



# international blood/plasma news

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AABB	CryoLife
ABBOTT	GENENTECH
ABX	GLIATECH
AdvaMed	HELENA LABORATORIES
ADVANCED BIOTHERAPY CONCEPTS	HEMATRONIX
ALPHA THERAPEUTIC	HUMAN GENOME SCIENCES
ALPHA THERAPEUTIC SERVICES	INTERGRATED BIOSYSTEMS
AMERICA'S BLOOD CENTERS	INTERPORE ORTHOPEDICS
AMERICAN RED CROSS	MITSUBISHI PHARMA
AMGEN	NEW ZEALAND BLOOD SERVICE
AVENTIS BEHRING	OraSure Technologies
AVENTIS PASTEUR	PPTA
AVENTIS PHARMA	SEPARATION TECHNOLOGY
Baxter BioScience	SeraCare Life Sciences
BAYER	SEROLOGICALS
BIOTEST	SERONO
BioTime	SMITHKLINE BEECHAM BIOL
BPL	ThermoGenesis
CANADIAN BLOOD SERVICES	WFH
CHENGDU SHUYANG PHARMA	WHATMAN HEMASURE
CHIRON	

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**BUSINESS BRIEFS**

\* **mitsubishi pharma is now offering alpha therapeutic, its U.S. plasma fractionation subsidiary, for sale**, according to an Alpha official. The business includes the company's network of 42 U.S. plasma centers and central testing laboratory in Memphis, its Los Angeles-based plasma fractionation facility, and **ALPHA THERAPEUTIC SERVICES**, its home infusion therapy unit. J.P. Morgan is identifying potential buyers and managing the sales process.

\* On a vote of eight in favor with two abstentions, **the U.S. FDA's Blood Products Advisory Committee (BPAC) has recommended that the FDA amend the labeling of 6% hetastarch in 0.9% saline to include an explicit warning that intraoperative use of this product increases the risk of excessive postoperative bleeding in cardiac surgery patients supported on cardiopulmonary bypass.** An anesthesiologist currently serving on the American Society of Anesthesiologists' Transfusion Committee reviewed two recent crossover studies, which documented substantial increases in both postoperative blood drainage from chest tubes and blood transfusion requirements in patients undergoing coronary artery bypass, valve or other cardiac surgeries. Using findings from one of those studies, a 444-patient review at the Mayo Clinic, another speaker estimated that elimination of the use of hetastarch in CPB circuit priming and intraoperative infusion may reduce hospital demand for allogeneic red blood cells by at least 128,000 units, and platelet concentrates by more than 300,000 units.

Several other presenters cited recent small clinical trials in which *HEXTEND*, **ABBOTT'S** 6% hetastarch in lactated electrolyte solution licensed from **BioTime**, was associated with a lower incidence of adverse events than 6% hetastarch in saline. **These findings convinced BPAC to specify only 6% hetastarch in 0.9% saline in its recommendation concerning use of this product in cardiac surgery patients.** FDA officials in attendance explained that, since they approved *HEXTEND* for marketing in 1999 on the basis of comparability to hetastarch in saline – and product safety-related labeling for the two products is currently identical – the BPAC recommendation creates the need to more clearly establish whether there is in fact a difference in safety. In 1999, about 510,000 adult cardiac surgeries were performed in the U.S., according to a government health agency.

\* The U.S. FDA has amended its new drug and biological product regulations to liberalize approval requirements for certain agents intended for use to reduce or prevent serious toxicity related to chemical, biological, radiological or nuclear materials. The agency announced last month that **marketing approval may be based on effectiveness from appropriate animal studies when human efficacy studies are not ethical or feasible.** The new rule is part of the FDA's effort to help improve the ability of the U.S. to respond to emergencies, including terrorist attacks.

\* **CANADIAN BLOOD SERVICES (CBS) has announced a major restructuring plan designed to ensure that Canada's blood supply system remains "one of the safest and most modern in the world."** Elements of the plan include:

- Centralization of blood testing in three laboratories located in Calgary, Toronto and Halifax, and outfitted with **ABBOTT Prism** technology to increase capacity, reduce product losses and recalls, and improve quality and safety; currently there are 11 testing labs across the country.
- Streamlining of blood component production functions; there are now 14 production sites across Canada.
- A new information system (the **MAK Progesa**) to be fully installed by late 2003 after pilot testing in Halifax next January. The Mak system will link blood donor recruitment, collections, component production from whole blood, testing, labeling, hospital orders and inventory management.
- Beginning in early 2003, a 24-hour, 7-day-per-week "National Contact Centre" to facilitate donor telerecruiting, appointments, eligibility inquiries and general questions from the public.
- Five new bloodmobiles to make blood donation easier for Canadians and help meet projected 8% annual growth in demand for blood.

CBS scientists continue to investigate new methods to improve blood product preparation and storage processes, while the organization is working with Canadian hospitals to exploit new methods to conserve and promote optimal utilization of blood and blood products. As part of this restructuring, CBS is eliminating 200 full-time positions.

\* **The Coalition for Blood Safety (CFBS), which includes the AABB, AMERICA'S BLOOD CENTERS, the AMERICAN RED CROSS, the PLASMA PROTEIN THERAPEUTICS ASSOCIATION (PPTA) and the Armed Services Blood Program Office, will reconvene after a long hiatus to address opportunities to influence regulatory and legislative policy regarding blood and blood safety.** In a conference call last month, members of the Coalition (originally known as the "Coalition for Regulatory Reform") identified BLA supplements, licensure of blood-related devices and licensure of **ABBOTT'S PRISM** automated diagnostic testing system as issues of particular interest. The Advanced Medical Technology Association (**AdvaMed**), has also recently joined the Coalition.

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\* **U.S. plasma prices have remained relatively stable in recent months**, according to a survey conducted in June 2002 by The Marketing Research Bureau. **For delivery in early 2003, however, plasma prices in general are expected to be higher by an estimated 2% to 5%.** These prices, which do not include PCR testing, were obtained from most U.S.-based suppliers of source, hyperimmune and recovered plasma, with a combined collection/fractionation volume in excess of ten million liters. The values reflect current contracts between either independent plasma suppliers and/or subsidiaries of plasma fractionators to fractionation customers, and not internal transactions.

- **Source plasma:** A range of \$108 to \$118 per liter was cited by most respondents, “closer to \$110 for current contracts.” For delivery in early 2003, prices are expected to edge closer to the \$115 to \$118 range.
- **Anti-D plasma:** Several manufacturers of Rh immune globulin built their inventory in recent months in anticipation of a price increase and/or a shortage of anti-D plasma. As a consequence, there is currently an ample supply of anti-D plasma in the marketplace, with relatively few transactions taking place. For this reason, recent price quotes may have limited predictive value for future transactions. It was reported that some potential sellers would be prepared to sell a liter of 25-35 mcg/mL of anti-D plasma for as low as \$250 per liter. However, the projected price once the situation normalizes is about \$450 per liter for plasma assayed at 25-35 mcg/mL, and \$550 to \$600 for plasma with a titer above 40 mcg/mL.
- **Anti-tetanus plasma:** A shortage of tetanus toxoid continues to cause a shortage of anti-tetanus plasma. However, the demand does not seem to have climbed dramatically, so that the price of tetanus plasma currently ranges from \$125 to 150 per liter (8-12 IU/mL), with the prospect that it will edge up in the near future.
- **Anti-rabies plasma:** If the titer of the plasma is not specified – i.e. the plasma is merely from immunized donors, without titer verification – the price of rabies plasma is about \$130 per liter. When the titer has been ascertained, the average price is stable at about \$250 per liter.
- **Anti-hepatitis B plasma:** For a titer of 40 IU/mL, anti-hepatitis B plasma costs about \$575 per liter, with a range from \$500 to \$650 per liter. For 50 IU/mL, the price exceeds \$650 per liter.
- **Anti-cytomegalovirus and varicella zoster plasmas:** These are screened plasmas, where the donors do not have to be immunized; therefore they are not as costly to produce. The prices of CMV or VZ plasmas have nevertheless climbed in recent months, and they are estimated to be in the range of \$135 to \$140 per liter. CMV plasma is at the low end of this range, VZ plasma at the higher end.

(continued)

- **Recovered plasma:** The price currently paid to blood banks for one liter of fresh frozen plasma (frozen within 24 hours of collection) is between \$86 and \$92 per liter and will continue to climb in the coming months. Recovered plasma frozen beyond 24 hours is priced at \$80 to \$84 per liter. Apparently, many people who donated a unit of blood in response to the terrorist events of September 11 have not returned, exercising some pressure on the availability of recovered plasma.
- **Liquid plasma:** Plasma separated from whole blood within five days and stored at 4°C, and cryopoor or cryo-removed (i.e. no Factor VIII activity), costs about \$60 per liter.

- \* Meanwhile, **in Austria, fresh frozen plasma (FFP) for transfusion which is frozen within six costs approximately €90 per liter** (about \$87) The price of plasma frozen after 24 hours and sent to fractionation is currently in the mid- €70 (approx. \$68) per liter range. According to another source, recovered plasma frozen within six hours costs €89 (approx. \$86) per liter, and source plasma is €98 (approx. \$95) per liter.

In **Sweden**, the price of source plasma is approximately 928 Krona (\$100) per liter. There is a wide price range for recovered plasma, depending on the specifications and volume. Source plasma (“GSP”) is currently sold in **Germany** for about €100 (approx. \$97) per liter.

- \* **CryoLife projects worldwide sales of its *BioGlue* bovine albumin-based tissue adhesive will total between \$4.9 million and \$5.3 million for the second quarter ending June 30.** This represents modest or no expected growth over actual sales of \$4.9 million posted for the first quarter of 2002. Prior to a U.S. FDA Premarket Approval (PMA) last December, the product was available in the **U.S.** under a Humanitarian Device Exemption for use in certain major vascular procedures. Since then, CryoLife reports, about 170 new hospital accounts have been added to its existing 600 U.S. accounts. In February, a third **European CE Mark** (product certification) was awarded, allowing the use of *BioGlue* in general surgical procedures, including soft tissue repairs.

*BioGlue* is approved for cardiac, vascular and pulmonary repairs in 36 countries outside the U.S, according to the company. Among a variety of *BioGlue* clinical applications, according to field reports, are abdominal aortic aneurysm repairs, endarterectomy surgeries, sealing of suture lines, aortic dissections and aortic root replacements, gluing/sealing of organs, dural sealing, A-V access device sealing, femoral popliteal bypasses, coronary artery anastomose.

- \* **SeraCare Life Sciences**, an Oceanside, California supplier of plasma-based diagnostic and therapeutic products and proteins for the biotechnology industry, **has reported that net sales for the six months ended March 31 were \$13.7 million, versus \$8.4 million during the first half of fiscal 2001.**

*The Marketing Research Bureau is pleased to announce the completion and delivery of a new market research report:*

### **THE WORLDWIDE PLASMA FRACTIONS MARKET - 2002**

This study, which has been completed every two years since 1984, has now been updated to 2000, with market projections to 2002 and 2004.

For each major plasma product this report features sales volumes in U.S. dollars and units, as well as market shares by company and region. Price trends over the last twelve years are also provided. The products include:

- Intramuscular Immune Globulin (IMIG)
- Intravenous Immune Globulin (IVIG)
- Tetanus Immune Globulin
- Fraction V (Albumin & PPF)
- Factor IX Concentrate and PPSB
- Activated Factor IX Complex
- Alpha-1 Antitrypsin
- RhoD Immune Globulin
- Hepatitis B Immune Globulin
- Rabies Immune Globulin
- Factor VIII Concentrate
- Factor XIII Concentrate
- Antithrombin III
- Fibrin Sealant

This study documents the changes that have occurred in the plasma industry over the last decade. In particular, it documents how recombinant Factor VIII and Factor IX concentrates have displaced the plasma-derived products, and describes the continued growth of IVIG.

For more information or to order, please contact The Marketing Research Bureau:

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- \* **Baxter BioScience has launched its *Baxject* needleless transfer device designed for use in reconstituting Factor VIII concentrates.** Calling it “a safer, faster and easier way to prepare hemophilia medication without the use of sharp needles or fear of accidental injury,” the company claims that the *Baxject* transfer device is easy and safe enough for children to use. Baxter licensed worldwide rights to use the device in hemophilia patients last September, and is compatible only with Baxter products. Initially, *Baxject* will be available only with *Recombinate* recombinant Factor VIII concentrate, but will eventually replace the transfer needles currently included in the packaging of all Baxter drugs for hemophilia therapy.
- \* **The U.S. FDA’s Blood Products Advisory Committee has voted unanimously to recommend that the FDA develop product standards for recovered plasma,** to include specific standards for storage conditions, dating periods and labeling requirements.

**BLOOD & BIOTECHNOLOGY**

\* With Phase III patient trials now completed, **Baxter BioScience expects to file for regulatory approval of its “next-generation” human- and animal protein-free recombinant Factor VIII concentrate in the U.S. and Europe by the third quarter of this year.** Assuming it is approved for marketing, it will become the only commercially available product manufactured without any added proteins or raw materials sourced from humans or animals. *Recombinate*, Baxter’s current rDNA Factor VIII product, was the driver behind 18% growth in the BioScience division’s sales in the first quarter. A company official projects >20% growth in *Recombinate* sales for the full year.

\* **Subcutaneous infusions of *Albuleukin*, an interleukin-2/human serum albumin fusion protein, suppressed the growth of both human renal cell carcinoma and B16 melanoma tumors in an experimental mouse model,** according to **HUMAN GENOME SCIENCES.** HGS has applied its proprietary recombinant albumin-fusion technology to develop this novel agent for treatment of solid cancers. In comparison with a brief circulating half-life of interleukin-2 alone, the plasma half-life of *Albuleukin* was reportedly extended six, five and eight hours in mice, rats and monkeys, respectively. At the recent American Association for Cancer Research meeting in San Francisco, *R & D Focus Drug News* was told that patient enrollment has begun in a Phase I trial of this agent at the University of Texas in San Antonio.

Other albumin-fusion products in development by HGS include *Albuferon*, an albumin-fusion form of human interferon  $\mu$ , which is currently in clinical trials to study its effect in patients infected with hepatitis C. Albumin-granulocyte colony-stimulating factor, albumin-parathyroid hormone, albumin-calcitonin and albumin-interferon beta are currently in preclinical testing.

\* **Overturing Orphan Drug protection for BIOGEN’S rival *Avonex* drug, SERONO’S *Rebif* interferon beta-1a product has been approved for marketing in the U.S. for treatment of the relapsing-remitting form of multiple sclerosis (MS).** In its unprecedented action, the FDA cited superior treatment results with *Rebif* as a key reason for voiding the Orphan Drug protection previously granted to the *Avonex* version of beta interferon. In the six-month, 677-patient “EVIDENCE” trial, three weekly subcutaneous doses of *Rebif* resulted in fewer relapses and reduced accumulation of MRI-detected brain lesions than once-weekly intramuscular injections of *Avonex*.

Serono reportedly will double its marketing budget to about \$60 million to support the U.S. launch of *Rebif*, which will be priced at an average of \$1,156 per month. Remaining to be seen is how these drugs will compare in terms of effectiveness and tolerability with longer-term use.

## RESEARCH AND DEVELOPMENT

- \* **The type of membranes used in chronic hemodialysis appears to have a substantial impact on circulating levels of the cytokine interleukin-6 (IL-6), whose elevation was in turn correlated with reduced serum albumin levels,** according to new research by **Italian** investigators at the University Federico II of Naples. This group compared the results of dialysis sessions conducted with cuprophane (CD), cellulose diacetate (CD) or synthetically modified cellulosic (SMC) membranes; SMC membranes are designed to reduce complement activation in relation to other cellulosic membranes. Heightened IL-6 output from peripheral blood mononuclear cells (PBMCs) was associated with higher circulating levels of C-reactive protein, a well-known inflammatory marker, and reduced serum albumin levels.

**“Protein malnutrition, a condition associated with an albumin concentration less than 3.5 g/dL, has been shown to be a major risk factor for increased mortality in hemodialysis,”** the authors noted in a recent issue of the *American Journal of Kidney Diseases*. “Data clearly show that a significant relationship exists between biocompatibility of the membranes and serum albumin changes,” which in turn were inversely related to PBMC spontaneous IL-6 release and CRP circulating levels.

## PLASMA FRACTIONATION NOTES

- \* **SEROLOGICALS has closed four of its 17 U.S. plasma donor centers in a cost-saving measure.** Donor centers in Asheville (North Carolina), Atlanta, Pittsburgh and Tuscaloosa (Alabama) were closed in mid-May. Their plasma collection activities are to be integrated into other centers, according to the company. The closures were part of the culmination of Serologicals’ “ACE (Achieving Collective Excellence) Project” within the company’s Plasma Operations division. Underway since July 2001, the ACE Project undertook “a complete review of the competitiveness, productivity and overall performance” of the company’s plasma collection activities.

After recording a one-time charge of about \$1.1 million, closure of the centers is projected to result in a recurring annual cost savings of at least \$1.5 million. Remaining are 13 centers in seven states. Notwithstanding the one-time charge, the closures will not affect the company’s sales and earnings guidance, according to a Serologicals official.

\* In a keynote speech at the 2002 annual meeting of the **PLASMA PROTEIN THERAPEUTICS ASSOCIATION (PPTA)** earlier this month, a senior **AVENTIS BEHRING** official proposed that several strategic initiatives will be required if the industry is to continue to provide patients with the therapies they need:

- Facilitate the increased collection of plasma;
- Continue to enhance manufacturing quality and efficiency;
- Educate customers about the industry’s complexity, value and future plans;
- Develop new and improved therapies and manufacturing standards.

Among a number of other initiatives outlined in this presentation were the following: (1) work with regulatory agencies to develop a harmonized and more predictable regulatory environment; (2) protect patient access to products, particularly in countries attempting to limit access to plasma products from foreign sources; and (3) advocate for patient care to be driven by medical need, and not distorted by inadequate reimbursement models.

\* In a presentation titled “Ten Years After...What Has Been Achieved by Consent Decrees,” a **U.S. FDA** official recently summarized the record of source plasma and plasma derivatives-related regulatory actions and industry compliance between **1996-97 and 2001**:

	<u>1996</u>	<u>1997</u>	<u>1998</u>	<u>1999</u>	<u>2000</u>	<u>2001</u>
Source plasma inspection classifications – action indicated	14	11	33	10	12	13
Source plasma compliance rate	96.0%	96.4%	89.5%	96.4%	94.6%	94.8%
Plasma derivatives: inspections vs. (enforcement)	-	30(12)	28(4)	29(2)	16(2)	17(4)
Plasma derivatives compliance	-	60.0%	85.8%	93.0%	92.0%	84.7%
Warning letters – blood and source plasma	11	10	5	3	2	1

The FDA concluded that (1) the blood supply is safer than ever, (2) there is increased CGMP awareness and compliance, and (3) injunctions protect the consumer from unapproved or potentially dangerous products.

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 P.O. Box available at \$10 plus postage.

- \* Over the 12-month period from April 2001 through March 2002, there were **no U.S. IVIG-related product recalls or withdrawals**, according to a report by the **PLASMA PROTEIN THERAPEUTICS ASSOCIATION (PPTA)** in the June 2002 issue of *The Source*, a journal. The ratio of monthly product inventory to distribution fluctuated between 0.44 and 1.88 over that period.
- \* **In Jordan, the results of the tender of the Directorate of Royal Medical Services have just been published.** As concerns plasma products, the following was reported:
- **Polyvalent IVIG:** 750 vials (2.5 grams) and 850 vials (5 grams). Average price is about \$18.00 per gram, approximately 10% higher than last year's tender;
  - **Albumin:** 500 vials (20%, 50 mL). Average price is \$1.90 per gram, 10% lower than last year's tender;
  - **Factor VIII:** 300 vials (1,000 IUs per vial) and 360 vials (500 units per vial). Average price is about \$0.23 per IU;
  - **Factor IX:** 100 vials (500 IUs per vial). Average price: approximately \$0.20 per IU;
  - **RhoD Immune Globulin (Anti-D):** 3,250 vials (250 mcg). Average price is approximately \$29.20 per vial, unchanged from last year.

The tender was awarded to three companies: **BIOTEST** and **BPL** were named as suppliers for IVIG, albumin and coagulation factor concentrates, while the RhoD immune globulin allotment was awarded to **AVENTIS BEHRING**.

- \* **BAYER scientists have presented data showing that the prion protein that causes variant Creutzfeld-Jakob Disease (vCJD) can be removed by purification processes used in the manufacture of plasma protein products**, reducing the theoretical risk of transmission through the use of one of these products. Their work, which utilized a Western blot assay to detect pathogenic prion proteins, was presented in an abstract at the recent XXV International Congress of the World Federation of Hemophilia (**WFH**) in Spain.

The investigators stressed that “although no cases of variant CJD or other transmissible spongiform encephalopathies have been reported from use of therapeutic plasma proteins, we remain diligent in our work to prevent this possibility.”

## VIRAL SAFETY UPDATE

- \* **The European Medicines Evaluation Agency (EMA) is conducting an expert workshop this month to review human transmissible spongiform encephalopathies (TSEs) in relation to plasma-derived products.** Participants will review the most updated information on human TSEs, in particular variant Creutzfeldt-Jakob disease. An EMA spokesperson emphasized that this review is routine and does not imply that there are new worries about the potential risks of using products derived from blood and plasma.
  
- \* **OraSure Technologies** has received notification from the U.S. FDA that its *OraQuick Rapid HIV-1 Antibody Test* is approvable, subject to submission of product labeling and resolution of specific validation and design control issues during a recent FDA pre-approval inspection of the company's manufacturing facilities. The *OraQuick* test is designed to detect HIV-1 antibodies in fingerstick whole blood within 20 minutes, according to the company.

## PEOPLE

- \* **ALPHA THERAPEUTIC** has appointed **David Hirsch** to the post of Senior Vice President, Worldwide Sales and Marketing, with responsibility to further expand the company's position in the global market for plasma-derived products. Hirsch previously was Vice President, Sales and Marketing at Nexell Therapeutics, which developed stem cell therapies for cancer treatment. His prior experience also includes sales and marketing roles with Boehringer Mannheim Pharmaceuticals and Schering-Plough, and senior management positions with a clinical research organization (CRO) and a non-profit cancer research and treatment entity.

Separately, **Mr. Shinji Wada** has moved from his position as Vice President, International Operations to Vice President, Business Operations at **WELFIDE INTERNATIONAL**, Alpha's U.S. holding company. **Mr. Armand Famiglietti** has now assumed the vacated Vice President, International Operations position.

- \* **ThermoGenesis** President **James Godsey, Ph.D.** has resigned to take a position as Executive Vice President, Development at **GEN-PROBE**, a leading manufacturer of molecular diagnostics. He will remain with ThermoGenesis until early July to help ensure a smooth transition to a successor in this post. ThermoGenesis is already interviewing several candidates, and anticipates hiring a new president "in the near future." In the interim, management of day-to-day operations will be assumed by company Chairman and CEO **Philip Coelho**.

- \* **Roland Gerritsen van der Hoop, M.D., Ph.D.** has joined **SEROLOGICALS** in the newly created position of Vice President, Global Research and Development. He will also serve as the company's Chief Scientific Officer, and serve as a member of the Executive Operating Committee. Dr. Gerritsen van der Hoop will be responsible for "directing the company's global activities, resources and investments to ensure the ongoing development and introduction of innovative value-added products and enabling technologies that support the success of its customers." He previously held various executive posts at Solvay Pharmaceuticals for more than ten years.
  
- \* **Dr. Lester Levy** has been appointed Chief Executive of the **NEW ZEALAND BLOOD SERVICE**, to start in August. He has been Chief Executive of MercyAscot Hospital since 1999, and previously served in the same capacity with South Auckland Health. NZBS recently created an integrated national blood service by merging what had been 23 separate hospital-based services.

## NEW PRODUCTS

- \* **HELENA LABORATORIES** (Beaumont, TX) **has introduced the *Triplet* Bleeding Time Device**, named after the noted physician expert in blood coagulation and hematopathology. This new device was designed to address the need for global standardization in bleeding time testing. The *Triplet* device makes a surgical incision 1.0 mm deep by 5.0 mm long. Its ergonomic design includes a large contact surface that distributes the downward force over a wider area of the skin, reducing the potential for deep, non-standardized cuts. A horizontal blade acceleration helps to produce an ultra-fast incision. The device is manufactured without exposure to chemicals or additives that could contaminate the bleeding site. For more information, call 1-409-842-3714 or visit [www.helena.com](http://www.helena.com).
  
- \* **SEPARATION TECHNOLOGY** (Altamonte Springs, FL) **now offers the *HemataSTAT Easy Read*, a self-contained, portable microhematocrit centrifuge that features a new automatic tube reader.** This reader provides a faster, easier hematocrit result and reduces the potential for human error. Up to six samples, in tubes of either size 0.5 ID or 1.1 ID, are centrifuged for 60 seconds. Each tube is then positioned on the built-in reader tray and a slider is moved from left to right. The quantitative hematocrit result is instantly displayed on the unit's LCD panel, and can be programmed to display in French, German, Italian or Spanish. Because *HemataSTAT Easy Read* uses standard 75 mm plastic or glass capillary tubes, the cost per test is very low. This CLIA-waived system also features "whisper quiet operation" and accuracy comparable to the NCCLS reference method. For more information, call 1-407-788-8791, or fax 1-407-788-8791, or visit [www.separationtechnology.com](http://www.separationtechnology.com).

**RECENT U. S. PATENTS**

- \* **Methods of Producing Immunoglobulins, Vectors and Transformed Host Cells for Use Therein. #6,331,415.** Assigned to **Genentech, Inc.** (South San Francisco, CA). A process for producing an immunoglobulin molecule or an immunologically functional immunoglobulin fragment comprising at least the variable domains of the immunoglobulin heavy and light chains, in a single host cell.

The host cell is transformed with a first DNA sequence encoding at least the variable domain of the immunoglobulin heavy chain, and a second DNA sequence encoding at least the variable domain of the immunoglobulin light chain. The first and second DNA sequences are independently expressed, so that the immunoglobulin heavy and light chains are produced as separate molecules in the transformed single host cell.

- \* **Treatment of Autoimmune Diseases. #6,333,032.** Assigned to **Advanced Biotherapy Concepts** (Carlsbad, CA). A method of treating an autoimmune disease, involving administration of antibody to gamma interferon in an amount effective to neutralize or reduce fluid activity levels of gamma interferon in the patient under treatment.

- \* **Process for Inhibiting Complement Activation Via the Alternative Pathway. #6,333,034.** Assigned to **Gliatech, Inc.** (Cleveland, OH). A process of inhibiting the adverse effects of alternative complement pathway activation products in a subject, by administering an amount of anti-properdin agent effective to selectively inhibit formation of an alternative complement pathway activation product.

- \* **Method and Device for Fractionated Distribution of a Blood Sample. #6,333,197.** Assigned to **ABX** (Montpellier Cedex, France). A method for fractionated distribution of a blood sample, involving uptake into a needle, distributing successive aliquots into successive flows of reagents, and collecting each mixture of aliquot and reagent in a mixing and/or measuring receptacle.

- \* **Protein Purification. #6,333,398.** Assigned to **Genentech, Inc.** (South San Francisco, CA). A method for purifying a protein, which comprises a  $C_H2/C_H3$  region, from a contaminated solution thereof by Protein A chromatography. The protein is adsorbed to Protein A immobilized on a solid phase comprising silica or glass, then contaminants bound to the solid phase are removed by washing with a hydrophobic electrolyte solvent. The protein is recovered from the solid phase.

- \* **Leukocyte Reduction Filtration Media. #6,337,026.** Assigned to **Whatman Hemasure, Inc.** (Marlborough, MA). A method for depleting leukocytes from a constant volume of leukocyte-containing blood products, in which the blood product is passed through a leukocyte reduction filtration media comprised of a matrix of fibers and a plurality of high specific surface area components distributed amongst the matrix of fibers having a specific surface area no greater than 100 m<sup>2</sup>/gm, removing at least 99.99% of leukocytes from the blood product.
  
- \* **Cryopreservation Vial Apparatus and Methods. #6,337,205.** Assigned to **Integrated Biosystems, Inc.** (Napa, CA). A biopharmaceutical product cryopreservation system described in detail in the patent.
  
- \* **Process of Preparing Immunoglobulin for Intravenous Injection by Viruses Double-Sterilized Without Adding Any Protectant. #6,338,849.** Assigned to **Chengdu Shuyang Pharmaceutical Factory** (Chengdu, China). A process of preparing a double-sterilized immunoglobulin without protectant product for intravenous injection.
  
- \* **Process for the Stabilization of Proteins in Complex Mixtures During Their Storage in Aqueous Solvents. #6,339,061.** Assigned to **Aventis Pharma Deutschland GmbH** (Frankfurt au Main, Germany). A process for the storage of a protein in an aqueous solution, in which cysteine is added to the solution to delay the temporal decrease in the effective concentration of the protein during storage.
  
- \* **Device and Method for Concentrating Plasma. #6,342,157.** Assigned to **Interpore Orthopedics, Inc.** (Irvine, CA). A device for concentrating a blood fraction, comprised of an ultrafiltration unit with a semi-permeable membrane with a molecular weight cut-off of about 30 kD, an outlet, first and second openings, and a first and second valve, all with functions specified in the patent.
  
- \* **Method for Viral Vector Delivery. #6,342,214.** Karl Tryggvason and others (Sweden and Finland). A method for effective *in vitro* delivery of a viral vector, in a recirculating, oxygenated perfusate solution, to a mammalian organ. The solution is held at about 37°C.
  
- \* **Recombinant Papillomavirus Vaccine and Method for Production and Treatment. #6,342,224.** Assigned to **SmithKline Beecham Biologicals, S.A.** (Rixensart, Belgium). A fusion protein comprising human papilloma virus antigen selected from the group consisting of fusion proteins E6, E7 and E6E7, linked to protein D or derivative thereof from *Haemophilus influenzae* B, wherein the derivative thereof comprises approximately the first N-terminal 100 amino acids of protein D.

- \* **Multi-Component Vaccine Comprising at Least Three Antigens to Protect Against Disease Caused by *Haemophilus influenzae*. #6,342,232.** Assigned to **Aventis Pasteur Limited** (Toronto, Canada). An immunogenic composition for conferring protection in a host against disease caused by *Haemophilus influenzae*.
  
- \* **Methods and Compositions for the Purification of Proteins or Other Macromolecules. #6,342,362.** Daniel S. Mytelka (Carmel, IN). A method for separating macromolecules comprising (1) mixing a binding region and a tag with a target macromolecule so the binding region binds to the target macromolecule, (2) optionally purifying the composition-target complex, (3) mixing the composition-target complex with other compositions, (4) incubating the mixture such that a desired chemical reaction occurs, and (5) removing the composition-target complex from the mixture by selectively removing molecules having the tag.
  
- \* **Eukaryotic Layered Vector Initiation Systems for Production of Recombinant Proteins. #6,342,372.** Assigned to **Chiron Corporation** (Emeryville, CA). A method for producing one or more recombinant proteins, by growing, under suitable nutrient conditions, an isolated, cultured eukaryotic host cell transformed or transfected with a eukaryotic layered vector initiation system in a manner allowing expression of the recombinant protein.
  
- \* **Human Collagenase Inhibitor, Recombinant Vector System for Using Same and Recombinant-DNA Method for the Manufacture of Same. #6,342,374.** Assigned to **Amgen Inc.** (Thousand Oaks, CA). A portable DNA sequence encoding a metalloproteinase inhibitor protein, which has an amino acid sequence selected from five options defined in the patent.
  
- \* **Modified Methyotrophic *Pichia Pastoris* Yeast Which Secretes Human Growth Hormone. #6,342,375.** Assigned to Universidad Autonoma de Nuevo Leon (Mexico). An isolated DNA molecule containing one or more copies of an expression cassette.
  
- \* **Lipid Vesicles Containing Adeno-Associated Virus Rep Protein for Transgene Integration and Gene Therapy. #6,342,390.** Assigned to The United States of American as represented by the Secretary of Health and Human Services (Washington, D.C.). A composition for delivering a DNA sequence to a cell through integration of the DNA into a chromosome of that cell, where the composition comprises genetic material, but does not generate viral particles.
  
- \* **Erythrocyte Sedimentation Rate Control. #6,342,391.** Assigned to **Streck Laboratories, Inc.** (La Vista, NE) and **Hematronix** (Plano, TX). An erythrocyte sedimentation rate (ESR) control with a synthetic base and an aggregating agent.

**MEETINGS**

August 24-29, 2002  
**27<sup>th</sup> Congress of the International Society of Blood Transfusion**  
Vancouver Convention and Exhibiting Centre  
Vancouver, British Columbia  
Canada  
Tel: 604-681-5226  
Fax: 604-681-2503  
Website: www.isbt2002.com

September 12-13, 2002  
**Blood Products Advisory Committee Meeting**  
Gaithersburg, MD  
Tel: 301-443-0572

October 26-29, 2002  
**American Association of Blood Banks Annual Meeting and TXPO 2002**  
Orlando, FL  
Tel: 301-215-6480  
Fax: 301-907-6895  
Email: meeting@aabb.org

August 29-30, 2002  
**DHHS Advisory Committee on Blood Safety and Availability**  
Washington, DC  
Tel: 202- 690-5558  
Fax: 202- 690-7560

October 5-6, 2002  
**Cambridge Healthtech Institute's Seventh Annual Surgical Applications of Tissue Sealants & Adhesives**  
Hyatt Regency Embarcadero  
San Francisco, CA  
Tel: 617-630-1352  
Email: johnr@healthtech.com

October 31- November 2, 2002  
**National Hemophilia Foundation 54<sup>th</sup> Annual Meeting**  
Disney Coronado Springs Resort  
Lake Buena Vista, FL  
Tel: 800-424-2634, Ext. 4  
Fax: 212-328-3766  
Website: www.hemophilia.org

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