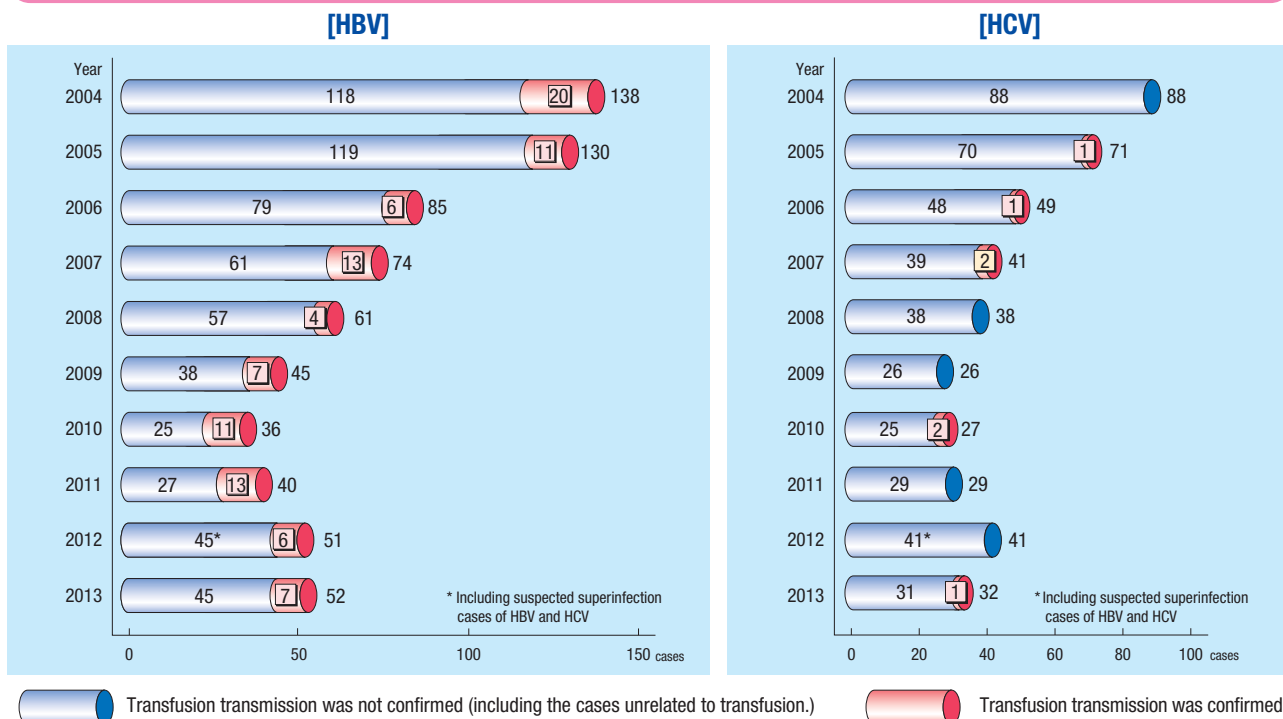


Infectious Cases of Probably Related to Transfused Blood Components (2013)

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 2013, seven cases of HBV infection, one case of HCV infection, one case of HIV infection and one case of HEV infection were confirmed by a positive viral nucleic acid test on a repository sample of the donation involved. One case of *Streptococcus equisimilis* (Group G hemolytic streptococcus) was confirmed by the bacterial culture test using the relevant blood bag in suspected bacterial infection cases.

The Cases Reported to JRC blood Centers as suspected Transfusion Transmitted Infections [HBV and HCV Infections] (2004 to 2013)



Since 2009, no fulminant hepatitis has been identified in the transfusion transmission confirmed cases.

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) (2013)

[HBV]

Voluntary reports: Cases reported by medical institutions

◆ No increase in ALT or no comparative available.

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test			ALT		Recipient's pre-transfusion sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
1	Chronic renal failure Glomerulonephritis	Ir-RCC-LR (2012.6)	50s	F	HBV-DNA, HBsAg, HBeAb	Neg.	0 day	HBsAg	Pos.	34 wks	738	34 wks	Available
2	Metastatic liver cancer Diabetes mellitus/renal failure	Ir-RCC-LR (2012.8)	60s	M	HBV-DNA, HBeAb	Neg.	0 day	HBsAb, HBeAb	Pos.	27 wks	252	24 wks	Available
3	Myelodysplastic syndrome	Ir-RCC-LR (2011.7)	90s	M	HBV-DNA	Neg.	143 days	HBV-DNA	Pos.	74 wks*	◆	◆	Available
4	Pure red cell aplasia Granular lymphocytosis	Ir-RCC-LR (2013.5)	70s	M	HBsAg, HBsAb, HBeAb	Neg.	220 days	HBsAg	Pos.	13 wks	◆	◆	Available

*A positive conversion of HBV-DNA was confirmed in the samples obtained from 8-weeks after transfusion by JRCS's investigation.

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 pre-transfusion sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
5	Multiple injuries	FFP-LR (2010.8)	70s	F	HBsAg	Neg.	0 day	HBV-DNA, HBsAg, HBeAb	Pos.	93 wks	◆	◆	Available
6	Trochanteric fracture of left femur	Ir-RCC-LR (2012.3)	90s	F	HBsAg	Neg.	1 day	HBsAg	Pos.	47 wks	◆	◆	Unavailable
7	Mitral incompetence	RCC-LR (2013.5)	80s	F	HBsAg	Neg.	20 days	HBV-DNA, HBsAg	Pos.	16 wks	◆	◆	Available

[HCV]

● Post donation information: A case reported by a medical institution 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 pre-transfusion sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
1	Basal fracture of the left femoral neck	Ir-RCC-LR (2009.6)	90s	F	HCV-Ab	Neg.	2 days	HCV-Ab	Pos.	212 wks	◆	◆	Unavailable

[HIV]

● Post donation information: A case reported by a medical institution 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 pre-transfusion sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
1	Chronic pancreatitis	FFP-LR (2013.2)	60s	M	HIV-Ab	Neg.	8 days	HIV-Ab	Pos.	5 wks	◆	◆	Available

[HEV]

● Post donation information: A case reported by a medical institution based on lookback studies of positive results at quality control of the source plasma for the manufacturing of plasma derivative

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Pre-transfusion test			Post-transfusion test			ALT		Recipient's pre-transfusion sample
					Test items	Result	Period to transfusion	Test items	Result	Period from transfusion	Maximum (IU/L)	Period from transfusion	
1	Unstable angina, Type 2 diabetes mellitus	Ir-RCC-LR (2012.12)	70s	M	HEV-RNA, IgM-HEV-Ab, IgG-HEV-Ab	Neg.	0 day	HEV-RNA	Pos.	6 wks	379	13 wks	Available

[Bacteria]

● Voluntary report: A case reported by a medical institution as suspected transfusion transmitted bacterial infectious case

Case no.	Primary disease	Blood component (year and month of blood collection)	Age	Sex	Results of post-transfusion blood culture		Symptom	Expression time (after administration)	Recipient's outcome
					Blood component	Recipient's blood			
1	Myelodysplastic syndrome	Ir-PC-LR (2013.12)	70s	M	<i>Streptococcus equisimilis</i> (group G hemolytic streptococcus)	<i>Streptococcus equisimilis</i> (group G hemolytic streptococcus)	Precordial pressure Chills, Fever	Approx. 150 min.	Recovery

Importance of storing pre-transfusion recipient samples and infection tests

Among suspected cases of transfusion transmitted infection reported by medical institutions in 2013, imputability with transfusion was denied in six cases of HBV and seven cases of HCV neither by medical institutions nor JRCS.

- Breakdown -

- ◆ Viral genome was detected in pre-transfusion recipient samples: Five HBV cases and three HCV cases.
- ◆ Both viral genome and serological tests of post-transfusion recipient samples turned out negative: One HBV case and three HCV cases.
- ◆ Viral genome was negative in post-transfusion recipient samples and serological tests of pre- and post- transfusions were positive: One HCV case

⇒ It is important to perform infection tests using pre-transfusion recipients' samples for the confirmation of transfusion transmitted infection.

Number of times that the nucleic acid amplification test (NAT) was performed and the frequency of positive samples (Aug. 2004 to Jul. 2014) (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; HBcAb: 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*1 to Aug. 2012	20,368,427	376 (1:5.4 x 10 ⁴)	22 (1:1.38 x 10 ⁶)	8 (1:3.79 x 10 ⁶)
Aug. 2012*2 to Jul. 2014	9,943,016	68 (1:1.5 x 10 ⁵)		

*1 Changed reagents and apparatuses for NAT *2 Criteria for HBcAb screening was restricted

In case any of adverse reactions and/or infections related to transfusion of blood components, 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."

Haemovigilance Information for Healthcare Professionals

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

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