudi Arabia). No cases have been reported in Canada to date.

## 3. New Initiatives

### *Multiplex Nucleic Acid Testing*

Canadian Blood Services tests for antibody to hepatitis C and HIV, and does two tests for hepatitis B (hepatitis B surface antigen and antibody to hepatitis B core antigen). An extra test called Nucleic Acid Testing (or NAT) identifies the genetic material of viruses, and can detect very recent infections. NAT for hepatitis C has been in place since 1999 and for HIV since 2001 in minipools of 24 donations. In February of 2011 these were replaced with a new NAT platform using a smaller minipool size (only 6 donations) which is better able to detect small amounts of genetic material. This new multiplex NAT tests for hepatitis C, HIV and hepatitis B. Since it was implemented, one donor with hepatitis C and one donor with hepatitis B that may have been missed with the previous testing have been identified, but none in 2013.

***Pathogen Reduction***

A study of the pathogen reduction system for platelet products is currently under way. The Mirasol Pathogen Reduction System for Platelets uses riboflavin (vitamin $B_2$) to inactivate many viruses and bacteria and parasites when exposed to ultraviolet light. It may also reduce the risk of graft versus host disease for platelet recipients. Before considering implementing such a system it is important to confirm that it does not reduce the effectiveness of the platelets to stop bleeding in patients. To do this, adult patients who have blood cancers and low platelets and who have volunteered to be in the study are randomly assigned to either receive the Mirasol pathogen reduced platelets or our regular platelets, and are being monitored for any adverse effects. This study is currently being carried out at selected hospitals in Canada and in the Netherlands and Norway. To date, over 300 platelet recipients are enrolled in the study, including 40 from Canada. In total the study will involve over 600 platelet recipients.

***Donor Re-entry Following a False Positive Transmissible Disease Test***

Due to the sensitivity of the screening tests Canadian Blood Services uses, sometimes donors will test positive but the confirmatory testing is negative. These are called 'false positives' and unfortunately, to date these donors are permanently deferred based on the screening result. Beginning in early 2014, when the necessary computer changes are made, donors with false positive HIV, HCV or HBV result (those with a final interpretation of negative or indeterminate by confirmatory testing) will be invited to return for 'specimens only' after a 6 month waiting period. If all testing is negative, then the donor will be able to return to donate blood.

***Donor Eligibility Criterion for Male to Male Sex***

Since the 1980's men who have had sex with another man even once since 1977 were not eligible to donate blood to reduce the risk from HIV. With much improved donor testing since then, and following consultation with patient and community stakeholders, in July, 2013 male donors became eligible to donate if they have not had sex with another man in the past 5 years. Some other countries have implemented even shorter deferral periods (for example 12 months in England and Australia) and have not seen any evidence of increased risk to the blood supply. Careful evaluation of safety will be carried out over the next few years, with the potential to further reduce the deferral period in the future.

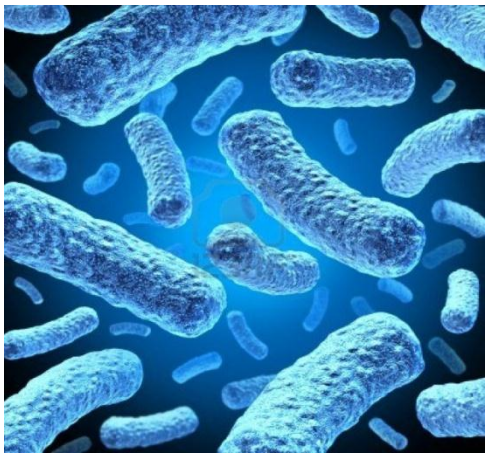
## 4. Lookback/Traceback

All cases of potential transfusion transmission of disease are investigated. When a donor tests positive for a transmissible disease, or if the donor reports a transmissible disease after donating (syphilis and WNV excluded) (either via public health notification or reported to CBS by the donor) a lookback file is opened. All previous donations are identified and the hospitals are asked to contact the recipients of these donations to arrange testing. A traceback is initiated when a recipient is found to have a transmissible disease and it is queried as to whether it could have been from their blood transfusion. All blood products that the recipient received are identified by the hospital, and Canadian Blood Services attempts to contact the donors of these products to arrange testing.

There were 242 lookback files opened in 2013 (124 for donors that tested positive, 113 from public health notification and 5 identified during traceback investigation). Of these, 141 were from first time donors who had no previous donations to examine. The remaining 101 cases included 6 HIV, 71 HCV, 21 HBV, 1 HTLV and 2 Chagas. Of these, 45 cases were closed (all recipients that could be contacted were tested) and 56 cases were still open. No cases were associated with transfusion transmission. There were 99 traceback cases opened in 2013 (1 HIV, 92 HCV, 5 HBV, and 1 HTLV). Of these, 86 were closed (all donors that could be contacted were tested), and 13 remain open. There were no cases associated with transfusion transmission.

## 5. Bacteria

Bacteria in blood products usually come from the skin of donors during their blood donation, although occasionally they may originate from a systemic infection in the donor. When a blood product is contaminated with bacteria, the amount of bacteria is usually very low, and frequently undetectable, but because platelet products are stored at room temperature the bacteria can multiply to the point that



they would pose a serious risk to the recipient. Canadian Blood Services tests all apheresis and pooled platelet products for bacteria using the BacT/ALERT System in which a sample from the product is inoculated into culture bottles and monitored for growth for the full 5-day shelf life of the product. The product would be returned if any bacterial growth were detected and the product is still available (ie, has not been transfused or discarded). In 2013, 107,003 platelet products (26,102 apheresis and 80,901 pooled products) were tested of which 38 apheresis and 48 pooled products had positive results for bacterial growth in the culture bottle. From these, 2 and 6 cultures were confirmed as true bacterial contaminations, for apheresis and pooled products, respectively. In addition, 9 of the 38 apheresis and 6 of the 48 pooled products with initial positive results were not confirmed as they were issued and/or transfused. On average, this represents 23 products in total (2.1 per 10,000) with chance of bacterial contamination with current testing, including both true positives and suspected positives.

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## Implementation Dates of Testing

| | Marker | Implementation Date* |
|---|---|---|
| 1 | **Syphilis** | 1949 |
| 2 | **HBV (Hepatitis B Virus)** | |
| | HBsAg | 1972 |
| | Anti-HBc | 2005 |
| | HBV NAT | 2011 |
| 3 | **HIV (Human Immunodeficiency Virus)** | |
| | Anti-HIV-1 EIA (Enzyme-linked Immunosorbent Assay) | 1985 |
| | Anti-HIV-1/2 EIA | 1992 |
| | HIV-1 p24 Antigen | 1996 (discontinued in 2003) |
| | HIV-1 NAT | 2001 |
| | Anti-HIV-1/2 (including HIV-1 subtype O) EIA | 2003 |
| 4 | **HTLV (Human T-Lymphotropic Virus)** | |
| | Anti-HTLV-I | 1990 |
| | Anti-HTLV-I/II | 1998 |
| 5 | **HCV (Hepatitis C Virus)** | |
| | Anti-HCV EIA/ELISA | 1990 |
| | HCV NAT | 1999 |
| 6 | **WNV (West Nile Virus)** | |
| | WNV NAT | 2003 |
| 7 | **Chagas' disease (*Trypanosoma cruzi)* selective testing** | 2010 |
| 8 | **Bacteria** | |
| | BacT Alert | 2004 |

*These are the dates that testing for the marker began. Tests have been upgraded as new versions of the test became available.