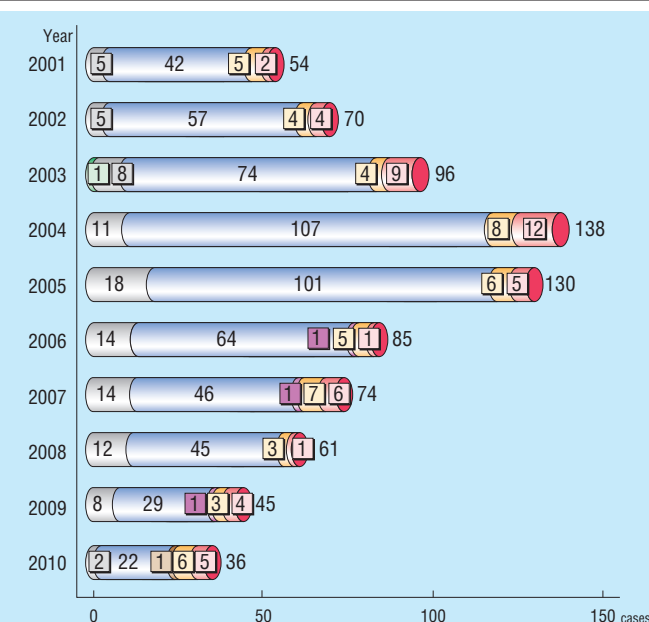
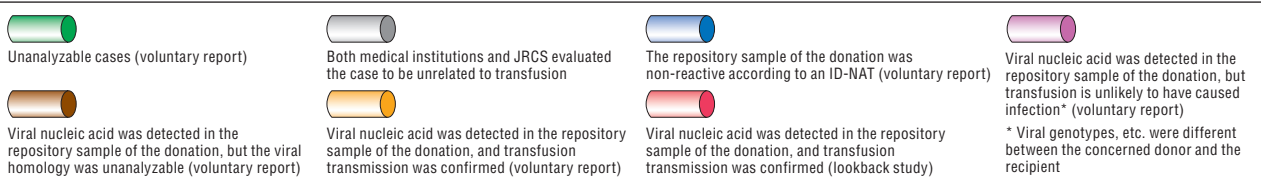


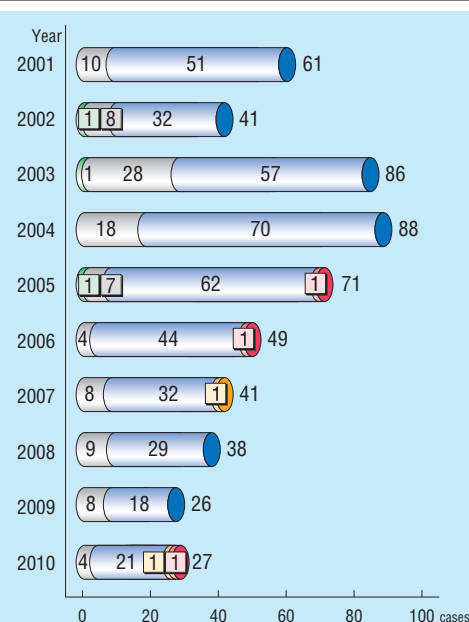
Infectious Cases of Probably Related to Transfused Blood Components (2010)

JRCS analyzed and evaluated suspected transfusion transmitted viral and other infectious cases reported voluntarily by medical institutions to JRC blood centers and lookback study cases based on post-donation information. In 2010, eleven cases of HBV infection (from nine blood donors), two cases of HCV infection (from one blood donor), and one case of HAV infection were confirmed by a positive viral nucleic acid test on a repository sample of the donation involved.

The Number of Cases Reported to JRC Blood Centers and/or Examined in Response to Post-donation Information on Suspected Transfusion-transmitted Infections, and the Results of Analysis [HBV and HCV infections] (2001 to 2010)



The number of suspected transfusion transmitted HBV cases reported by medical institutions (recipients who tested positive for HBV markers after transfusion)* and the results of analysis



The number of suspected transfusion transmitted HCV cases reported by medical institutions (recipients who tested positive for HCV markers after transfusion)* and the results of analysis

*The data includes cases in which both the medical institutions and JRCS had denied a causal relationship with transfusion in the past for reasons such as suspected infection before the transfusion.

Summary of Case Reports (Transfusion transmission confirmed cases in which viral nucleic acid or bacteria was detected in the repository sample and/or relevant component of the concerned donor) (2010)

[HBV]

Voluntary reports: Cases reported by medical institutions

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test*			ALT		Recipient's sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
1	Acute leukemia	FFP5 (2008.10)	30s	F	HBV-DNA, HBsAg, HBsAb, HBcAb	Neg.	2 days	HBsAb, HBcAb	Pos.	33 wks	1559	33 wks	Unavailable
2	Chronic lymphocytic leukemia	Ir-RCC-LR (2009.8)	70s	M	HBsAg, HBsAb, HBcAb	Neg.	21 days	HBV-DNA	Pos.	19 wks	1952	19 wks	Available
3	Gastric cancer/Rectal cancer	RCC-LR (2009.4)	60s	M	HBsAg, HBsAb, HBcAb	Neg.	8 wks	HBsAg	Pos.	36 wks	1583	35 wks	Available
4	Trauma due to a traffic accident	FFP-LR (2008.11)	30s	M	HBsAg, HBsAb, HBcAb	Neg.	0 day	HBV-DNA	Pos.	14 wks	2590	22 wks	Available
5	Malignant lymphoma	Ir-RCC-LR (2009.11)	60s	M	HBsAg, HBsAb, HBcAb	Neg.	1 day	HBsAg	Pos.	24 wks	352	25 wks	Available
6	Pancreatic cancer	FFP-LR (2009.8)	70s	M	HBsAg, HBsAb, HBcAb	Neg.	1 day	HBsAg	Pos.	17 wks	◆	◆	Unavailable

*Test results at medical institutions (on the day of the positive test result) ◆ No increase in ALT or no comparative data available

● Post donation information: Cases reported by medical institutions based on lookback studies of positive conversion of a repeat donor

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test*			ALT		Recipient's sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
7	Pseudoaneurysm of the ascending aorta	Ir-RCC-LR (2009.10)	10s	F	HBV-DNA, HBsAg, HBsAb, HbCAb	Neg.	1 day	HBsAb, HbCAb	Pos.	33 wks	◆	◆	Available
8	Uterine myoma	Ir-RCC-LR ^{*1} (2010.4)	50s	F	HBV-DNA, HBsAg, HBsAb, HbCAb	Neg.	0 day	HBV-DNA	Pos.	19 wks	◆	◆	Available
9	Gastric cancer	RCC-LR ^{*1} (2009.4)	70s	F	HBsAg	Neg.	14 days	HBsAg	Pos.	27 wks	589	27 wks	Available
10	Aplastic anemia	Ir-PC-LR ^{*2} (2010.6)	10s	M	NA			HBV-DNA	Pos.	10 wks	◆	◆	Unavailable

*1 Blood components derived from the same blood donor

*2 The relevant donation had tested negative for HBV-DNA

● Post-donation information: Case reported by the medical institution that had supplied the plasma component derived from the same donation of the possible case of voluntary report no.3

11	Pancreatic cancer	FFP-LR (2009.4)	70s	M	HBsAg	Neg.	74 days	HBV-DNA	Pos.	10 wks	◆	◆	Unavailable
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[HCV]

● Voluntary reports: Cases reported by medical institutions

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test*			ALT		Recipient's sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
1	Refractory reflux oesophagitis, Mallory-Weiss syndrome	RC-M•A•P (2006.11)	40s	F	HCV-Ab	Neg.	48 days	HCV-Ab	Pos.	33 wks	796	7 wks	Unavailable

● Post-donation information: Case reported by the medical institution that had supplied the plasma component derived from the same donation of the voluntary report case no.1

2	Intrahepatic lithiasis	FFP (2006.11)	70s	M	HCV-Ab	Neg.	40 days	HCV-RNA	Pos.	168 wks	◆	◆	Unavailable
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[HAV]

● Post-donation information: Case reported by a medical institution based on lookback studies of the donor's health information

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test*			ALT		Recipient's sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
1	Chronic renal failure, etc.	Ir-RCC-LR (2010.2)	70s	M	NA			HAV-RNA	Pos.	5 wks	◆	◆	Available

*Test results at medical institutions (on the day of the positive test)

◆ No increase in ALT or no comparative data available

Number of times that the nucleic acid amplification test (NAT) was performed and the frequency of positive samples (July 1999 to May 2011)

The table below describes the number of positive NAT results against donated blood samples with seronegative results (HBsAg: Negative; HbCAb: Negative; HCV-Ab: Negative; HIV-1- and HIV-2-Abs: Negative; ALT level: Normal).

Pooled size of samples	Number of tested samples	Number of positive NAT confirmed by ID-NAT (frequency)		
		HBV	HCV	HIV
500 (Jul. 1999 to Jan. 2000)	2,140,207	19 (1/11×10 ⁴)	8 (1/27×10 ⁴)	0 (-)
50 (Feb. 2000 to Aug. 2004)	24,702,784	473 (1/5×10 ⁴)	72 (1/34×10 ⁴)	8 (1/309×10 ⁴)
20 (Aug. 2004 to May 2011)	33,446,728	611 (1/5×10 ⁴)	45 (1/74×10 ⁴)	14 (1/239×10 ⁴)

In case any of adverse reactions and/or infections related to transfusion of blood components or administration of plasma derivatives, please notify the medical representatives of your local JRC blood center immediately. Please provide the residual products, the recipient's pre- and post-transfusion samples, and any other related materials; it is helpful to investigate and/or identify the cause. For storage of residual products and the recipient's samples, refer to the "Guidelines for lookback studies of blood products."

Online Haemovigilance Information for Healthcare Professionals

URL <http://www.jrc.or.jp/mr/english/>

Issued by:

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*For more information, please contact the medical representatives of your local JRC blood center.