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医薬品 研究報告 調査報告書

識別番号・報告回数			報告日	第一報入手日	新医薬品等の区分	総合機構処理欄
				2008. 11. 20	該当なし	

一般的名称	人血清アルブミン	研究報告の公表状況	古居 保美、五十嵐 正志、蕎麦田 理英子、猪俣 尋史、星 友二、福田俊洋、松本 千恵子、鈴木 光、柚木 久雄、内田 茂治、三根 英子、田所 憲治 日本赤十字社NAT研究グループ. 第32回 日本血液事業学会総会; 2008 Oct 2-4; 大阪市.	公表国 日本
販売名(企業名)	赤十字アルブミン20(日本赤十字社) 赤十字アルブミン25(日本赤十字社)			

研究報告の概要

○NATスクリーニング検査で検出されたHCV-RNA陽性検体の解析

【はじめに】1999年7月のNATスクリーニング検査(以下「NAT」という)導入以降、2008年3月までに111本のHCV-RNA陽性検体が検出され、Genotypeの分類結果について献血者情報等をもとに解析を行い、HCVの感染動向を調査した。

【対象と方法】NATで検出されたHCV-RNA陽性検体のGenotypeについて、Core領域196bpの塩基配列をRT-PCR direct sequence法で決定し、分子系統樹解析により分類した。

【結果】HCV-RNA陽性検体のGenotypeは、1b:30本(27.0%)、2a:52本(46.8%)、2b:29本(26.1%)で、その他のGenotypeは検出されなかった。献血者の性別は男性71人(64.0%)、女性40人(36.0%)で、平成18年度の全献血者男女比(男性64.5%、女性35.5%)と完全に一致した。Genotypeの男女比は1bが15:15、2aは33:19、2bは23:6で、Genotype 2bで男性の割合が高かった。献血者の年齢別では、10代～20代で平成18年度の献血者の年代別構成比よりも高かった。また献血者100万人あたりの陽性者数を求めたところ、1bは中部地方以西で多く、関東地方以北では少なかった。2aは中部地方で若干多いものの、北海道を除き、その他の地域ではあまり差は見られなかった。2bは関東地方で多く、中部地方及び東北地方では検出されていない。

【考察】NATで検出されたHCV-RNA陽性検体はGenotype 2aが最も多く、1bと2bがほぼ同数だった。RNA陽性献血者のGenotypeを分類して感染傾向を調査していくことは、日本の急性肝炎患者の動向を予測するのに有用であると思われるので、引き続き行っていきたい。

使用上の注意記載状況・その他参考事項等

赤十字アルブミン20
赤十字アルブミン25

血液を原料とすることに由来する感染症伝播等

報告企業の意見	今後の対応
1999年7月からの2008年3月までにNATで検出された111本のHCV-RNA陽性検体のGenotype解析の結果、Genotype 2aが最も多く、1bと2bがほぼ同数だったとの報告である。 これまで、本剤によるHCV感染の報告はない。本剤の製造工程には、平成11年8月30日付医薬発第1047号に沿ったウイルス・プロセスバリデーションによって検証された2つの異なるウイルス除去・不活化工程が含まれている。また最終製品についてHCV-NAT陰性であることを確認していることから、本剤の安全性は確保されていると考える。	本剤の安全性は確保されていると考えるが、NATでのみ陽性となる献血者は新規感染者の可能性があるため、Genotypeを分類して感染傾向を調査していくことは、日本の急性肝炎患者の動向を予測するのに有用であり、今後もGenotypeの調査を継続するとともに、情報の収集に努める。なお、献血時のHCVスクリーニング法としてより感度の高い化学発光酵素免疫測定法(CLEIA)および新NATシステムを導入した。

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HBVの一過性感染におけるeAg/eAb セロコンバージョンとプレコア領域の変異

埼玉県赤十字血液センター

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〈目的〉HBVの慢性持続感染者においては，一般的にプレコア変異，プロモーター変異が生じることによりe抗原の産生が低下し，e抗原期からe抗体期へセロコンバージョンすることが報告されている。HBVの一過性感染でも同様な現象が生じているかどうかを献血者のNAT陽性者を追跡調査した結果から調べたので報告する。〈対象と方法〉1999年から2003年までの間に日赤の血清学的検査陰性でNAT陽性になった349症例の内，e抗原陽性期からe抗体にセロコンバージョンしている追跡可能な症例を対象とした。塩基配列はプレコア領域のPCRを行い，PCR-ScriptAmpCloningKit（STRATAGENE）を用いてクローニングした。得られたクローンはプラスミッドをQIAprepMiniprepKit（QIAGEN）にて抽出しDNAシークエンスを解析した。〈結果と考察〉野生株に一過性感染した献血者のe抗原陽性期の検体から7クローン，e抗体にセロコンバージョンした検体から17クローンを調べたところプレコア変異部位の塩基配列に変異は生じていなかった。一方プレコア変異株の一過性感染では，感染当初はe抗原もe抗体も認められないものの，コア抗体出現に伴いe抗体が認められるようになったが塩基配列の変異は認められなかった。一過性感染では，慢性持続感染の場合と異なり，核酸の変異をほとんど伴わず，野生株のままe抗原からe抗体にセロコンバージョンし，血中HBV-DNA量も定量限界以下に減少することが確かめられた。

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NATスクリーニング検査で検出された HCV-RNA陽性検体の解析

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【はじめに】1999年7月のNATスクリーニング検査（以下「NAT」という）導入以降，2008年3月までにHCV-RNA陽性検体111本が検出された。その111本についてGenotype分類を行ってきたので，その結果について献血者情報等を基に解析を行いHCVの感染動向を探ることとした。【対象と方法】NATで検出されたHCV-RNA陽性検体111本を対象とした。GenotypeはCore領域196bpの塩基配列をRT-PCR direct sequence法で決定し，分子系統樹解析により分類した。【結果】HCV-RNA陽性検体111本のGenotypeは，1b：30本（27.0%），2a：52本（46.8%），2b：29本（26.1%）で，その他のGenotypeは検出されなかった。献血者の性別は男性71人（64.0%），女性40人（36.0%）と男性が多かったが，平成18年度の全献血者男女比（男性64.5%，女性35.5%）と完全に一致した。Genotypeの男女比は1bが15：15，2aは33：19，2bは23：6で，Genotype 2bで男性の割合が高かった。献血者の年齢別では，10代～20代で平成18年度の献血者の年代別構成比よりも高かった。また地域別に献血者100万人あたりの陽性者数を求めたところ，1bについては中部地方より西の地方で多く，関東以北では少なかった。2aについては，中部地方で若干多いものの，北海道を除くその他の地域ではあまり差は見られなかった。2bについては関東地方で多く，中部地方及び東北地方では検出されていない。【考察】NATで検出されたHCV-RNA陽性検体はGenotyp2aが最も多く，1bと2bがほぼ同数であった。NATで検出されたHCV検体のGenotypeを分類して感染傾向を調査していくことは，日本の急性肝炎患者の動向を予測するのに有用であると思われるので，引き続き行なっていきたい。

医薬品 研究報告 調査報告書

識別番号・報告回数			報告日	第一報入手日	新医薬品等の区分	総合機構処理欄
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一般的名称	乾燥濃縮人血液凝固第Ⅷ因子	研究報告の公表状況	Ikeda H, Matsubayashi K, Sakata H, Takeda H, Kon E, Sato S, Kato T, Abe I, Satoru H, Tadokoro K. AABB Annual Meeting and TXPO 2008; 2008 Oct 4-7; Montreal.	公表国
販売名(企業名)	クロスエイトM250(日本赤十字社) クロスエイトM500(日本赤十字社) クロスエイトM1000(日本赤十字社)			日本

研究報告の概要

○北海道の献血者におけるHEV感染症

背景:日本を含む先進工業国でHEVの輸血伝播が複数認められているが、献血者のHEV感染は未解明である。一方、日本のHEV感染は、主に人畜獣共通伝染病の食物介在経路であると考えられており、E型肝炎の散発性症例を引き起こしている。

方法:2005～2007年まで、北海道においてプールNATによりHEV RNAの有無についてスクリーニングを実施した。HEV -NAT RNA陽性(RT-PCR)献血者および抗HEV抗体陽性(ELISA)献血者について遡及及び追跡調査を実施した。HEV遺伝子型はダイレクトシーケンス法により決定した。また、献血者の食事歴についてアンケート調査を実施した。

結果:献血者834,843名のうち、HEV-NAT陽性献血者が100名特定され、男女比72/28、平均年齢41.0±2.5、遺伝子3/4型比92/6であった。74名からは抗HEV抗体は検出されず、20名からIgM抗HEV抗体が検出された。6ヵ月以内の前回献血歴がある39名の前回検体中からは、HEVマーカーは検出されなかった。献血時に肝炎の臨床症状を示す者はなかった。追跡調査を実施できた23名中13名は、ALT値の一過性の上昇(60IU/L超)が見られ、内2名がE型肝炎を発症した(最大ALT値:1,250、3,366 IU/L)。HEV RNAは、数ヶ月以内に消失することが確認され、HEVウイルス血症は献血から最長55日間持続した。NAT陽性献血者の76%(59/78)は、献血前に動物内臓を食べていた。

結論:北海道の献血者の約1/8,300はHEV RNA陽性で、多くは無症候性であったがウイルス血症は数ヶ月間持続する。これら献血者は、動物の内臓の摂取による人畜共通性食物媒介感染の可能が高い。

使用上の注意記載状況・その他参考事項等

クロスエイトM250
クロスエイトM500
クロスエイトM1000

血液を原料とすることに由来する感染症伝播等
vCJD等の伝播のリスク

報告企業の意見	今後の対応
2005～2007年に北海道で実施したプールNATによるHEV RNAスクリーニングの結果、献血者の約1/8,300はHEV RNA陽性であった。ほとんどの献血者は動物内臓を摂取しており、無症候性であったがウイルス血症は数ヶ月間持続したとの報告である。HEVは脂質膜のないRNAウイルスである。これまで、本剤によるHEV感染の報告はない。本剤の製造工程には、平成11年8月30日付医薬発第1047号に沿ったウイルス・プロセスバリデーションによって検証された2つの異なるウイルス除去・不活化工程が含まれていることから、本剤の安全性は確保されていると考える。	本剤の安全性は確保されていると考えるが、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。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。加えて、北海道における輸血後HEV感染報告を受け、試験的に北海道では本報告のベースとなった研究的NATを行うなど安全対策を実施している。

negative. Self-trigger sites had fewer TPs (1) than primary and neighbor sites (21 and 11 respectively); primary and self-trigger sites yielded more FPs (10 and 4) than the neighbor trigger (2 FPs), $p < 0.0001$. 75% of centers (6 of 8) using primary trigger criteria had ID-yields versus 67% (8 of 12) using neighbor triggers, and 8% (1 of 12) using self triggers. At 57 centers that did not trigger, 17 (30%) had at least 1-PVD identified by MP. FPs occurred more frequently with ID vs MP ($p < 0.0001$); FP rates did not differ between automated (Tigris) and semi-automated (eSAS) testing, $p < 0.2792$. **Conclusions:** These data demonstrate that the recommended minimal AABB trigger criteria of 2-PVDs and a rate of 1:1000 missed viremic donors; therefore it is reasonable to adopt more stringent triggers for the 2008 season, including elimination of the rate criterion and triggering on 1 PVD for regions adjacent to centers which have already triggered. However, self triggering prior to the detection of any PVDs had very limited yield and required a significant proportion of testing capacity.

TABLE 1. WNV Procleix Assay Test Results: June–November 2007

Test Format	Negative		Initial Positives		False Positives		True Positives	
	#	%	#	%	#	%	#	%
MP-NAT	1,143,590	93.88572	103	0.008	5	0.00041	129	0.0106
ID-NAT	74,273	6.097617	100	0.008	35	0.00287	34	0.0028
Total	1,217,863	NA	203		40		163	

Note: MP-NAT true positives include ID-tested donations, positive at 1:16 (MP) dilution.

Disclosure of Conflict of Interest

Joan Dunn Williams, Gene Robertson, Sally Caglioti, Robert Williams, Michael P. Busch, Randall Spizman, Steven Kleinman: Nothing to Disclose

SP156

Effectiveness of Single Unit Testing in Detecting West Nile Virus in Viremic Donations

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Background: A Canadian blood agency has tested all donations for West Nile Virus (WNV) in pools of 6 since July 1, 2003. There are strategies in place to test donations for WNV by Single Unit testing (SUT) following the identification of one positive donation found through Minipool testing (MP) or when human cases within the previous 2 weeks were identified in the population of a health region at a rate of greater than 1 in 1000 in rural areas or greater than 1 in 2500 in urban areas. A study was undertaken to determine the effectiveness of SUT in 2006 and 2007. **Methods:** Plasma was available from 50 donations (4 from 2006 and 46 from 2007) identified as WNV positive by SUT and confirmed by an alternate WNV NAT assay and/or by the presence of WNV IgM and/or IgG antibodies. Master 1 in 6 dilutions of each donation were prepared with 4.5 mL of donor sample plus 22.5 mL of Normal Human Plasma (NHP) as diluent to mimic MP. Each of 2 WNV testing laboratories was sent 3 replicates of each dilution from the 50 donations and 3 replicates of NHP as controls. All replicates were labelled as "blind" samples for each testing site. Testing was performed with the Roche cobas TaqScreen West Nile Virus Test, for use with the cobas s 201 System. **Results:** WNV was consistently detected in MP for 46% of the samples as 23 of 50 donations were MP positive for all 6 replicates. WNV was not consistently detected in MP in 54% of the samples – 12 of 50 donations (24%) were MP negative in 1 to 5 replicates and 15 of 50 donations (30%) were MP negative for all 6 replicates. All NHP controls were MP negative. When IgG and/or IgM WNV antibodies were present, the samples were less likely to be MP positive. The 3 donor samples that were negative by alternate WNV NAT but had detectable WNV IgG and IgM antibodies were negative by MP. **Conclusion:** WNV SUT has proven to be an effective strategy to detect WNV viremic donors through the infectious season. MP testing is still not sensitive enough to detect all potentially infectious donations.

No. MP Replicates Positive	No. Donations	Alternate NAT			WNV IgG and/or IGM Antibodies		
		Pos	Neg	Neg	Pos	Equiv.	NT
All (6)	23	23	0	16	2	0	5
Some (1-5)	12	12	0	2	7	2	1
None (0)	15	12	3	1	13	0	1
Total	50	47	3	19	22	2	7

Equiv. = Equivocal NT = Not Tested

Disclosure of Conflict of Interest

Gordon Hawes, Margaret Fearon, Jamie Brown: Nothing to Disclose
Edna Zuber: Roche Molecular Systems – Board NewGen – No honoraria or financial support
Nicholas Dibdin: Not Specified

SP157

Evaluation of NS1 Antigen Detection of Dengue Virus in Healthy Blood Donors During a Dengue Outbreak in Martinique

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Background: A dengue virus type 2 (DENV-2) outbreak occured in Martinique from Sptember 2007 to January 2008. Among an insular population of 400,000 inhabitants, 17,990 people were infected (5%) according to the dengue vigilance network. Since the first care in blood transfusion remains the viral safety, it was decided by the "Etablissement français du Sang" (EFS) to evaluate the validity of NS1 antigen (Ag) detection in blood donations as screening assay. **Methods:** The presence of NS1 Ag was detected by the Platelia dengue NS1 Ag kit purchased from Bio-Rad Company. The performance of ELISA was evaluated with, as reference test, RT-PCR using serotype-specific primers. Three studies were conducted to evaluate NS1 Ag detection. A first retrospective study included 136 blood samples coming from a clinic serum library and known as RT-PCR positive for dengue virus (DENV-1: 2; DENV-2: 125; DENV-3: 3; DENV-4: 6). All these samples were tested for the presence of NS Ag. A second prospective studies consisted of 110 blood samples from patients consulting, during dengue outbreak, for severe febrile syndrome compatible with dengue infection. On each of the second series NS1 Ag was carried out in comparison with RT-PCR technique. The third study was a prospective screening for NS1 Ag and dengue genomic material on 561 blood samples from healthy blood donors. This last investigation was performed during the epidemical peak of dengue outbreak. **Results:** In the first series, NS1 Ag was found positive in 83/136 (61%) samples positive for dengue virus with RT-PCR. No false positive (NS1 Ag+/RT-PCR-) were observed. In the second prospective study, one half of the samples (55/110) were negative for dengue markers (NS1 Ag and RT-PCR). The other half was positive in RT-PCR for DENV-2. Among these positive samples, 36/55 (65%) reacted with the NS1 Ag assay. In the last prospective investigation in healthy blood donors, one sample was found positive as well for the NS1 Ag as for the DENV-2 RT-PCR (1/561, or 1,8 per thousand). The donor concerned was asymptomatic before and after (1 week) his blood donation. In the mean time, we have performed NS1 Ag detection as screening test for all blood donors during dengue outbreak and we have found 6 sera positive for NS1 Ag among the 6,904 tested donations (1,5 per thousand). All the six donors concerned were asymtomatic. **Conclusions:** In comparison with RT-PCR technique, NS1 Ag assay showed sensitivity around 60-65%. According to these results, dengue NS1 Ag detection did not totally fit the gold standard in transfusion screening. Our first evaluation concerning incidence of dengue virus in healthy blood donors are preliminary results. More specific studies with accurate epidemiological tools will follow.

Disclosure of Conflict of Interest

Michel Rits, Raymond Cesaire: Nothing to Disclose
Najioullah Fatiha, Pascale Richard: Not Specified

SP158

HEV Infection Among Blood Donors in Hokkaido, Japan

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Background: Several cases of transfusion-transmission of HEV have been recognized in industrialized countries including Japan. However, little is known about the situation of the HEV infection among blood donors. On the other hand, zoonotic food-borne route is regarded as a main route of HEV infection in Japan, which causes sporadic cases of hepatitis E. **Methods:** Blood donors were screened for the presence of HEV RNA by pooled NAT from 2005 to 2007 in Hokkaido. Look-back and follow-up studies were carried out for the NAT-positive donors with HEV RNA (real-time RT-PCR) and anti-HEV antibodies (ELISA). For look-back, the samples at previous

donations were used. HEV genotype was determined by direct sequencing of PCR products of partial regions within ORF1 and/or ORF2. Questionnaire survey on eating history before the donation was also conducted for the NAT-positive donors. **Results:** Out of 834,843 donors, 100 of HEV NAT-positive donors were detected. Male/female, average age and genotype 3/4 were 72/28, 41.0 ± 12.5 and 92/6, respectively. In 74 HEV positive donors, no anti-HEV was detected and in 20 donors, IgM anti-HEV was detected at the donation. Thirty-nine positive donors had histories of previous donations within 6 months and no HEV marker was detected in the samples of such previous donations. None of donors showed clinical sign of hepatitis at the donation. Out of 23 NAT-positive donors who could be followed up more than twice within a month after the donation, 13 showed elevation of ALT level higher than 60 IU/L. The ALT elevation was transient in 11 donors. However, two of the 13 developed hepatitis E and their peak ALT levels were 1250 and 3366 IU/L, respectively. HEV RNA of all the 23 donors was confirmed to disappear within a few months. HEV viremia persisted up to 55 days at the longest after the HEV-positive donation. In 3 donors, IgG anti-HEV became undetectable after 1 to 1.5 year after donations. Most of NAT-positive donors (59/78, 76%) had histories of eating animal viscera before their donations. **Conclusion:** About 1/8300 of blood donors in Hokkaido were HEV RNA-positive. Most of them were in their early phase of HEV infection at donation and remained asymptomatic, although HEV viremia persists for a few months. They are likely to be infected via zoonotic food-borne route by eating animal viscera.

Disclosure of Conflict of Interest

Hisami Ikeda, Keiji Matsubayashi, Hidekatsu Sakata, Hiromi Takeda, Emi Kon, Shinichiro Sato, Toshiaki Kato, Ikuma Abe, Hino Satoru, Kenji Tadokoro: Nothing to Disclose

SP159

Switching to Single-unit Testing: Importance of an In-house Test for Blood Donor West Nile Virus Testing

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Background: West Nile Virus (WNV) nucleic acid testing (NAT) is routinely done in mini-pool format. Single-donor testing is used for mini-pool resolution, when there are not enough samples to prepare a mini-pool or in situations of high incidence of WNV infection in a given area. Since the summer of 2004, Hema-Québec has performed single-unit testing on blood donors from areas with high WNV activity. The decision to switch from mini-pool to individual donor testing is based on the identification of a positive donor sample by the testing laboratory. This report describes the contribution of a previously described in a previous AABB meeting (San Diego, 2003) in-house assay to the management of the decision-making process concerning the switch from mini-pools to single-donor testing. **Methods:** Routine screening of blood donations is performed by our testing laboratory in mini-pools of 6 donors using the Cobas TaqScreen WNV NAT assay (Roche Molecular Systems). An in-house confirmatory WNV NAT was designed by our Operational Research unit with specific DNA primers distinct from those used in the Roche Molecular Systems testing kit. In-house kits were produced within a Good Manufacturing Practices environment and their use was approved by Health Canada. Stability and sensitivity were monitored monthly and results were reviewed by quality assurance. WNV-positive samples were sent to the research testing unit for confirmation and test results were returned to the Medical Director within 24 hours. **Results:** During summers of 2004 to 2007, 499,681 blood donors were tested and 10 mini-pools were positive with the WNV assay. After resolution, samples from 2 mini-pools were all negative and 8 samples were found positive. Of these, 7 were tested with the in-house assay. Two samples were confirmed positive while 5 came out negative for WNV. None of the 5 unconfirmed donors have developed antibodies to WNV on follow-up, whereas the two confirmed by our in-house assay were also confirmed by seroconversion with an immunological assay. **Conclusion:** Single-donor testing has a major impact on resources in the blood testing laboratory. Decisions based on false-positive screening test results could lead to substantial costs. The rapid availability of confirmatory results through a close collaboration between Research and Operations contributes to well-informed decisions by Operations management.

Disclosure of Conflict of Interest

Isabel Chateauneuf, Marie-Claire Chevrier, Louis Thibault, Gilles Delage, Cindy Castilloux, Marie-Eve Nolin, Matthieu Guerin, Brigitte Caron, France Bernier, Maryse St-Louis: Nothing to Disclose

SP160

The Role of Platelet Bound Antibodies on Thrombocytopenia in Acute Dengue Virus Infection

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Background: Dengue is an endemic-epidemic mosquito-borne viral disease, caused by the dengue virus (DV) with an increasing incidence in the world-wide distribution. This disease may have unusual complications such as hepatic damage, cardiomyopathy, encephalopathy and severe hemorrhagic manifestations. Even patients with mild symptoms may present thrombocytopenia and the exact mechanism for the low platelet count has not yet been established. The mechanisms proposed are: transient marrow suppression, platelet aggregation to endothelial cells targeted by DV, hemophagocytosis and platelet immune destruction with dengue antibody complexes. The aim of the present study was to identify the prevalence of thrombocytopenia and evaluate a possible correlation to platelet bound antibodies on acutely DV infected (ADI) patients during the 2007 spring outbreak. **Methods:** 47 ADI patients were included (49% female, 51% male; median age: 38.5 years, range: 17-69 y). Platelet counts were performed in an automated counter. Sera were evaluated by flow cytometric assay to investigate the presence of platelet bound IgG or IgM antibodies in patients and in a group of 50 non-transfused group O male blood donors as a control group. A positive result was defined as a fluorescence ≥2 standard deviation (sd) from negative control and inconclusive result as a fluorescence ≥1 sd, <2 sd from negative control. **Results:** Positive IgG or IgM tests were significantly lower in the control group compared to patients (64% x 23.4%, P = 0.00013, x = 14.58). The prevalence of thrombocytopenia found among patients was 68.1%. No correlation was found between thrombocytopenia and IgG or IgM tests among patients. Nevertheless, a significantly higher prevalence of positive tests was found in thrombocytopenic patients, when compared to controls (40.6% x 22.0%, P = 0.002, x = 5.65). The results are summarized in the table below. **Conclusions:** The results of this study confirm that thrombocytopenia is a frequent finding (68%) in ADI patients. Platelet bound antibodies are also frequent in these patients (=45%). These antibodies may have a role on thrombocytopenia as they have higher prevalence in thrombocytopenic ADI (=41%) than in controls (22%), but other mechanisms are probably involved since non-thrombocytopenic patients also have a high prevalence of these antibodies. Study granted by FAPESP (Fundação de Amparo à Pesquisa do Estado de São Paulo – São Paulo State Research Support Foundation.)

	Acute Dengue Patients			
Platelet Bound Antibody	Plt ≤ 150 x 10^3/L N = 32 (68.1%)	Plt > 150 x 10^3/L N = 15 (31.9%)	Total N = 47	Controls N = 50
IgG/M Negative	9 (28.1%)	2 (13.3%)	11 (23.4%)	32 (64.0%)
IgG/M Inconclusive	10 (31.3%)	5 (33.3%)	15 (31.9%)	8 (16.0%)
IgG/M Positive	13 (40.6%)*	8 (53.4%)	21 (44.7%)#	11 (22.0%)*#

* P = 0.002, x^2 = 5.65; # P = 0.00013, x^2 = 14.58

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TTID 1: Testing Issues (Virology)

SP161

Development of a Parvovirus B19 DNA Assay and Systems Software for Plasma Screening

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Background: Recently the FDA asked manufacturers of derivatives to include "in-process" screening of recovered plasma for high titer Parvovirus