

## National biovigilance system a (net)work in progress

Karen L. Wagner

**T**he United States has lagged behind other developed countries in creating a nationwide monitoring system that tracks and analyzes errors and accidents associated with blood transfusion. But, as the 1964 Bob Dylan song proclaims, "The times they are a-changin'."

The leadership of the AABB, working with the Centers for Disease Control and Prevention, has spearheaded a broad-based movement to create a biovigilance network to track adverse events and ultimately improve blood safety and patient outcomes. The network initially will include a hemovigilance system to track blood

transfusions. It will eventually be expanded to collect data on donor-related events. Efforts are also underway to track tissue grafting and organ transplantation through a cooperative agreement between a number of organizations, among them the AABB, CDC, and United Network for Organ Sharing.

A pilot phase of the hemovigilance network, which will test the network at a small number of transfusion services of varying sizes and locations, is scheduled to get underway late next spring.

**H**ospitals in the United States have had their own internal hemovigilance systems in place for decades, says James AuBuchon, MD, chair-

man of the Working Group for the Interorganizational Task Force on the U.S. Biovigilance Network and chair of the CAP Transfusion Medicine Resource Committee. But, he adds, these data are reported to internal transfusion committees only and not transferred to a national repository for compilation and analysis, as they are in other countries.

"All we have had is a requirement from the FDA to report deaths associated with transfusion and, more recently, a requirement to report blood product deviations," Dr. AuBuchon continues. However, he says, hospitals generally are reluctant to report such events because of

*continued on page 14*

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## Letters

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reported out on unacceptable specimens.

I have been a medical technologist for almost 40 years, the last 17 in management but I still work the bench. Though preanalytical factors are now buzzwords, they have been important to most laboratorians for years. Standard laboratory practice includes not running tests on hemolyzed specimens, unfilled coagulation tubes, specimens drawn above an IV, clotted CBCs, and so on. In my opinion, if you run tests on these specimens, it is comparable to running tests on the wrong patient.

We spend a lot of time in the laboratory ensuring the integrity of the patient samples. We then run quality control, look at Levey-Jennings charts, follow Westgard rules, etc., to give clinicians the most accurate laboratory test results possible so they can best treat their patients.

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Most laboratorians I have come across over the years consider themselves professionals, and, much like the medical doctor oath, we strive to "do no harm."

Marilyn C. Kenyon, MT(ASCP)  
Director of Laboratory Services  
St. Joseph Hospital  
Bangor, Me.

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## Biovigilance system

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the risk of negative consequences, such as lawsuits.

"And the FDA has never had the manpower to focus on the analysis of these data and then turn around and provide useful information to help the reporters improve their processes," Dr. AuBuchon adds. "That's what hemovigilance is all about—not only gathering the data in a confidential system immune from discovery, but having it analyzed so that it makes sense and it can be used to improve things."

**A**lthough the U.S. biovigilance network is a work in progress, plans call for it to be voluntary and Web based. Hospital and blood bank employees will manually input data into the system. The data will consist of information on transfusion reactions and incidents or situations in which standard procedures were not followed, explains Dr. AuBuchon, who is chairman of pathology at Dartmouth-Hitchcock Medical Center, Lebanon, NH.

In return for taking time to input the data, Dr. AuBuchon says, hospitals and other participants will gain access to a robust system that will offer internal analysis and anonymized data comparison among facilities of similar size or within the same region. "So, they will be able to track and trend incidents and reactions over time," he explains. "They can look for correlations in their own set of data and try to learn from their amalgamated experiences."

"What blood bank software can do for biovigilance monitoring," page 16

**"U**ltimately, what we'd like to be able to do is build a system that will facilitate data entry," says AABB president D. Michael Strong,



Dr. Strong

PhD. An eventual goal might be to link individual laboratory information systems with the network, but many more details of the system need to be defined first, adds Dr. Strong, who is also clinical laboratory director and chief operating officer at the Puget Sound Blood Center, Seattle.

Dr. Strong says that with the Centers for Medicare and Medicaid Services' recent announcement that it will no longer reimburse when transfusion-related errors occur, the network potentially will offer hospitals cost savings by identifying and reducing such errors. "Those are all things that, if corrected, can save an organization a fair amount of money," he says.

**T**he developers of the biovigilance network hope that it will be as successful as systems used in other countries, such as the United Kingdom's SHOT (Serious Hazards of Transfusion) system. SHOT was instrumental in detecting transfusion-related acute lung injury, or TRALI, as a primary cause of post-transfusion fatality. Users of the SHOT network linked TRALI to the plasma of female donors who had

been immunized during pregnancy. So, Dr. AuBuchon explains, a decision was made to use only plasma from male donors for transfusion. While not all plasma in the United Kingdom as yet comes from male donors, the country has already

# Quick Takes

*"If anatomic pathology were to go digital, we'd have to go way beyond what we're already doing in radiology."*

—Michael Montalto, PhD, of GE, on image size for digitized AP slides and how surprised GE was to learn it.  
(*"Two peas in a pod: digital AP, radiology,"* page 56)

*"There's an awful lot about TRALI that we don't know."*

—Morris Blajchman, MD, on the research that will be needed to better understand the pathogenesis of TRALI.  
(*"Catching, tracking, and tackling TRALI,"* page 1)

seen a dramatic reduction in cases of TRALI since working toward that end, he adds.

Following the lead of the United Kingdom's SHOT system, the CDC, which is funding the initial development of the infrastructure for the online system, has guaranteed that data that are input into the system will not be released. The information cannot be divulged under the Freedom of Information Act, by subpoena in a civil suit, or by Congressional subpoena, says Dr. AuBuchon. "Furthermore," he adds, "the information in that system is not releasable to any other federal agencies, including the FDA. So no regulatory action can take place as a result of anything that is submitted.

"These," he continues, "are exactly the kinds of protection that a biovigilance system needs in order to be successful in a very litigious society." □

Karen Wagner is a freelance writer in Forest Lake, Ill.

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## What blood bank software can do for biovigilance monitoring

Karen L. Wagner

As the AABB and federal government develop a nationwide biovigilance network (story, page 12), blood bank vendors have an opportunity to focus on how their software can support biovigilance monitoring.



Bentley

Noah Bentley, MS, SBB(ASCP), senior marketing director for Wyndgate Technologies, El Dorado Hills, Calif., says because data storage is so important for a hemovigilance program, a

component of biovigilance monitoring, a software system should provide on-line capability to track and manage post-transfusion cases in real time. It should also manage donors who are implicated in post-transfusion events.

A data warehouse is also important because "it facilitates a uniform format for data across organizations," he says. In a warehouse, data can be more easily combined, manipulated, extracted, and analyzed. "In addition," Bentley continues, "performing these tasks in a data warehouse removes concern about manipulating data in production databases since the manipulation occurs in an offline environment, where reporting can be more easily accomplished."

"Perhaps the most important feature that blood bank and transfusion software can contribute to hemovigilance is the ability to exchange data with other systems," he says. Bentley explains that in the United States, blood centers generally operate independently from transfusion services, and transfusion services rarely share databases. To better provide the connectivity that hemovigilance requires, he adds, software should incorporate the use of standardized interface transactions, such as those governed by HL7.



Simon

Flexibility is key, says Beth Simon, president and CEO of Blood Bank Computer Systems, Auburn, Wash. "The data should be stored in a relational database that allows for the ease of performing statistical analysis," she says. "Additionally, the application should provide multiple mechanisms for reporting and analyzing desired information."

The ability to compile and analyze the information gathered from biovigilance monitors is important in preventing future errors, stresses Laurie Sapp, BS, MT, SoftBank product manager for SCC Soft Computer, Clearwater, Fla. "Traditionally, transfusion medicine software systems have provided the means to track and monitor unexpected transfusion-related events for blood and blood products," she adds.

Systems should also offer a comprehensive alerting system, says Yves Charron, product manager for Montreal-based MediSolution, which distributes Mak-System's blood bank software. "This includes, but is not limited to, alerts related to previous testing, incompatibilities of proposed products, and specific attributes for the patient involved," he says. "A full-featured alert system provides technologists with the ability to proactively identify

issues before they develop into an event or incident."

Bar-coding functionality is important as well, says Charron. The transfusion service's computer system should not accept manual entry of any data that can be entered easily using bar coding or similar technology. "Reduction of clerical errors is paramount to practice improvement," he asserts.

Cost, however, can be a hurdle to adopting those technologies that would support biovigilance, as Brian Keefe, MT(ASCP), points out. Because of financial barriers, "many blood banks, particularly in small, rural community hospitals, do not have technology in place to support even the most basic needs, let alone any biovigilance initiative," says Keefe, director of marketing for clinical products at Psyche Systems Corp., Milford, Mass.

Smaller facilities shouldn't be overburdened with a manual system, responds James AuBuchon, MD, of the Working Group for the Interorganizational Task Force in the U.S. Biovigilance Network. "You don't need an LIS in order to upload data," he says. "We will keep it simple so that anyone can input data."

In larger urban facilities, however, lab software systems clearly will capture some biovigilance information, says AABB president D. Michael Strong, PhD. "[But] it's not clear yet whether it's going to capture everything that's necessary. . . . But again, facilitation of data entry is important, whether there be an interface to be able to push data across or things like bar coding to help facilitate that."

"For systems with more computer capabilities," adds Dr. AuBuchon, "someday we hope to be able to support automatic uploading of key data elements to the hemovigilance system."

Taking data entry to the next level, Arthur Bracey, MD, chair of the U.S. Department of Health and Human

Services Advisory Committee on Blood Safety and Availability, says one of the problems with current information systems is finding efficient ways to extract the most meaningful data. As biovigilance develops, Dr. Bracey says, there should be some way of linking the laboratory information system into other databases, such as those that provide such outcome measures as length of stay or length of time in the intensive care unit. Such data would be helpful in determining how transfusion affects patient outcomes, he says. For example, cardiac bypass surgery patients who have undergone transfusions can be compared with those cardiac patients who haven't had transfusions in terms of length of stay and incidence of infection.

It's important as we move ahead with biovigilance systems that we look at not only emerging infectious disorders and diseases but at "the relative proportion of selected adverse physiologic complications that affect people with and without transfusion," says Dr. Bracey, who is transfusion service medical director at St. Luke's Episcopal Hospital, Houston. This is necessary, he adds, to better understand how transfusion influences patient outcomes.

Having an automated system that can track blood inventories on a national basis is also needed to avert the chances for chronic shortages of blood, he says. "In an ideal world, the computer systems should be searchable so that we would have a real-time idea of the inventories that we have," he continues. Dr. Bracey adds that inventory functionality would also support another piece of biovigilance—tracking adverse events and extracting other kinds of outcomes data with minimal delay. "Computer systems," he says, "that are designed ideally should be able to address all of those needs." □

Karen Wagner is a freelance writer in Forest Lake, Ill.



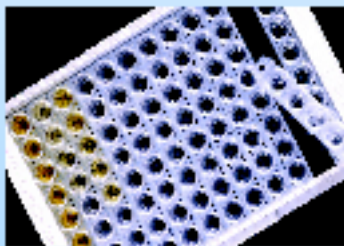
Keefe



Dr. Bracey

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### STATE DATES

US state pathology societies meet

State	Meeting	Date	Contact
AZ	Arizona Society of Pathologists Fall Meeting 2007	10/27/07	Patrice Hand 602-246-8001 patrich@azsmetsoc.org
CA	60th Annual California Seminars in Pathology	12/05/07	Dawn A. Hummel 916-446-6001 dhummel@smggroup.us
MO	MSP Annual Meeting	4/19/08	Jeff Craver 573-886-4659 jcraver@sal.com
TX	87th Annual Meeting of the Texas Society of Pathologists	1/9/08	Shari Rhodes 512-370-1510 shari.rhodes@texasnet.org

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## Blood bank information systems

Name of blood bank system	Blood Bank Control System	Cerner Millennium PathNet Blood Bank Transfusion
<b>Part 1 of 10</b>	<b>Blood Bank Computer Systems</b>	<b>Cerner Corp.</b>
<b>See accompanying articles on pages 12 and 38</b>	<b>Brian Forbis</b> bforbis@bbcinc.com 1002 15th St. SW, Suite 120 Auburn, WA 98001-6502 253-333-0046 www.bbcinc.com	<b>Jared Blankenship</b> jared.blankenship@cerner.com 2800 Rockcreek Parkway Kansas City, MO 64117 816-201-0696 www.cerner.com
First ever blood bank system installation	1987	1985
Last major product release (for product featured)	2005	2006
Total number of contracts for operational sites	34	113
•U.S. hospitals with donor and transfusion service	4	0
•U.S. hospitals with transfusion service only	0	104
•U.S. regional blood centers with donor service only	26	0
•U.S. regional blood centers with donor and transfusion service	4	0
•Centralized transfusion services in the U.S.	0	0
•Foreign hospitals and regional blood centers	0	9
No. of contracts signed between July 2006–July 2007	5	unavailable
Total number of sites operational	119	267
Installs not yet live (hospitals/regional blood centers/others)	5 (1/4/0)	187 (151/36/0)
No. of sites that went live between July 2006–July 2007	3	17
Percentage of installations that are stand-alone systems	100%	0.5%
Staff to develop/install and support/other* in entire company	10/9/7	1,590/2,287/3,542
Staff to develop/install and support/other* in blood bank systems	10/9/7	15+/34+/15
No. of different versions of software installed	2	11
•Versions of product in field covered by FDA 510(k) clearance	Blood Bank Control System 5.0, 4.4	HNA Classic 306, 2001.01, 2002.01, 2003.01, 2004.01, 2004.M04.01.0, 2004.M04.02.01, 2004.M04.03.01, 2005.01, 2005.02, 2007.01
•Versions of product that did not require FDA 510(k) clearance	—	none
Range in No. of interactive workstations in live sites (average)	10–150 (average, 40)	not tracked
Central hardware or computer platform or services	IBM iSeries	IBM RS/6000, HP (Compaq)
Workstations	IBM 5250-compatible workstations and PCs	Intel Pentium PCs
Software programming language(s)	RPG 400, Java	Visual C, C++, Visual Basic
Operating system(s)	OS/400	AIX, Open VMS, Windows NT
Databases and tools	IBM DB2	Oracle (Cerner Millennium)
Features (listed as percentage of live installs or based on availability)		
•Full support of ISBT 128 unit labeling	installed	installed
•Bar-code reading of donor and unit information	installed	100%
•Unit inventory	installed	100%
•Autologous and directed unit tracking	installed	100%
•Direct entry of test results	installed	100%
•Crossmatch results	installed	100%
•Electronic crossmatch decision making	installed	100%
•Antigen typing	installed	100%
•Handheld devices for positive patient ID	not available	installed
•Integrated bedside check for transfusion	not available	not available
•Track all steps in production of product	installed	100%
•Print donor unit labels—bar coded	installed	installed
•Interface with automated instruments	installed	installed
•Interface with blood irradiator or centrifuges	installed	not available
•Centralized transfusion service capability	installed	100%
•Donor recruitment/donor questionnaire	installed/installed	not available/not available
•Mobile scheduling screen instruments	installed	not available
•Laptop-based mobile donor registration module	installed	not available
•Source or recovered plasma management	installed	not available
•Accounts receivable	installed	installed
•Management reports/ad hoc report writer	installed/installed	100%/100%
•Quality control management	installed	installed
System provides standard ASTM/HL7 interface?	yes, versions 2.1, 2.2, 2.3, 2.3.1, 2.4, or 2.5 (configurable)	yes, version 2.3.1
Interfaces to automated donor infectious disease testing instruments	uni-directional to Ortho, Immucor, Abbott, Olympus, DiaMed, IDM via Surround	—
Interfaces to automated ABO/Rh/antibody screening instruments	uni-directional to Ortho ProVue, Immucor Galileo, Olympus Tango, IBG	bi-directional to Immucor ABS2000, Immucor Rosys, Micro Typing Systems Reader M/SA, Ortho ProVue
FDA 510(k)-approved interface to bedside patient ID system?	no	no
Tools to help clients validate their systems	department dedicated to development of validation protocols, flow charts, management guides, validation guide documents, risk mitigation online portal, and 24/7 client support	Cerner Millennium support validation documents
Complete blood bank ASP solution?	yes	yes
Method of charging for ASP service	transaction based	fixed fee
Client software required	browser based, requires software be installed on a client PC	requires software be installed on a client PC
ASP information conduit	operates over the Internet	requires use of a private, dedicated circuit
Client contracts supported from data center not operated by client	5	33
How data center is operated	by a third party (blood bank or IBM Business Partner)	by vendor
System provides indexed field in each test definition for LOINC code?	no	yes
Provide LOINC dictionary for each new installation?	no	yes
HIS and LIS interfaces	Cerner, Medware, IDM, Meditech	n/a
User group?	yes (meets in person annually)	yes (meets via Internet quarterly; in person annually)
Source code?	escrow	escrow
Can user modify screens?	no	yes
User-defined report writer/custom programming?	yes/yes	yes/yes
Cost for smallest & largest stand-alone HW/SW/install & training/mo. maint.	—	—
Cost for smallest & largest integrated HW/SW/install & training/mo. maint.	—	—
Distinguishing features (supplied by vendor)	<ul style="list-style-type: none"> <li>• ISBT 128-compatible version 5.0 was FDA 510(k) cleared in 2005</li> <li>• self registration and online questionnaire</li> <li>• system is highly configurable to fit client needs</li> </ul>	<ul style="list-style-type: none"> <li>• customized historical and current patient demographic displays</li> <li>• clinical validation</li> <li>• flexible specimen expiration parameters</li> </ul>
*other=sales, marketing, administration, other company functions		

## Blood bank information systems

<b>Part 2 of 10</b>  <i>See accompanying articles on pages 12 and 38</i>	<b>GE Healthcare</b> <b>Barbara Mullarky</b> barbara.mullarky@ge.com <b>3100 Steeles Ave. East, Suite 900</b> <b>Markham, Ontario, Canada L3R 8T3</b> <b>520-722-9734</b> www.gehealthcare.com	<b>Haemonetics Software Solutions†</b> <b>Shannon Swiderski</b> sms@idm.com <b>9701 W. Higgins Rd., Suite 500</b> <b>Rosemont, IL 60018</b> <b>847-825-2300</b> www.idm.com
Name of blood bank system	Centricity Ultra Laboratory	IDM Select Series
First ever blood bank system installation Last major product release (for product featured) Total number of contracts for operational sites •U.S. hospitals with donor and transfusion service •U.S. hospitals with transfusion service only •U.S. regional blood centers with donor service only •U.S. regional blood centers with donor and transfusion service •Centralized transfusion services in the U.S. •Foreign hospitals and regional blood centers No. of contracts signed between July 2006–July 2007 Total number of sites operational Installs not yet live (hospitals/regional blood centers/others) No. of sites that went live between July 2006–July 2007 Percentage of installations that are stand-alone systems	1996 2007 9 0 1 0 0 0 8 0 9 1 (1/0/0) 1 0	1991 — 10 0 0 9 0 0 1 2 8 2 (0/2/0) — 100%
Staff to develop/install and support/other* in entire company Staff to develop/install and support/other* in blood bank systems	43,500 (total) —	28/14/20 28/14/20
No. of different versions of software installed •Versions of product in field covered by FDA 510(k) clearance •Versions of product that did not require FDA 510(k) clearance	4 3.3, 4.0 2.4, 3.2	1 DMIS 2.1 none
Range in No. of interactive workstations in live sites (average)	2–10 (average, 6)	4–80 (average, 30)
Central hardware or computer platform or services Workstations	Unix-based platforms PCs with Windows 2000, XP	HP 9000 business servers Unix terminals, X-terminals, PCs
Software programming language(s) Operating system(s) Databases and tools	C, C++, 4GL Unix Unify Dataserver	C, C++ Unix Oracle
Features (listed as percentage of live installs or based on availability) •Full support of ISBT 128 unit labeling •Bar-code reading of donor and unit information •Unit inventory •Autologous and directed unit tracking •Direct entry of test results •Crossmatch results •Electronic crossmatch decision making •Antigen typing •Handheld devices for positive patient ID •Integrated bedside check for transfusion •Track all steps in production of product •Print donor unit labels—bar coded •Interface with automated instruments •Interface with blood irradiator or centrifuges •Centralized transfusion service capability •Donor recruitment/donor questionnaire •Mobile scheduling screen instruments •Laptop-based mobile donor registration module •Source or recovered plasma management •Accounts receivable •Management reports/ad hoc report writer •Quality control management	installed installed 100% installed 100% 100% 100% installed installed installed (via third-party vendor) installed (via third-party vendor) not available not available installed not available installed not available not available installed not available/not available not available not available not available 100%/100% not available	50% 100% 100% 100% 100% not available not available 100% not available not available 100% not available not available not available 100% not available not available 100% not available 100%/100% not available
System provides standard ASTM/HL7 interface? Interfaces to automated donor infectious disease testing instruments Interfaces to automated ABO/Rh/antibody screening instruments FDA 510(k)-approved interface to bedside patient ID system? Tools to help clients validate their systems	yes, versions 2.2, 2.3 — bi-directional to Ortho ProVue, Immucor Galileo, Olympus Tango, AutoVue, Wadiana, DiaMed no validation checklists that cover setup, testing, and verification; internal test case manual used for FDA validation available on request	no — — no complete product users manuals, product validation guide, configuration worksheets, training classes and materials, post go-live consultation, automated testing tools
Complete blood bank ASP solution? Method of charging for ASP service Client software required ASP information conduit Client contracts supported from data center not operated by client How data center is operated	no — — — — —	yes fixed fee uses dumb terminals requires use of a private, dedicated circuit 0 —
System provides indexed field in each test definition for LOINC code? Provide LOINC dictionary for each new installation?	yes no	no no
HIS and LIS interfaces	Cerner, Meditech, Siemens, GE, others	IDM
User group? Source code? Can user modify screens? User-defined report writer/custom programming?	yes (meets via Internet at least quarterly; in person annually) escrow yes yes/no	yes (meets in person annually) escrow yes yes/yes
Cost for smallest & largest stand-alone HW/SW/install & training/mo. maint. Cost for smallest & largest integrated HW/SW/install & training/mo. maint.	n/a \$40k–\$60k/\$150k/—/\$2.5k to \$125k/\$400k/—/\$6k	— —
Distinguishing features (supplied by vendor)	• fully integrated with other laboratory disciplines in single relational database • full security control over data access; extensive audit tracking • multi-site capabilities that allow numerous blood banks to maintain inventory and information individually	• longevity; large customer base; financial stability; continual R&D ensuring customer investment protection • proactive stance on regulatory affairs • commitment to superior 24/7 customer support services <i>†formerly IDM, a Haemonetics company</i>

Tabulation does not represent an endorsement by the College of American Pathologists.

## Blood bank information systems

<i>Part 3 of 10</i>	Haemonetics Software Solutions† Shannon Swiderski sms@idm.com 9701 W. Higgins Rd., Suite 500 Rosemont, IL 60018 847-825-2300 www.idm.com	Haemonetics Software Solutions† Shannon Swiderski sms@idm.com 9701 W. Higgins Rd., Suite 500 Rosemont, IL 60018 847-825-2300 www.idm.com
<i>See accompanying articles on pages 12 and 38</i>		
<b>Name of blood bank system</b>	<b>IDM Surround</b>	<b>IDM Symphony Suite-Prelude</b>
First ever blood bank system installation	1991	1991
Last major product release (for product featured)	—	—
Total number of contracts for operational sites	31	8
•U.S. hospitals with donor and transfusion service	0	0
•U.S. hospitals with transfusion service only	0	0
•U.S. regional blood centers with donor service only	27	8
•U.S. regional blood centers with donor and transfusion service	3	0
•Centralized transfusion services in the U.S.	0	0
•Foreign hospitals and regional blood centers	1	0
No. of contracts signed between July 2006–July 2007	—	2
Total number of sites operational	26	1
Installs not yet live (hospitals/regional blood centers/others)	—	7 (0/7/0)
No. of sites that went live between July 2006–July 2007	1	1
Percentage of installations that are stand-alone systems	72%	0
Staff to develop/install and support/other* in entire company	28/14/20	28/14/20
Staff to develop/install and support/other* in blood bank systems	28/14/20	28/14/20
No. of different versions of software installed	5	2
•Versions of product in field covered by FDA 510(k) clearance	4.0, 4.1, 4.2, 4.3, 4.4	Prelude 1.1
•Versions of product that did not require FDA 510(k) clearance	none	Prelude 1.2
Range in No. of interactive workstations in live sites (average)	3–40 (average, 5)	average, 25
Central hardware or computer platform or services	Intel Pentium server	compatible with HP-Unix or Windows operating systems
Workstations	PC workstation	any compatible with Windows
Software programming language(s)	Java	Java J2EE
Operating system(s)	Windows NT, 2000, 2003	Unix, Windows 2000/2003 server, Windows 2000, XP
Databases and tools	Oracle	Oracle 10g
Features (listed as percentage of live installs or based on availability)		
•Full support of ISBT 128 unit labeling	100%	50%
•Bar-code reading of donor and unit information	not available	100%
•Unit inventory	not available	100%
•Autologous and directed unit tracking	not available	100%
•Direct entry of test results	100%	not available
•Crossmatch results	not available	not available
•Electronic crossmatch decision making	not available	not available
•Antigen typing	not available	not available
•Handheld devices for positive patient ID	not available	not available
•Integrated bedside check for transfusion	not available	not available
•Track all steps in production of product	not available	100%
•Print donor unit labels—bar coded	not available	not available
•Interface with automated instruments	100%	not available
•Interface with blood irradiator or centrifuges	not available	not available
•Centralized transfusion service capability	not available	not available
•Donor recruitment/donor questionnaire	not available/not available	not available/100%
•Mobile scheduling screen instruments	not available	not available
•Laptop-based mobile donor registration module	not available	available but not installed
•Source or recovered plasma management	not available	not available
•Accounts receivable	not available	not available
•Management reports/ad hoc report writer	100%/100%	not available/not available
•Quality control management	not available	not available
System provides standard ASTM/HL7 interface?	no	no
Interfaces to automated donor infectious disease testing instruments	uni-directional to Ortho, Immucor, Abbott, Olympus, Biotech, DOMS	—
Interfaces to automated ABO/Rh/antibody screening instruments	uni-directional to Ortho ProVue, Immucor Galileo, Olympus Tango	—
FDA 510(k)-approved interface to bedside patient ID system?	no	—
Tools to help clients validate their systems	complete product users manuals, configuration worksheets, training classes and materials, product validation guide, post go-live consultation	complete product users manuals, configured worksheets, automated testing tools, training classes and materials, complete product validation guide, post go-live consultation
Complete blood bank ASP solution?	yes	yes
Method of charging for ASP service	fixed fee	fixed fee
Client software required	requires software be installed on a client PC	requires software be installed on a client PC
ASP information conduit	requires use of a private, dedicated circuit	requires use of a private, dedicated circuit
Client contracts supported from data center not operated by client	n/a	0
How data center is operated	—	—
System provides indexed field in each test definition for LOINC code?	no	no
Provide LOINC dictionary for each new installation?	no	no
HIS and LIS interfaces	Cerner, Mak System, Medware, Wyndgate, others	n/a
User group?	yes (meets in person annually)	yes (meets in person annually)
Source code?	escrow	escrow
Can user modify screens?	no	no
User-defined report writer/custom programming?	yes/yes	no/yes
Cost for smallest & largest stand-alone HW/SW/install & training/mo. maint.	—	—
Cost for smallest & largest integrated HW/SW/install & training/mo. maint.	—	—
Distinguishing features (supplied by vendor)	<ul style="list-style-type: none"> <li>• longevity; large customer base; financial stability; continual R&amp;D ensuring customer investment protection</li> <li>• proactive stance on regulatory affairs</li> <li>• commitment to superior 24/7 customer support services</li> </ul>	<ul style="list-style-type: none"> <li>• longevity; large customer base; financial stability; continued R&amp;D ensuring customer investment protection</li> <li>• proactive stance on regulatory affairs</li> <li>• commitment to superior 24/7 customer support services</li> </ul>
*other=sales, marketing, administration, other company functions	†formerly IDM, a Haemonetics company	†formerly IDM, a Haemonetics company

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## Blood bank information systems

Name of blood bank system	Patient Health Software (PHS)	Progesa
Part 4 of 10 See accompanying articles on pages 12 and 38	Mak-System Corp. Stephane Sajt sales.us@mak-system.net 2720 River Rd., Suite 225 Des Plaines, IL 60018 847-803-4863 www.mak-system.net	Mak-System Corp. Stephane Sajt sales.us@mak-system.net 2720 River Rd., Suite 225 Des Plaines, IL 60018 847-803-4863 www.mak-system.net
First ever blood bank system installation	1985	1985
Last major product release (for product featured)	2007	—
Total number of contracts for operational sites	433	625
•U.S. hospitals with donor and transfusion service	0	1
•U.S. hospitals with transfusion service only	0	0
•U.S. regional blood centers with donor service only	0	5
•U.S. regional blood centers with donor and transfusion service	1	—
•Centralized transfusion services in the U.S.	1	—
•Foreign hospitals and regional blood centers	431	619
No. of contracts signed between July 2006–July 2007	38	37
Total number of sites operational	423	598
Installs not yet live (hospitals/regional blood centers/others)	15 (14/1/0)	17 (8/9/0)
No. of sites that went live between July 2006–July 2007	—	—
Percentage of installations that are stand-alone systems	100%	100%
Staff to develop/install and support/other* in entire company	145/116/72	145/116/72
Staff to develop/install and support/other* in blood bank systems	145/116/72	145/116/72
No. of different versions of software installed	1	1
•Versions of product in field covered by FDA 510(k) clearance	1.0	4.4
•Versions of product that did not require FDA 510(k) clearance	—	—
Range in No. of interactive workstations in live sites (average)	3–2,000 (average, 35)	10–1,400 (average, 100)
Central hardware or computer platform or services	Unix, Windows, Linux	no restrictions
Workstations	PC, Windows XP, 2000	Sun, IBM, Wyse, HP, DEC, PC
Software programming language(s)	Delphi, Java	C, C++, Pro5, Java
Operating system(s)	Windows	Unix, Web technology, client/server, Solaris
Databases and tools	Oracle	Oracle, Caché, C-ISAM
Features (listed as percentage of live installs or based on availability)		
•Full support of ISBT 128 unit labeling	100%	installed
•Bar-code reading of donor and unit information	100%	100%
•Unit inventory	100%	100%
•Autologous and directed unit tracking	100%	100%
•Direct entry of test results	100%	100%
•Crossmatch results	100%	installed
•Electronic crossmatch decision making	100%	100%
•Antigen typing	100%	100%
•Handheld devices for positive patient ID	—	100%
•Integrated bedside check for transfusion	100%	100%
•Track all steps in production of product	100%	100%
•Print donor unit labels—bar coded	100%	100%
•Interface with automated instruments	not available	100%
•Interface with blood irradiator or centrifuges	100%	installed
•Centralized transfusion service capability	not available	100%
•Donor recruitment/donor questionnaire	not available/not available	100%/100%
•Mobile scheduling screen instruments	not available	100%
•Laptop-based mobile donor registration module	not available	100%
•Source or recovered plasma management	not available	100%
•Accounts receivable	100%	100%
•Management reports/ad hoc report writer	100%/100%	100%/100%
•Quality control management	100%	100%
System provides standard ASTM/HL7 interface?	yes, version 2.x	yes, version 2.x
Interfaces to automated donor infectious disease testing instruments	uni- and bi-directional to Ortho, Immucor, Abbott, Olympus, DiaMed	uni- and bi-directional to Ortho, Immucor, Abbott, Olympus, DiaMed
Interfaces to automated ABO/Rh/antibody screening instruments	uni- and bi-directional to Ortho ProVue, Immucor Galileo, Olympus Tango	uni- and bi-directional to Ortho ProVue, Immucor Galileo, Olympus Tango
FDA 510(k)-approved interface to bedside patient ID system?	—	—
Tools to help clients validate their systems	user guides, hazard analysis, training manuals, data conversion, validation scenario samples	user guides, hazard analysis, training manuals, data conversion, validation scenario samples
Complete blood bank ASP solution?	no	no
Method of charging for ASP service	—	—
Client software required	—	—
ASP information conduit	—	—
Client contracts supported from data center not operated by client	—	—
How data center is operated	—	—
System provides indexed field in each test definition for LOINC code?	yes	no
Provide LOINC dictionary for each new installation?	—	—
HIS and LIS interfaces	no restrictions	no restrictions
User group?	yes (meets in person biannually)	yes (meets in person biannually)
Source code?	escrow	escrow
Can user modify screens?	no	no
User-defined report writer/custom programming?	—	—
Cost for smallest & largest stand-alone HW/SW/install & training/mo. maint.	—	—
Cost for smallest & largest integrated HW/SW/install & training/mo. maint.	—	—
Distinguishing features (supplied by vendor)	<ul style="list-style-type: none"> <li>comprehensive communication capabilities with Progesa blood bank software</li> <li>abundant functionality, including hemovigilance features and transfusion documentation at bedside</li> <li>highly customizable through parameters</li> </ul>	<ul style="list-style-type: none"> <li>modules fully integrated from donor to patient</li> <li>abundant functionality</li> <li>highly customizable through parameters</li> </ul>
*other=sales, marketing, administration, other company functions	software for PHS supplied by MediSolution	

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## Blood bank information systems

<b>Part 5 of 10</b>	<b>McKesson Corp.</b> Joseph Stabile joseph.stabile@mckesson.com 5995 Windward Parkway Atlanta, GA 30005 404-338-6000 www.mckesson.com	<b>Medical Information Technology</b> Paul Berthiaume pberthiaume@meditech.com Meditech Circle Westwood, MA 02090 781-821-3000 www.meditech.com
<i>See accompanying articles on pages 12 and 38</i>		
<b>Name of blood bank system</b>	<b>Horizon Blood Bank</b>	<b>Blood Bank System-Client/Server</b>
First ever blood bank system installation	2004	1981
Last major product release (for product featured)	2006	2006
Total number of contracts for operational sites	35	244
•U.S. hospitals with donor and transfusion service	0	—
•U.S. hospitals with transfusion service only	33	—
•U.S. regional blood centers with donor service only	0	—
•U.S. regional blood centers with donor and transfusion service	0	—
•Centralized transfusion services in the U.S.	0	—
•Foreign hospitals and regional blood centers	2	—
No. of contracts signed between July 2006-July 2007	22	—
Total number of sites operational	35	222
Installs not yet live (hospitals/regional blood centers/others)	26 (26/0/0)	22 (22/0/0)
No. of sites that went live between July 2006-July 2007	9	—
Percentage of installations that are stand-alone systems	0	2%
Staff to develop/install and support/other* in entire company	32,000+	622/1,631/504
Staff to develop/install and support/other* in blood bank systems	93 (total)†	—
No. of different versions of software installed	3	2
•Versions of product in field covered by FDA 510(k) clearance	all	Magic, client/server
•Versions of product that did not require FDA 510(k) clearance	—	—
Range in No. of interactive workstations in live sites (average)	1-6 (average, 2)	—
Central hardware or computer platform or services	Intel-based and Unix-based servers	Hewlett-Packard, Dell, EMC, IBM
Workstations	PCs	Hewlett-Packard, Dell, EMC, IBM
Software programming language(s)	Delphi, SQL, Crystal Reports	Magic
Operating system(s)	Windows XP Professional, 2003 (Unix optional)	Windows 2000, XP (client); Windows 2000, 2003 (server)
Databases and tools	Oracle	Magic, SQL server 2005
Features (listed as percentage of live installs or based on availability)		
•Full support of ISBT 128 unit labeling	installed	installed
•Bar-code reading of donor and unit information	installed	installed
•Unit inventory	installed	100%
•Autologous and directed unit tracking	installed	100%
•Direct entry of test results	installed	100%
•Crossmatch results	installed	100%
•Electronic crossmatch decision making	installed	not available
•Antigen typing	installed	installed
•Handheld devices for positive patient ID	not available	installed
•Integrated bedside check for transfusion	available in 2008	installed
•Track all steps in production of product	installed	installed
•Print donor unit labels—bar coded	installed	installed
•Interface with automated instruments	installed	installed
•Interface with blood irradiator or centrifuges	installed	not available
•Centralized transfusion service capability	not available	installed
•Donor recruitment/donor questionnaire	not available/not available	installed/installed
•Mobile scheduling screen instruments	not available	installed
•Laptop-based mobile donor registration module	not available	installed
•Source or recovered plasma management	not available	installed
•Accounts receivable	not available	installed
•Management reports/ad hoc report writer	installed/installed	100%/100%
•Quality control management	installed	installed
System provides standard ASTM/HL7 interface?	yes, version 2.2 and higher	yes, version 2.4
Interfaces to automated donor infectious disease testing instruments	—	—
Interfaces to automated ABO/Rh/antibody screening instruments	uni- and bi-directional to Ortho ProVue, Immucor Galileo, Olympus Tango	uni-directional to Ortho ProVue, Ortho AutoVue, Immucor Galileo
FDA 510(k)-approved interface to bedside patient ID system?	under development	Meditech supplies own patient ID system
Tools to help clients validate their systems	validation services and guidelines available for purchase	comprehensive user manual, which is reviewed during training
Complete blood bank ASP solution?	yes	no
Method of charging for ASP service	fixed fee, transaction based	—
Client software required	browser based, requires software be installed on a client PC	—
ASP information conduit	operates over the Internet, requires use of a private, dedicated circuit	—
Client contracts supported from data center not operated by client	—	—
How data center is operated	—	—
System provides indexed field in each test definition for LOINC code?	no	yes
Provide LOINC dictionary for each new installation?	no	no
HIS and LIS interfaces	McKesson	Cerner, Siemens, Misys, McKesson, others
User group?	yes (meets in person annually)	yes (meets via Internet and in person)
Source code?	escrow	yes
Can user modify screens?	no	yes
User-defined report writer/custom programming?	yes/no	yes/no
Cost for smallest & largest stand-alone HW/SW/install & training/mo. maint.	—	—
Cost for smallest & largest integrated HW/SW/install & training/mo. maint.	—	—
Distinguishing features (supplied by vendor)	<ul style="list-style-type: none"> <li>• numerous safety features, including Patient-At-A-Glance Bar</li> <li>• patent-pending CTS and other transfusion service functionality</li> <li>• Wyndgate's Service 360 commitment to ensure quality implementation and support experience</li> </ul>	<ul style="list-style-type: none"> <li>• fully integrated applications</li> <li>• developed 100% in house by Meditech</li> <li>• 36 years of LIS experience</li> </ul>
*other=sales, marketing, administration, other company functions	software for Horizon Blood Bank supplied by Wyndgate Technologies	†from Wyndgate Technologies

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## Blood bank information systems

<i>Part 6 of 10</i>	Medical Information Technology Paul Berthiaume pberthiaume@meditech.com Meditech Circle Westwood, MA 02090 781-821-3000 www.meditech.com	Mediware Information Systems Steve Sedlock steve.sedlock@mediware.com 1900 Spring Rd., Suite 450 Oak Brook, IL 60523 630-218-2700 www.mediware.com
See accompanying articles on pages 12 and 38		
Name of blood bank system	Blood Bank System—Magic	HCLL Transfusion and Donor†
First ever blood bank system installation	1981	1980
Last major product release (for product featured)	2006	2007
Total number of contracts for operational sites	776	164
•U.S. hospitals with donor and transfusion service	—	30††
•U.S. hospitals with transfusion service only	—	125††
•U.S. regional blood centers with donor service only	—	1††
•U.S. regional blood centers with donor and transfusion service	—	4††
•Centralized transfusion services in the U.S.	—	8††
•Foreign hospitals and regional blood centers	—	5
No. of contracts signed between July 2006–July 2007	—	47
Total number of sites operational	660	54
Installs not yet live (hospitals/regional blood centers/others)	8 (8/0/0)	219 (219/0/0)
No. of sites that went live between July 2006–July 2007	—	34
Percentage of installations that are stand-alone systems	2%	85%
Staff to develop/install and support/other* in entire company	622/1,631/504	59/83/59
Staff to develop/install and support/other* in blood bank systems	—	21/54/14
No. of different versions of software installed	2	6
•Versions of product in field covered by FDA 510(k) clearance	Magic, client/server	HCLL Donor 1.0
•Versions of product that did not require FDA 510(k) clearance	—	HCLL Transfusion 2.7, HCLL Transfusion 2.8, HCLL Transfusion 2.9, HCLL Donor 1.1.0, HCLL Donor 1.1.1
Range in No. of interactive workstations in live sites (average)	—	2–50 (average, 8)
Central hardware or computer platform or services	Hewlett-Packard, Dell, EMC, IBM	Microsoft compatible
Workstations	Hewlett-Packard, Dell, EMC, IBM	Microsoft compatible
Software programming language(s)	Magic	Visual Basic, C++ Com, Microsoft .Net, C++
Operating system(s)	Windows 2000, XP (client); Magic (server)	Windows XP, 2000, 2003
Databases and tools	Magic, SQL server 2005	Microsoft SQL 2000, 2005
Features (listed as percentage of live installs or based on availability)		
•Full support of ISBT 128 unit labeling	100%	installed
•Bar-code reading of donor and unit information	installed	installed
•Unit inventory	installed	installed
•Autologous and directed unit tracking	100%	installed
•Direct entry of test results	100%	installed
•Crossmatch results	100%	installed
•Electronic crossmatch decision making	available but not installed	installed
•Antigen typing	installed	installed
•Handheld devices for positive patient ID	installed	available but not installed
•Integrated bedside check for transfusion	installed	available but not installed
•Track all steps in production of product	100%	installed
•Print donor unit labels—bar coded	installed	installed
•Interface with automated instruments	installed	installed
•Interface with blood irradiator or centrifuges	not available	not available
•Centralized transfusion service capability	100%	installed
•Donor recruitment/donor questionnaire	installed/installed	not available/not available
•Mobile scheduling screen instruments	installed	not available
•Laptop-based mobile donor registration module	installed	not available
•Source or recovered plasma management	installed	not available
•Accounts receivable	installed	not available
•Management reports/ad hoc report writer	100%/100%	installed/installed
•Quality control management	installed	installed
System provides standard ASTM/HL7 interface?	yes, version 2.4	yes, versions 2.1–2.5
Interfaces to automated donor infectious disease testing instruments	—	—
Interfaces to automated ABO/Rh/antibody screening instruments	uni-directional to Ortho ProVue, Ortho AutoVue, Immucor Galileo	uni-directional to Ortho ProVue, Immucor Galileo, ABS2000
FDA 510(k)-approved interface to bedside patient ID system?	Meditech supplies own patient ID system	yes (to Mediware's BloodSafe)
Tools to help clients validate their systems	comprehensive user manual, which is reviewed during training	validation scripts provided with system and each new release
Complete blood bank ASP solution?	no	no
Method of charging for ASP service	—	—
Client software required	—	—
ASP information conduit	—	—
Client contracts supported from data center not operated by client	—	—
How data center is operated	—	—
System provides indexed field in each test definition for LOINC code?	yes	no
Provide LOINC dictionary for each new installation?	no	no
HIS and LIS interfaces	Cerner, Siemens, Misys, McKesson, others	to HL7-compliant HIS and LIS vendors
User group?	yes (meets via Internet and in person)	yes (meets via Internet quarterly; in person annually)
Source code?	yes	escrow
Can user modify screens?	yes	yes
User-defined report writer/custom programming?	yes/no	yes/no
Cost for smallest & largest stand-alone HW/SW/install & training/mo. maint.	—	\$13.15k/\$51k/\$49.1k/\$.935k to \$27.9k/\$90k/\$72.5k/\$1.81k
Cost for smallest & largest integrated HW/SW/install & training/mo. maint.	—	\$16.06k/\$68k/\$58.67k/\$1.25k to \$31.78k/\$118.5k/\$100k/\$2.33k
Distinguishing features (supplied by vendor)	<ul style="list-style-type: none"> <li>fully integrated applications</li> <li>developed 100% in house by Meditech</li> <li>36 years of LIS experience</li> </ul>	<ul style="list-style-type: none"> <li>offer FDA 510(k)-cleared bedside transfusion administration package to extend blood safety controls outside the blood bank</li> <li>over 27 years' experience in blood banking software industry</li> <li>over 12% of staff in blood management division are SBB certified</li> </ul>
*other=sales, marketing, administration, other company functions		†company did not indicate if answers apply to both products or just one product ††breakdown reflects contracts that fit more than one category

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## Blood bank information systems

<b>Part 7 of 10</b> <b>See accompanying articles on pages 12 and 38</b>	<b>Mediware Information Systems</b> <b>Steve Sedlock</b> steve.sedlock@mediware.com <b>1900 Spring Rd., Suite 450, Oak Brook, IL 60523</b> <b>630-218-2700</b> www.mediware.com	<b>Misys Healthcare Systems</b> <b>Sylvia Rothrock</b> sylvia.rothrock@misyshealthcare.com <b>250 S. Williams Blvd., Tucson, AZ 85711</b> <b>www.misyshealthcare.com</b>
Name of blood bank system	LifeTrak	Misys Laboratory Blood Bank and Blood Donor modules†
First ever blood bank system installation	1980	1985
Last major product release (for product featured)	2007	2007
Total number of contracts for operational sites	12	356
•U.S. hospitals with donor and transfusion service	6†	37
•U.S. hospitals with transfusion service only	0	305
•U.S. regional blood centers with donor service only	2†	0
•U.S. regional blood centers with donor and transfusion service	4†	0
•Centralized transfusion services in the U.S.	2†	0
•Foreign hospitals and regional blood centers	0	14
No. of contracts signed between July 2006–July 2007	2	—
Total number of sites operational	66	>400
Installs not yet live (hospitals/regional blood centers/others)	4 (3/1/0)	8 (8/0/0)
No. of sites that went live between July 2006–July 2007	2	12
Percentage of installations that are stand-alone systems	100%	0
Staff to develop/install and support/other* in entire company	59/83/59	410/270/80
Staff to develop/install and support/other* in blood bank systems	21/54/14	230/250/80 (blood bank and LIS combined)
No. of different versions of software installed	4	2
•Versions of product in field covered by FDA 510(k) clearance	LifeTrak 2.03, 3.02	blood bank and blood donor v6.0.1 distributed with laboratory versions v6.1 and v6.2
•Versions of product that did not require FDA 510(k) clearance	LifeTrak 3.01, 3.1.1	blood bank and blood donor v6.0.2 distributed with laboratory v6.3
Range in No. of interactive workstations in live sites (average)	10–300 (average, 100)	5+–100+ (average, 20)
Central hardware or computer platform or services	Intel-based server (Linux), HP 9000 (HP-UX 11)	IBM p5, p6, HP Alpha servers, HP Integrity
Workstations	Microsoft compatible	Dell, HP Windows
Software programming language(s)	Oracle forms and reports, Pro*C	ANSI Standard M, Caché Script, Standard C/C++, Visual Basic,
Operating system(s)	HP-UX, Linux AS	Visual C++, Active X
Databases and tools	Oracle	AIX, HP UX, OpenVMS Intersystems Caché
Features (listed as percentage of live installs or based on availability)		
•Full support of ISBT 128 unit labeling	available but not installed	100%
•Bar-code reading of donor and unit information	installed	100%
•Unit inventory	installed	100%
•Autologous and directed unit tracking	installed	100%
•Direct entry of test results	installed	100%
•Crossmatch results	not available	100%
•Electronic crossmatch decision making	not available	10%
•Antigen typing	installed	100%
•Handheld devices for positive patient ID	not available	20%
•Integrated bedside check for transfusion	not available	available in 2008 (pending FDA 510[k] clearance)
•Track all steps in production of product	installed	100%
•Print donor unit labels—bar coded	installed	10%
•Interface with automated instruments	installed	10%
•Interface with blood irradiator or centrifuges	available in 2008	not available
•Centralized transfusion service capability	not available	100%
•Donor recruitment/donor questionnaire	installed/installed	15%/not available
•Mobile scheduling screen instruments	installed	not available
•Laptop-based mobile donor registration module	installed	not available
•Source or recovered plasma management	installed	installed
•Accounts receivable	not available	100% (charge capture)
•Management reports/ad hoc report writer	installed/installed	100%/100%
•Quality control management	installed	100%
System provides standard ASTM/HL7 interface?	yes, versions 2.1–2.5	yes, versions 2.3–3.0
Interfaces to automated donor infectious disease testing instruments	uni-directional to Ortho, Abbott, Olympus, BioMérieux, Chiron	uni-directional to Ortho, Immucor, Abbott, Olympus, DiaMed
Interfaces to automated ABO/Rh/antibody screening instruments	uni-directional to Immucor Galileo, Olympus Tango, Olympus PK, MTS, Immucor Dias, Immucor Rosys	uni-directional to Ortho ProVue, Immucor Galileo, Olympus Tango, DiaMed
FDA 510(k)-approved interface to bedside patient ID system?	yes (to Mediware's BloodSafe)	no (pending FDA 510[k] clearance)
Tools to help clients validate their systems	validation scripts provided with system and each new release	client testing guidelines, documentation, training and consulting services
Complete blood bank ASP solution?	no	no
Method of charging for ASP service	—	—
Client software required	—	—
ASP information conduit	—	—
Client contracts supported from data center not operated by client	—	—
How data center is operated	—	—
System provides indexed field in each test definition for LOINC code?	no	no
Provide LOINC dictionary for each new installation?	no	no
HIS and LIS interfaces	via HL7 to Cerner	Epic, McKesson, Meditech, Siemens, Eclipsys, Cerner, GE, others
User group?	yes (meets via Internet quarterly; in person annually)	yes (meets quarterly via Internet and in person)
Source code?	escrow	escrow
Can user modify screens?	no	no
User-defined report writer/custom programming?	no/no	yes/yes
Cost for smallest & largest stand-alone HW/SW/install & training/mo. maint.	\$15k/\$75k/—/\$2.6k to \$250k/\$400k/—/\$23k	\$70k/\$208k/\$100k/\$38k to \$180k/\$980k/\$185k/\$202k
Cost for smallest & largest integrated HW/SW/install & training/mo. maint.	—	\$0 with Misys Lab/\$50k/\$58k/\$12k to \$0 with Misys Lab/\$790k/\$77k/\$168k
Distinguishing features (supplied by vendor)	<ul style="list-style-type: none"> <li>• complete donor center suite from recruitment through final distribution</li> <li>• ISBT 128 compliant; can manage ABC Codabar and ISBT simultaneously</li> <li>• over 27 years' experience in the blood banking software industry; sole focus is blood, biologics, and medication management</li> </ul>	<ul style="list-style-type: none"> <li>• full integration with LIS for reporting, inquiry, maintenance, quality assurance</li> <li>• full multi-facility capability, including unit inventory tracking and management</li> <li>• service and interoperability excellence</li> </ul>
*other=sales, marketing, administration, other company functions	†breakdown reflects contracts that fit more than one category	†company did not indicate whether answers apply to both modules combined or just one module

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## Blood bank information systems

Name of blood bank system	AutoFusion	Systematic Blood Bank
<b>Part 8 of 10</b>	<b>Netlims LLC</b> Avi Allerhand avi@netlims.com 111 Town Square Place, Suite 700 Jersey City, NJ 07310 201-894-5300 www.netlims.com	<b>Psyche Systems Corp.</b> Rachel Stratman sales@psychesystems.com 321 Fortune Blvd. Milford, MA 01757 800-345-1514 www.psychesystems.com
<i>See accompanying articles on pages 12 and 38</i>		
First ever blood bank system installation	2002	1987
Last major product release (for product featured)	2007	2001
Total number of contracts for operational sites	3	13
•U.S. hospitals with donor and transfusion service	—	0
•U.S. hospitals with transfusion service only	—	13
•U.S. regional blood centers with donor service only	—	0
•U.S. regional blood centers with donor and transfusion service	—	0
•Centralized transfusion services in the U.S.	—	0
•Foreign hospitals and regional blood centers	—	0
No. of contracts signed between July 2006–July 2007	—	2
Total number of sites operational	12	9
Installs not yet live (hospitals/regional blood centers/others)	4 (4/0/0)	4 (4/0/0)
No. of sites that went live between July 2006–July 2007	—	5
Percentage of installations that are stand-alone systems	0	23%
Staff to develop/install and support/other* in entire company	55/37/12	10/16/10
Staff to develop/install and support/other* in blood bank systems	6/5/3	3/5/2
No. of different versions of software installed	2	1
•Versions of product in field covered by FDA 510(k) clearance	n/a	Systematic Blood Bank (SBB) 3.0
•Versions of product that did not require FDA 510(k) clearance	—	none
Range in No. of interactive workstations in live sites (average)	3–20 (average, 10)	1–6 (average, 3)
Central hardware or computer platform or services	Wintel (HP, IBM, Dell)	hosted/Web deployed
Workstations	Wintel (HP, IBM, Dell)	PCs
Software programming language(s)	C++	Visual Basic, Fortran
Operating system(s)	Windows	any
Databases and tools	SQL, Oracle	proprietary
Features (listed as percentage of live installs or based on availability)		
•Full support of ISBT 128 unit labeling	installed	100%
•Bar-code reading of donor and unit information	installed	100%
•Unit inventory	installed	100%
•Autologous and directed unit tracking	installed	100%
•Direct entry of test results	installed	100%
•Crossmatch results	installed	100%
•Electronic crossmatch decision making	installed	100%
•Antigen typing	installed	100%
•Handheld devices for positive patient ID	installed	available but not installed
•Integrated bedside check for transfusion	—	available but not installed
•Track all steps in production of product	installed	100%
•Print donor unit labels—bar coded	—	not available
•Interface with automated instruments	installed	10%
•Interface with blood irradiator or centrifuges	—	not available
•Centralized transfusion service capability	installed	100%
•Donor recruitment/donor questionnaire	—/installed	not available/not available
•Mobile scheduling screen instruments	—	not available
•Laptop-based mobile donor registration module	installed	not available
•Source or recovered plasma management	not available	not available
•Accounts receivable	not available	not available
•Management reports/ad hoc report writer	installed/installed	100%/100%
•Quality control management	—	100%
System provides standard ASTM/HL7 interface?	yes, version 2.3	yes, version 2.3.1
Interfaces to automated donor infectious disease testing instruments	bi-directional to Abbott, Olympus	—
Interfaces to automated ABO/Rh/antibody screening instruments	uni-directional to Wadiana; bi-directional to Olympus Tango	uni-directional to Immucor Galileo
FDA 510(k)-approved interface to bedside patient ID system?	no	no
Tools to help clients validate their systems	system is being validated as a part of company's automated QA testing processes and formal system validation plan	software validation guidelines
Complete blood bank ASP solution?	no	yes
Method of charging for ASP service	—	fixed fee
Client software required	—	browser based, requires software be installed on a client PC
ASP information conduit	—	operates over the Internet
Client contracts supported from data center not operated by client	—	8
How data center is operated	—	by vendor
System provides indexed field in each test definition for LOINC code?	yes	no
Provide LOINC dictionary for each new installation?	no	no
HIS and LIS interfaces	any HL7	CPSI, Psyche Systems, Meditech, Siemens, McKesson, Cerner, Misys, others
User group?	no	yes (meets via Internet periodically; in person biannually)
Source code?	escrow	escrow
Can user modify screens?	yes	yes
User-defined report writer/custom programming?	yes/yes	yes/no
Cost for smallest & largest stand-alone HW/SW/install & training/mo. maint.	\$40k/\$75k—/\$2k to \$140k/\$300k—/\$4.5k	\$0/\$10k/\$5k/\$.350k to \$1 k/\$40k/\$5k/\$.8k
Cost for smallest & largest integrated HW/SW/install & training/mo. maint.	—	\$0/\$30k/\$10k/\$.6k to \$5k/\$10k/\$15k/\$1.5k
Distinguishing features (supplied by vendor)	<ul style="list-style-type: none"> <li>• full integration with all other lab modules and free choice of database on same database</li> <li>• highly customizable and open system on all levels</li> <li>• unique user interface to provide unparalleled ease of use and safety</li> </ul>	<ul style="list-style-type: none"> <li>• complete, affordable blood bank system for the small to mid-size blood bank</li> <li>• flexible and easy to use</li> <li>• securely hosted Web-deployed system that requires no additional hardware investment</li> </ul>
*other=sales, marketing, administration, other company functions		

Tabulation does not represent an endorsement by the College of American Pathologists.

## Blood bank information systems

<b>Part 9 of 10</b>  <i>See accompanying articles on pages 12 and 38</i>	<b>SCC Soft Computer</b> <b>Ellie Vahman</b> ellie@softcomputer.com <b>5400 Tech Data Drive</b> <b>Clearwater, FL 33760</b> <b>727-789-0100, ext. 4052</b>	<b>SCC Soft Computer</b> <b>Ellie Vahman</b> ellie@softcomputer.com <b>5400 Tech Data Drive</b> <b>Clearwater, FL 33760</b> <b>727-789-0100, ext. 4052</b>
<b>Name of blood bank system</b>  First ever blood bank system installation Last major product release (for product featured) Total number of contracts for operational sites •U.S. hospitals with donor and transfusion service •U.S. hospitals with transfusion service only •U.S. regional blood centers with donor service only •U.S. regional blood centers with donor and transfusion service •Centralized transfusion services in the U.S. •Foreign hospitals and regional blood centers No. of contracts signed between July 2006–July 2007 Total number of sites operational Installs not yet live (hospitals/regional blood centers/others) No. of sites that went live between July 2006–July 2007 Percentage of installations that are stand-alone systems	<b>SoftBank</b>  1992 — 148 8 133 0 0 0 7 13 244 27 (27/0/0) 19 3%	<b>SoftDonor</b>  1992 2006 8 8 0 0 0 0 0 1 8 7 (7/0/0) 2 10%
<b>Staff to develop/install and support/other* in entire company</b> <b>Staff to develop/install and support/other* in blood bank systems</b>	720/297/218 34/23/15	720/297/218 34/23/15
<b>No. of different versions of software installed</b> •Versions of product in field covered by FDA 510(k) clearance •Versions of product that did not require FDA 510(k) clearance	6 19.1, 21, 22, 23 with Softscape, 23.1 with Oracle none	2 4.3, 4.4 none
<b>Range in No. of interactive workstations in live sites (average)</b>	1–90+ (average, 8)	3–8 (average, 8)
<b>Central hardware or computer platform or services</b> <b>Workstations</b>	IBM pSeries PCs	IBM pSeries PCs
<b>Software programming language(s)</b> <b>Operating system(s)</b> <b>Databases and tools</b>	C, C++, .Net IBM AIX (Unix) RDM, Oracle	C, C++, .Net IBM AIX (Unix) RDM, Oracle
<b>Features (listed as percentage of live installs or based on availability)</b> •Full support of ISBT 128 unit labeling •Bar-code reading of donor and unit information •Unit inventory •Autologous and directed unit tracking •Direct entry of test results •Crossmatch results •Electronic crossmatch decision making •Antigen typing •Handheld devices for positive patient ID •Integrated bedside check for transfusion •Track all steps in production of product •Print donor unit labels—bar coded •Interface with automated instruments •Interface with blood irradiator or centrifuges •Centralized transfusion service capability •Donor recruitment/donor questionnaire •Mobile scheduling screen instruments •Laptop-based mobile donor registration module •Source or recovered plasma management •Accounts receivable •Management reports/ad hoc report writer •Quality control management	70% — 100% 100% 100% 100% 70% 100% — available third quarter 2008 100% 30% (component labels only) 2% available fourth quarter 2007 100% — — — 50% 95% 100%/100% 90%	installed 100% 100% 100% 100% — — 100% available in December 2007 100% — 100%/100% 50% 90% 100% 100% 100%/100% 50%
<b>System provides standard ASTM/HL7 interface?</b> <b>Interfaces to automated donor infectious disease testing instruments</b> <b>Interfaces to automated ABO/Rh/antibody screening instruments</b>  <b>FDA 510(k)-approved interface to bedside patient ID system?</b> <b>Tools to help clients validate their systems</b>	yes, versions 2–2.7 — uni-directional to ABS2000, Ortho MTS; bi-directional to Ortho ProVue, Immucor Galileo no provide critical control points and instructions on how to write test cases with electronic screen capture	yes, versions 2–2.7 bi-directional to Abbott bi-directional to Ortho ProVue, Immucor Galileo no provide critical points and instructions on how to write test cases with electronic screen capture
<b>Complete blood bank ASP solution?</b> <b>Method of charging for ASP service</b> <b>Client software required</b>  <b>ASP information conduit</b> <b>Client contracts supported from data center not operated by client</b> <b>How data center is operated</b>	yes fixed fee requires software be installed on a client PC  operates over the Internet 1 by vendor	yes fixed fee requires software be installed on a client PC  operates over the Internet 0 by vendor
<b>System provides indexed field in each test definition for LOINC code?</b> <b>Provide LOINC dictionary for each new installation?</b>	no no	no no
<b>HIS and LIS interfaces</b>	Cerner, Meditech, McKesson, Siemens, IDX, CPSI, QuadraMed, Epic, Eclipsys, other vendors that support HL7 protocol	Meditech, McKesson, Siemens, IDX, Cerner, CPSI, QuadraMed, Epic, Eclipsys, other vendors that support HL7 protocol
<b>User group?</b> <b>Source code?</b> <b>Can user modify screens?</b> <b>User-defined report writer/custom programming?</b>	yes (meets in person annually) escrow yes yes/yes	yes (meets in person annually) escrow no yes/yes
<b>Cost for smallest &amp; largest stand-alone HW/SW/install &amp; training/mo. maint.</b> <b>Cost for smallest &amp; largest integrated HW/SW/install &amp; training/mo. maint.</b>	\$25k/\$30k/\$50k/\$.45k to \$50k/\$125k/\$80k/\$1.875k \$40k/\$215k/\$150k/\$4.59k to \$400k/\$2.5m/\$1.1m/\$35k	\$25k/\$30k/\$50k/\$.45k to \$50k/\$125k/\$80k/\$1.875k \$40k/\$215k/\$150k/\$4.59k to \$400k/\$2.5m/\$1.1m/\$35k
<b>Distinguishing features (supplied by vendor)</b>	<ul style="list-style-type: none"> <li>• .Net, Oracle thin-client technology</li> <li>• management tools, including audits and reporting</li> <li>• development, support, and implementation through blood bankers</li> </ul>	<ul style="list-style-type: none"> <li>• .Net, Oracle thin-client technology</li> <li>• nearly 30 years of leading clinical software solutions</li> <li>• development, support, and implementation by donor specialists</li> </ul>

\*other=sales, marketing, administration, other company functions

## Blood bank information systems

Part 10 of 10	Wyndgate Technologies Scott Dustin dustins@wyndgate.com 4925 Robert J. Mathews Parkway, Suite 100 El Dorado Hills, CA 95762 916-404-8400 www.wyndgate.com	Wyndgate Technologies Scott Dustin dustins@wyndgate.com 4925 Robert J. Mathews Parkway, Suite 100 El Dorado Hills, CA 95762 916-404-8400 www.wyndgate.com
See accompanying articles on pages 12 and 38		
Name of blood bank system	SafeTrace	SafeTrace Tx
First ever blood bank system installation	1996	1996
Last major product release (for product featured)	—	2006
Total number of contracts for operational sites	55	228
•U.S. hospitals with donor and transfusion service	15 (+3 with donor service only)	22†
•U.S. hospitals with transfusion service only	0	210†
•U.S. regional blood centers with donor service only	24	0
•U.S. regional blood centers with donor and transfusion service	9	12†
•Centralized transfusion services in the U.S.	0	16†
•Foreign hospitals and regional blood centers	4	7
No. of contracts signed between July 2006–July 2007	9	78
Total number of sites operational	224	202
Installs not yet live (hospitals/regional blood centers/others)	15 (8/7/0)	113 (111/2/0)
No. of sites that went live between July 2006–July 2007	4	32
Percentage of installations that are stand-alone systems	100%	100%
Staff to develop/install and support/other* in entire company	40/34/19	40/34/19
Staff to develop/install and support/other* in blood bank systems	40/34/19	40/34/19
No. of different versions of software installed	3	3
•Versions of product in field covered by FDA 510(k) clearance	all	all
•Versions of product that did not require FDA 510(k) clearance	none	none
Range in No. of interactive workstations in live sites (average)	3–200+ (average, 40)	1–75 (average, 8.5)
Central hardware or computer platform or services	Unix-based servers, Sun, HP, IBM	Intel-based and Unix-based servers
Workstations	PCs	PCs
Software programming language(s)	Delphi, PL/SQL, .Net, C, 4GL	Delphi, SQL, Crystal Reports
Operating system(s)	Unix	Windows XP Professional, 2003 (Unix optional)
Databases and tools	Oracle	Oracle
Features (listed as percentage of live installs or based on availability)		
•Full support of ISBT 128 unit labeling	100%	100%
•Bar-code reading of donor and unit information	100%	100%
•Unit inventory	100%	100%
•Autologous and directed unit tracking	100%	100%
•Direct entry of test results	100%	100%
•Crossmatch results	—	100%
•Electronic crossmatch decision making	—	45%
•Antigen typing	100%	100%
•Handheld devices for positive patient ID	not available	—
•Integrated bedside check for transfusion	not available	—
•Track all steps in production of product	100%	100%
•Print donor unit labels—bar coded	100%	installed
•Interface with automated instruments	100%	20%
•Interface with blood irradiator or centrifuges	—	installed
•Centralized transfusion service capability	not available	100%
•Donor recruitment/donor questionnaire	100%/—	not available/not available
•Mobile scheduling screen instruments	100%	not available
•Laptop-based mobile donor registration module	installed	not available
•Source or recovered plasma management	100%	not available
•Accounts receivable	not available	not available
•Management reports/ad hoc report writer	100%/100%	100%/installed
•Quality control management	not available	installed
System provides standard ASTM/HL7 interface?	no	yes, versions 2.1, 2.2, 2.3
Interfaces to automated donor infectious disease testing instruments	uni-directional to Ortho, Immucor, Abbott, Olympus, DiaMed, Hitachi; bi-directional to Gambro	—
Interfaces to automated ABO/Rh/antibody screening instruments	uni-directional to Ortho ProVue, Immucor Galileo, Olympus Tango	uni- and bi-directional to Ortho ProVue, Immucor Galileo
FDA 510(k)-approved interface to bedside patient ID system?	no	no
Tools to help clients validate their systems	validation guidelines, templates, and validation test plan for safety critical control checks	validation guidelines, templates, and validation test plan for safety critical control checks
Complete blood bank ASP solution?	yes	yes
Method of charging for ASP service	fixed fee, transaction based	fixed fee, transaction based
Client software required	browser based	browser based
ASP information conduit	operates over the Internet, requires use of private, dedicated circuit	operates over the Internet, requires use of private, dedicated circuit
Client contracts supported from data center not operated by client	8	3
How data center is operated	by a third party (Hemo-Net)	by a third party (Hemo-Net)
System provides indexed field in each test definition for LOINC code?	no	no
Provide LOINC dictionary for each new installation?	no	no
HIS and LIS interfaces	—	McKesson, Cerner, Siemens, Aspyra, Misys, GE Medical, CPSI, Meditech, Keane, IDX, SCC, Sysmex, others
User group?	yes (meets via Internet quarterly and ad hoc; in person annually)	yes (meets via Internet quarterly and ad hoc; in person annually)
Source code?	yes or escrow	escrow
Can user modify screens?	no	no
User-defined report writer/custom programming?	yes/yes	yes/yes
Cost for smallest & largest stand-alone HW/SW/install & training/mo. maint.	—	—
Cost for smallest & largest integrated HW/SW/install & training/mo. maint.	—	—
Distinguishing features (supplied by vendor)	<ul style="list-style-type: none"> <li>extensive safety checks throughout the system with an outstanding record of compliance</li> <li>open workflow and extensive user-defined table-based rules</li> <li>Service 360 commitment to ensure quality implementation and support experience</li> </ul>	<ul style="list-style-type: none"> <li>extensive safety checks throughout the system</li> <li>numerous safety features, including the trademarked Patient-At-A-Glance Bar</li> <li>Patented CTS and other transfusion service functionality</li> </ul>
*other=sales, marketing, administration, other company functions		†breakdown reflects contracts that fit more than one category

Tabulation does not represent an endorsement by the College of American Pathologists.

## The next step: bringing autoverification into the blood bank

Suzanne Butch, MT(ASCP)SBB  
Theresa Downs, MT(ASCP)SBB

**N**ow that we have automation in the transfusion service and blood bank instruments interfaced with laboratory information systems, it's time to consider adding these instruments to the core lab automation line and autoverification.

This might seem like a radical suggestion since no automated typing and screening instrument for the transfusion service can yet be added to an automation line and since au-

toverification is only now being accepted as a standard operating procedure in other areas of the lab. But it makes sense. Except for allogeneic stem cell transplant patients, a person's blood type doesn't change, and negative antibody screens predominate. Furthermore, samples requiring technologist intervention may hold up other normal results, delaying the time that blood components are available for the patient.

So why address this now? Because

in order for instruments and software to be interfaced in five to 10 years, blood bank and transfusion service specialists need to start asking for such capabilities today. Vendors want to make sure a market exists for a new product before beginning the development process.

Federal requirements for FDA 510(k) premarket approval of blood establishment software add to the delay in adopting new features. Take electronic crossmatch as an example. The FDA just issued draft guidance on

electronic crossmatch, more than 10 years after the first facilities were approved to use the technique. And LIS vendors only recently began offering electronic crossmatch features in their software.

So we pose the question, what would it take to satisfy you that instruments are ready for autoverification of results? For us, the software should compare current with previous results. If the past two times the patient has been O-positive and the patient types as O-positive today, we feel confident the specimen and patient are O-positive. There is no need to send the results to a technologist. Likewise, if the patient has always had a negative antibody screen and the current specimen's results are also negative, there is no need for technologist intervention. Just as with hematology and biochemistry, the algorithms determine whether autoverification is appropriate.

One caveat is that the strengths of the reactions used by the instrument or software to determine a patient's blood type must be controlled by the user, not hard coded by the vendor. For example, a weakly positive (1+) result may be used by an instrument to conclude that a patient is Rh positive, but the end user may decide that a 1+ reaction with anti-D is not sufficient to automatically conclude that a person is Rh positive.

Some blood bankers may be slow to embrace the concept of autoverification because of the burden of validation. Since blood bankers, overall, are a conservative group, many may feel more comfortable monitoring for problems themselves. These individuals could review a daily report of patients with positive antibody screens and typing discrepancies to allay their concerns.

One must keep in mind that autoverification with a hematology instrument will be different than with a blood bank instrument. Once a hematology result is autoverified, the laboratory is finished with it. The process is more complex for verifying a type and screen. The blood bank may be using the sample to prepare blood components or may file it away to be used in the future. How will the technologist know that testing is complete and components can be prepared? For blood banks that use electronic crossmatch, samples with one blood type need to be identified for a second blood type. The sample would have to be located and re-tested.

To convey to instrument and LIS vendors what you want their respective software to do, you should start documenting process specifications. These include the goals of autoverification, the type of results that do not need intervention, an explanation of what constitutes a problem sample, or details of how the instru-

continued on page 40

### Opinion



From Nature for Life

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## Multiplex technology

continued from page 1

"liquid bead array"—microspheres suspended in a buffer to which capture probes are attached and to which target molecules can bind. Reactions on this type of microarray support have certain theoretical advantages. According to Luminex Corp., which markets the beads (called the xMAP system) and associated readers, the high ratio of surface area to volume of the microspheres and the three-dimensional exposure they provide yield superior kinetics relative to flat arrays.

Certainly, companies that have developed assays based on liquid bead array technology (xMAP is an open-architecture system) find practical advantages to the method. At Planet xMAP USA 2007, a conference sponsored by Luminex last

spring, Harry Prince, PhD, scientific director of immunology at Focus Diagnostics, which has devised an assay that distinguishes herpes simplex virus types 1 and 2, said obtaining multiple results in the same well "saves labor, cost, and time and decreases turnaround time." Tm Bioscience, now a division of Luminex, developed a clinical assay, using the xMAP system, for a panel of respiratory viruses. "We are at least as sensitive as real-time PCR and in some cases more sensitive," Richard Janeczko, PhD, chief scientific officer of Tm Bioscience, said of the assay.

Scientists at Quest Diagnostics Nichols Institute have developed and validated two genetic assays using liquid bead array technology: an Ashkenazi Jewish panel and a thrombophilia panel. Of the problem of doing assays for different genes on different platforms, Weimin Sun, PhD, of Quest said,

Among 227 patients, the respiratory virus panel detected all 125 specimens containing one of seven conventional viruses, while DFA detected 113 (90.4 percent).

"Multiplexing is the solution." The advantages of the xMAP-based assays are fewer controls, better turnaround time, a saving of labor owing to fewer DNA extractions, and being able to run a full microtiter plate of samples much of the time, according to Dr. Sun, who is scientific director of the molecular genetics department at Quest.

Perhaps the highest endorsement of xMAP's potential was given by a group at the Broad Institute of the Massachusetts Institute of Technology and Harvard. They measured gene expression using a combination of ligation-mediated amplification with "an optically addressed microsphere and flow cytometric detection system"—xMAP. This combination, they wrote, has the potential to be a "transformative technology" in the gene expression field (Peck D, et al. *Genome Biol.* 2006;7:R61).

A variety of applications of xMAP have been devised or are under development, from the immediately clinical to the futuristic. They range from assays for a few analytes, such as a 10-autoantibody panel, to one that stretches the potential of the technology—measuring hundreds of miRNAs. But they all depend on the same fundamental reagents and procedures, which, along with underlying principles, are presented and illustrated on Luminex's Web site ([www.luminexcorp.com/technology/index.html](http://www.luminexcorp.com/technology/index.html)).

Basically, 5.6-micron polystyrene microspheres are impregnated with differing ratios of red and infrared fluorophores, giving rise to 100 distinct beads. Capture reagents, typ-

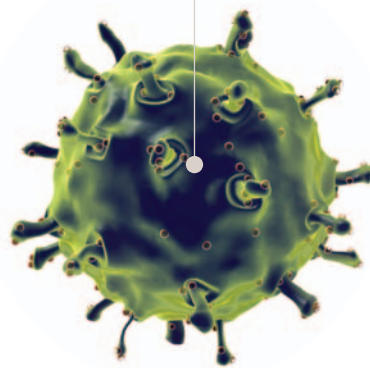
continued on page 45

## Your world is three-dimensional. Shouldn't your detection system be?

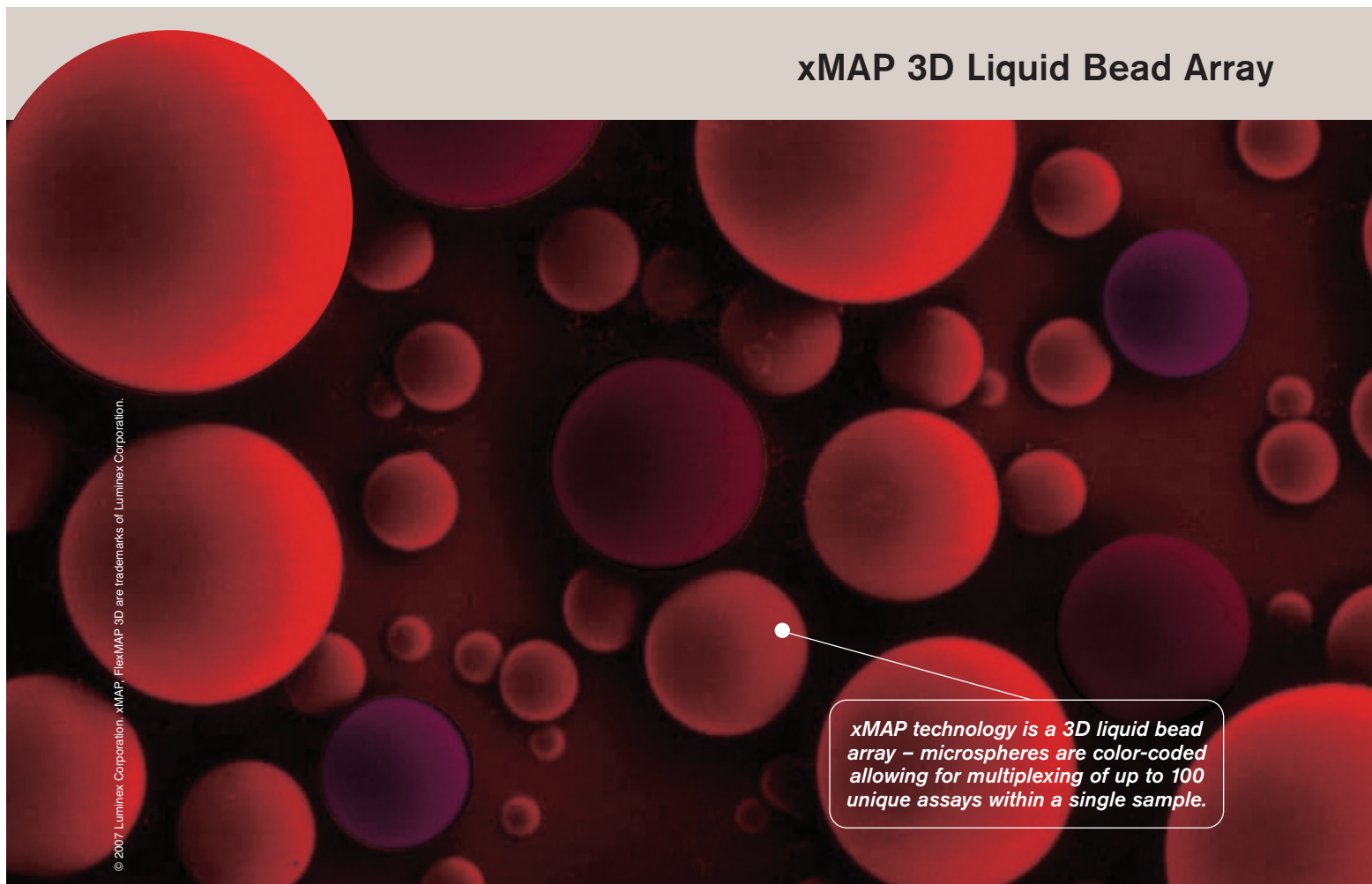
xMAP® technology gives you all the advantages of a 3D liquid bead array. While two dimensional planar arrays simply sit and wait for markers to find the single exposed surface, our microspheres are suspended throughout the sample and actively seek the analytes. By actively exposing multiple surfaces to the whole sample, xMAP's 3D liquid bead arrays give you faster, more reproducible and more accurate results. Plus, xMAP's open-architecture platform makes it ideal for a wide range of applications – like molecular infectious and genetic disease, immunoassays, protein and molecular research just to name a few. To find out more about the advantages of three-dimensional multiplexing, visit [www.luminexcorp.com/3D](http://www.luminexcorp.com/3D)

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xMAP technology can easily detect multiple different analytes or viral pathogens in a single patient sample (like the virus shown here in 3D).



### xMAP 3D Liquid Bead Array



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## Autoverification

continued from page 38

ment will identify a problem that needs technologist intervention. A process flow chart could help define the path of a normal versus a problem sample.

Instrument limitations will continue to determine process flow. For example, a chylous sample will influence a gel technology result but might not be a problem with a microtiter plate. Examples of questions that relate to process flow are, Will the repeat test be on the same instrument or use another test method? If the instrument on the line is in another building, and the tube is needed for additional work in the blood bank, how will it be transported? Will the blood bank be completely paperless?

Think about process specifications now and then ask for what you want and need for the future. In other words, ask for today what you want tomorrow. □

Suzanne Butch is administrative manager, and Theresa Downs is supervisor, Blood Bank and Transfusion Service, University of Michigan Hospitals, Ann Arbor.