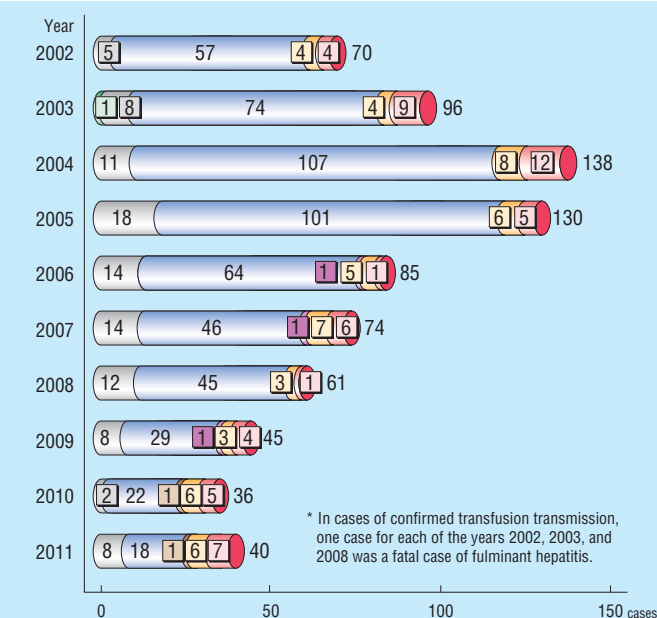
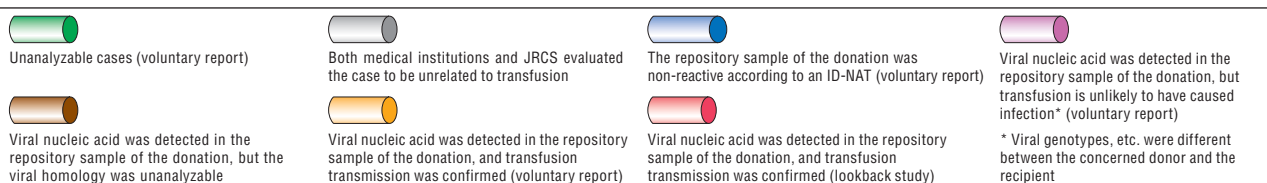


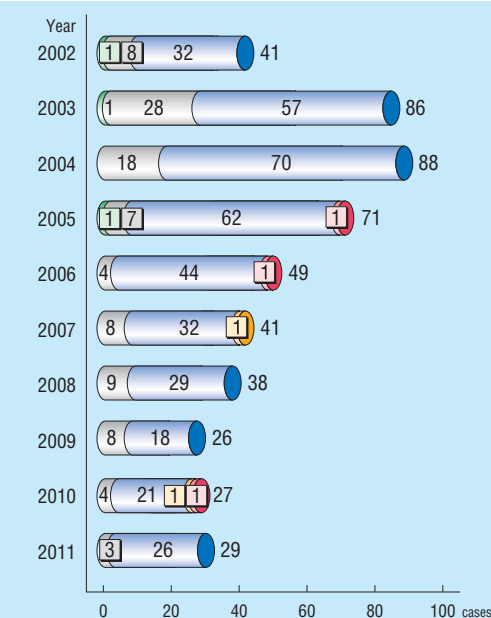
Infectious Cases of Probably Related to Transfused Blood Components (2011)

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 2011, thirteen cases of HBV infection and one case of human parvovirus B19 were confirmed by a positive viral nucleic acid test on a repository sample of the donation involved. One case of *Streptococcus dysgalactiae* subsp. *equisimilis* (Group G hemolytic streptococcus) was confirmed by the bacterial culture test using the relevant blood bag in suspected bacterial infection cases.

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] (2002 to 2011)



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

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) (2011)

[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	Dissecting aortic aneurysm	FFP-LR (2009.11)	80s	F	HBV-DNA, HBsAg, HBsAb, HBeAb	Neg.	0 day	HBV-DNA	Pos.	26 wks	359	21 wks	Unavailable
2	Trauma due to a traffic accident	FFP-LR* (2010.2)	20s	M	HBsAg, HBsAb, HBeAb	Neg.	0 day	HBV-DNA	Pos.	17 wks	◆	◆	Available
3	Acute myeloid leukemia	PC-LR* (2010.7)	80s	M	HBsAg, HBeAb	Neg.	24 days	HBsAg	Pos.	29 wks	◆	◆	Available
4	Aortic valve stenosis, etc.	FFP-LR (2010.6)	80s	F	HBsAg, HBsAb, HBeAb	Neg.	31 days	HBsAg	Pos.	19 wks	503	20 wks	Available
5	Chronic heart failure	FFP-LR-Ap (2010.7)	50s	M	HBsAg	Neg.	5 days	HBV-DNA	Pos.	26 wks	2022	27 wks	Available
6	Uterine myoma	FFP-LR (2010.11)	30s	F	HBsAg, HBsAb, HBeAb	Neg.	15 days	HBsAg	Pos.	13 wks	◆	◆	Available

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

*The relevant donation had tested negative for HBV-DNA, but the donor had a positive conversion at HBV screening in the subsequent donation

● 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	Chronic renal failure	RCC-LR (2009.12)	50s	M	HBV-DNA, HBsAg, HBsAb, HBeAb	Neg.	0 day	HBV-DNA	Pos.	64 wks	◆	◆	Unavailable
8	Pancreatic head carcinoma	RCC-LR (2011.5)	70s	M	HBsAg	Neg.	0 day	HBsAg	Pos.	13 wks	◆	◆	Available
9	Idiopathic thrombocytopenic purpura	Ir-PC-LR (2011.5)	60s	F	HBsAg, HBsAb, HBeAb	Neg.	10 days	HBV-DNA	Pos.	14 wks	◆	◆	Unavailable
10	Mitral valve insufficiency	FFP-LR ^{**} (2009.2)	70s	M	HBsAg	Neg.	18 days	HBV-DNA	Pos.	20 wks	2034	19 wks	Unavailable
11	Aplastic anemia	Ir-PC-LR (2011.9)	70s	M	HBV-DNA, HBsAg, HBsAb, HBeAb	Neg.	2 days	HBV-DNA	Pos.	9 wks	◆	◆	Available

^{**} Blood components derived from the same blood donor of the possible case of voluntary report No.2

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

12	Hypopharyngeal cancer	RCC-LR (2011.3)	60s	M	HBV-DNA, HBsAg, HBsAb, HBeAb	Neg.	6 days	HBV-DNA	Pos.	13 wks	◆	◆	Available
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● Post-donation information: Case reported by the medical institution that had supplied the red cell concentrate derived from the same donation of the possible case of voluntary report no.4

13	Ovarian tumor	RCC-LR (2010.6)	40s	F	HBV-DNA, HBsAg, HBsAb, HBeAb	Neg.	1 day	HBV-DNA	Pos.	12 wks	◆	◆	Available
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[Human parvovirus B19]

● 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 [▲]			Recipient's sample	Donor's information	
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion		Test item	Result
1	Pregnancy with previous cesarian section	Ir-RCC-LR (2011.6)	30s	F	IgM-B19-Ab, IgG-B19-Ab	Neg.	0 day	IgM-B19-Ab, IgG-B19-Ab	Pos.	19 days	Available	B19-DNA, IgM-B19-Ab, IgG-B19-Ab	Pos.

● Symptoms such as fever were observed in the above cases, followed by recovery.

● The homology of the viral genome partial sequences was confirmed using a recipient sample and repository sample of the donor. Because parvovirus B19 spreads through respiratory secretion, a source of infection other than transfusion was also considered.

[Bacteria]

● Voluntary reports: Cases reported by medical institutions

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Result of post-transfusion blood culture		Symptom		Recipient's outcome
					Blood component	Recipient's blood	Major complaint	Expression time (after administration)	
1	Aplastic anemia	Ir-PC-LR (2011.8)	80s	M	<i>Streptococcus dysgalactiae</i> subsp. <i>equisimilis</i> (Group G hemolytic streptococcus)	<i>Streptococcus dysgalactiae</i> subsp. <i>equisimilis</i> (Group G hemolytic streptococcus)	Chill, fever, hypotension, hypoxemia	Approx. 60 min.	Recovery

[▲]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 (Aug. 2004 to June 2012) (Pooled Size of samples: 20-pool samples)

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

Test period	Number of tested sample	Number of positive Nat confirmed by ID-NAT (frequency)		
		HBV	HCV	HIV
Aug.2004 to Jul.2008	18,514,278	334 (1:5.5×10 ⁴)	32 (1:5.8×10 ⁵)	11 (1:1.7×10 ⁶)
Aug.2008* to Jun.2012	19,853,083	371 (1:5.4×10 ⁴)	15 (1:1.3×10 ⁶)	7 (1:2.8×10 ⁶)

*Changed reagents and apparatuses for NAT

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.