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1 **FIGURE LEGENDS**

2

3 **Fig. 1.** Specificity of serum anti-GOR detection assay in occult HCV infection. GOR  
4 antibody detection was blocked by pre-incubation with GOR peptide but not by an irrelevant  
5 peptide. The results shown are mean percentages of anti-GOR blocking at each peptide  
6 concentration plus the standard error of the mean from five GOR antibody-positive  
7 individuals with occult HCV infection.

8

9 **Fig. 2.** Comparison of GOR antibody titres between occult HCV infection and chronic  
10 hepatitis C. Box-plot representation of anti-GOR titres (expressed as end-point serum dilution)  
11 measured in GOR antibody-positive patients with occult HCV infection ( $n = 22$ ) and chronic  
12 hepatitis C ( $n = 70$ ).

13

14 **Fig. 3.** Relationship between hepatic HCV infection and GOR antibody responses in  
15 occult HCV infection. Box-plot representation of the percentages of HCV-infected  
16 hepatocytes in occult HCV-infected patients with negative ( $n = 87$ ) and positive ( $n = 21$ ) anti-  
17 GOR detection tests in serum. Outliers are represented by single circles.

**TABLE 1.** Characteristics of the patients with occult HCV infection according to GOR antibody status.

	Anti-GOR positive (n=22)	Anti-GOR negative (n=88)	P value
Age (yr.) *	45.5 (39.9-51.1)	45.1 (42.7-47.5)	0.86
Gender (M/F)	19/3	64/24	0.18
Duration of disease (yr.) * <sup>§</sup>	6.2 (3.4-9.0)	6.4 (3.6-9.2)	0.56
ALT (IU/l) *	67 (51-84)	68 (59-79)	0.67
AST (IU/l) *	38 (29-47)	41 (35-46)	0.86
GGTP (IU/l) *	111 (73-148)	94 (76-112)	0.32
Necroinflammation**	19 (50)	31 (35)	0.20
Fibrosis **	5 (23)	17 (19)	0.72
Cirrhosis	1 (4)	2 (2)	0.88
Steatosis **	4 (18)	14 (16)	0.79

\* expressed as the mean (95% CI of the mean).

\*\* expressed as the number of cases (%).

<sup>§</sup> refers to the estimated duration of abnormal liver function tests since first alteration was detected.

Figure 1

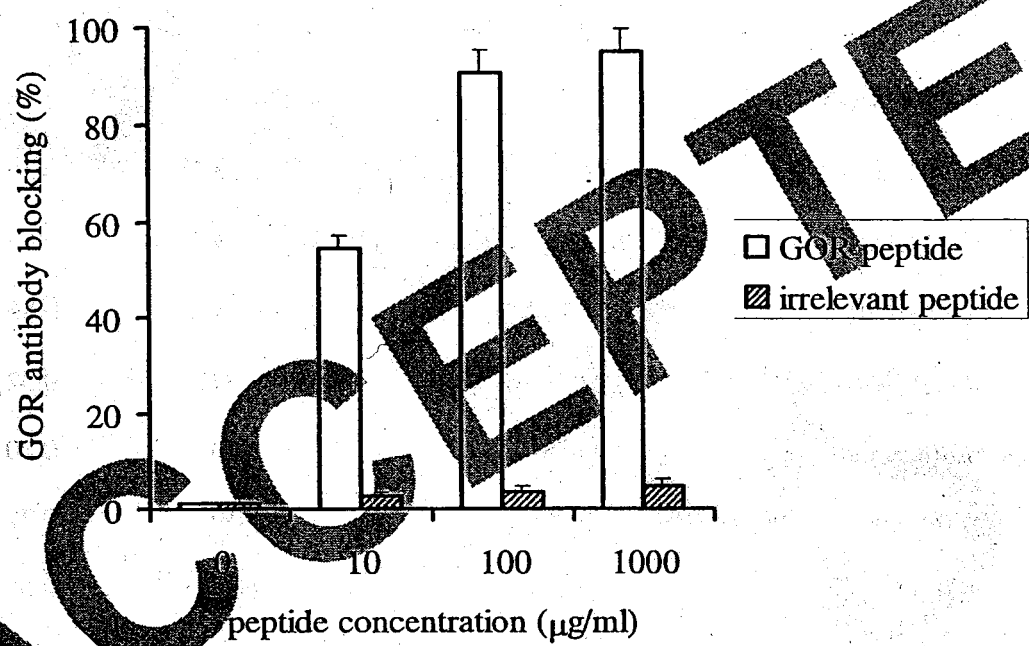


Figure 2

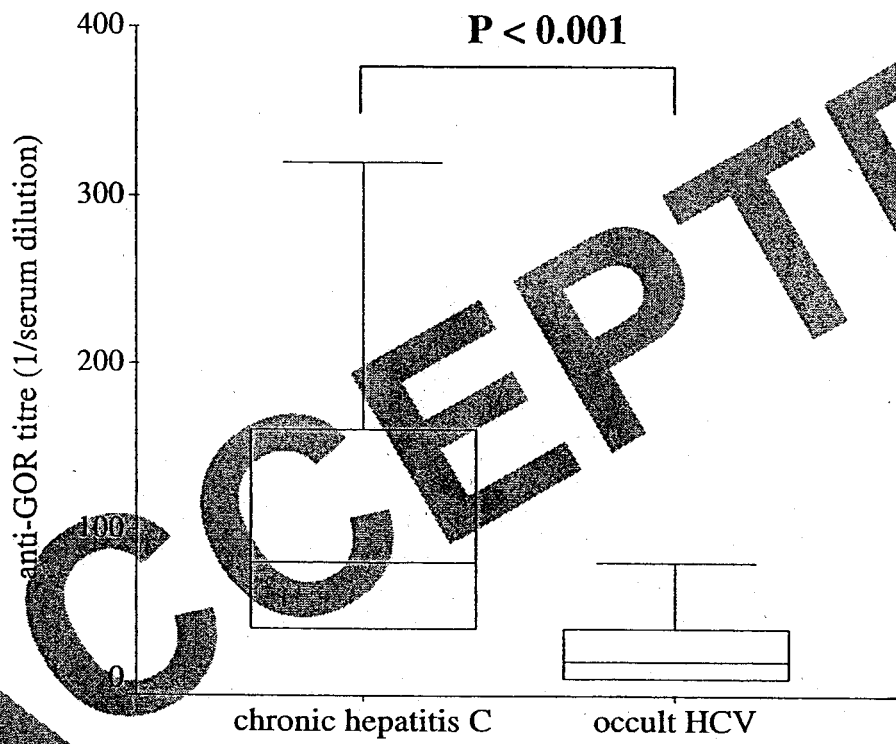
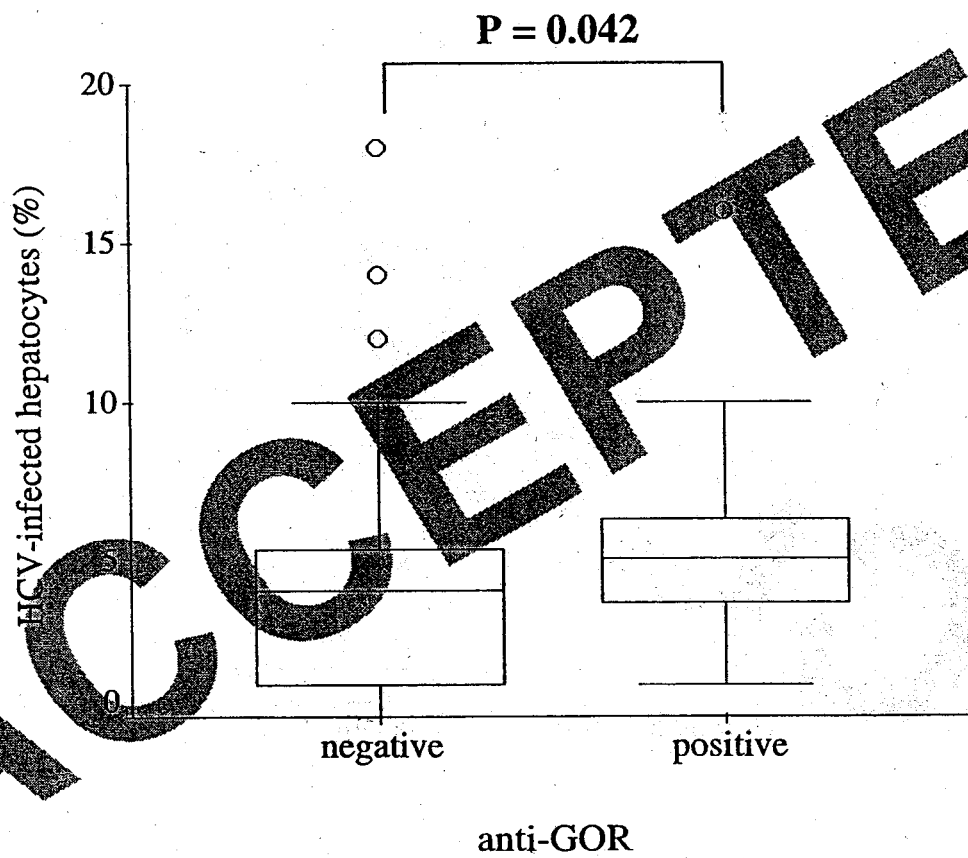




Figure 3



医薬品 研究報告 調査報告書

<p>識別番号・報告回数</p>			<p>報告日</p>	<p>第一報入手日 2007. 10. 4</p>	<p>新医薬品等の区分 該当なし</p>	<p>機構処理欄</p>
<p>一般的名称</p>	<p>人赤血球濃厚液</p>		<p>研究報告の公表状況</p>	<p>Fukuda S, Ishikawa M, Ochiai N, Suzuki Y, Sunaga J, Shinohara N, Nozawa K, Tsuda F, Takahashi M, Okamoto H. Arch Virol. 2007 Sep;152(9):1623-35. Epub 2007 May 29.</p>	<p>公表国  日本</p>	
<p>販売名(企業名)</p>	<p>赤血球濃厚液-LR「日赤」(日本赤十字社) 照射赤血球濃厚液-LR「日赤」(日本赤十字社)</p>					
<p>研究報告の概要</p>	<p>○ALT上昇を伴う日本の献血者ではE型肝炎ウイルス抗体およびHEV RNAの高陽性率は1991年～2006年において変化していない E型肝炎は本邦では稀であるが、今まで考えられていた以上に発生している。本邦において、E型肝炎ウイルス(HEV)の新たな不顕性感染症が近年増加しているかどうかを検討するため、1991年～2006年の期間に、ALT高値(≥61 IU/L)が認められ、現在HEVに感染している可能性の高い献血者4,019名から得た血清検体中のHEV RNAを調べた。2004年～2006年の献血者3,185名のanti-HEV IgG、anti-HEV IgM/IgA、HEV RNAの全体的な陽性率は、1998年の献血者594名と同等であった(5.3 vs. 5.2%、0.2 vs. 0.5%、0.2 vs. 0.3%)。献血年別に3群(1991年～1995年[n=156]、1996年～1999年[n=116]、2004年～2006年[n=61])に分けたALT ≥ 201 IU/Lの献血者間において、anti-HEV IgG (5.8、4.3、6.6%)、anti-HEV IgM/IgA (1.9、3.4、3.3%)、HEV RNA (1.3、3.4、3.3%)の陽性率に検出可能な差はなかった。本試験で得られた11のHEV分離ウイルスは、ORF2配列にそれぞれ1.7～22.8%の相違があり、遺伝子型3または4に分類された。1991年～2006年の期間に、本邦における多様なHEV株によるHEV不顕性感染の発現率は本質的に変化していない。</p>					<p>使用上の注意記載状況・ その他参考事項等</p>
<p>報告企業の意見</p>			<p>今後の対応</p>			
<p>日本において、1991年～2006年の期間にALT高値(≥61 IU/L)が認められ、現在HEVに感染している可能性が高い献血者の血清中のHEV RNAを調べたところ、この期間のHEV不顕性感染の発現率は本質的に変化していなかったとの報告である。</p>			<p>日本赤十字社では、厚生労働科学研究「E型肝炎の感染経路・宿主域・遺伝的多様性・感染防止・診断・治療に関する研究班」と共同して、献血者におけるHEV感染の疫学調査を行っている。北海道における輸血HEV感染報告を受け、試験的に北海道では研究的NATを行うなど安全対策を実施している。また、輸血による肝炎ウイルス感染防止のため、血液中のALT値61IU/L以上の血液を輸血用から排除している。今後もHEV感染の実態に関する情報の収集及び安全対策に努める。</p>			

3

